PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	05 FEB 2020
Applicant's or agent's file reference 292010-2010	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2019/064324	03 December 2019	03 December 2018

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61M 25/09; A61M 25/01; A61M 25/088 (2020.01)
CPC - A61M 25/0127; A61M 25/0158; A61M 25/0194; A61M 2025/0197 (2020.01)

Applicant THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	20 January 2020	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-24	YES
	Claims	None	NO
Inventive step (IS)	Claims	21-24	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 10, 11, 13, and 20 lack an inventive step under PCT Article 33(3) as being obvious over Grantham et al. (hereinafter Grantham) in view of Tejani.

Regarding Claim 1, Grantham discloses a system comprising: a small-diameter tube (guide 32, Fig 2a-2b) having an elongated body (guide 32 has elongated body section shown in Figs 2a-2b), a distal tip (magnetic connection tip 36, see Figs 2a-2b and para [0023]), and an inner lumen that extends the length of the tube (guide 32 includes an inner lumen, see para [0023]: "The device 30 includes a first guide 32, which may be a catheter including a central lumen 34 capable of facilitating passage of another catheter or guide wire, or a guide wire"), the distal tip including a magnetic element that generates a strong focal magnetic field (para [0023]: "a magnetic connection tip 36 to provide for delivery of energy at the tip...One or more magnets or magnetic alignment elements, shown in FIGS. 3a, 3b and 5a, 5c, are secured within or on the catheter connection tip"); and a crossing wire (guidewire 40, see Figs 2a-2b, para [0024]: "The second guide wire or catheter 40 is advanced to the occlusion site CTO via an adjacent vessel to enable an approach to the distal end of the occlusion, opposite from the first guide wire or catheter 32, as shown in FIGS. 1, 2a and 2b.") having an elongated body (guidewire 40 has elongated body, as shown in Figs 2a-2b) and a distal tip (tip 42, see Figs 2a-2b), the distal tip of the crossing wire including a element that is magnetically attracted to the distal tip of the small-diameter tube when the distal tip of the crossing wire is placed in proximity to the distal tip of the small-diameter tube so as to facilitate alignment of the distal tips (distal tip 42 has a magnetic element, as described in para [0023]: "One or more magnets or magnetic alignment elements, shown in FIGS. 3a, 3b and 5a, 5c, are secured within or on the catheter connection tip to provide the desired positioning or alignment of the catheter tip with respect to a second guide 40, which may be a guide wire or catheter, also having a magnetic connection tip 42 and providing for delivery or receiving of energy at the tip.", the magnetic elements are used to align the distal tips as described in para [0024]: "The magnets or magnetic alignment elements 50 on each connection tip 36, 42 are arranged such that opposite polarity magnets 50 are used to attract the magnetic tips 36, 42 and their respective guide wire or catheter 32"). Grantham fails to explicitly teach the distal tip of the crossing wire including a ferromagnetic element, though it does teach the distal tip of the crossing wire including a magnetic element. Tejani teaches a system utilizing a crossing wire distal tip utilizing a ferromagnetic element which is attracted to a magnetic capture element (Tejani: Fig 5a-5b includes recanalization wire 508 and ferromagnetic tip 524, see para [0028]: "FIGS. 5A and 5B illustrate partial cutaway views of a peripheral artery in which another embodiment of a distal or retrograde approach to traversing a CTO is carried out, wherein a wire is advanced from the distal cap of the CTO through the proximal cap (FIG. 5A), where it is then captured by a capture wire using a neodymium magnet (FIG. 5B), in accordance with various embodiments"..."In various embodiments, the recanalization wire 508 may include a ferromagnetic tip 524."). It would have been obvious to combine Grantham's magnetic crossing-wire and small-diameter tube/catheter system with the ferromagnetic distal tip crossing wire of Tejani for the purposes of enhancing the magnetic bonding strength to enable a more snug connection between the crossing wire and capture device, as recognized in para [0029] of Tejani, and ensure proper alignment between the tube and wire as recognized in Grantham para [0023].

Regarding Claim 10, modified Grantham discloses the system of claim 1, and Grantham further discloses wherein the inner lumen of the small-diameter tube is configured to receive the crossing wire (Grantham: see Fig 2b - crossing wire 40 received by catheter 32, see also para [0023]: "The device 30 includes a first guide 32, which may be a catheter including a central lumen 34 capable of facilitating passage of another catheter or guide wire, or a guide wire, and having a magnetic connection tip 36 to provide for delivery of energy at the tip.").

Regarding Claim 11, modified Grantham discloses the system of claim 10, and Grantham further discloses wherein the small-diameter tube is configured to automatically draw the distal tip of the crossing wire into the inner lumen when the distal tip of the crossing wire is placed in close proximity to the distal tip of the small diameter tube (see para [0024]: "One or more magnets or magnetic alignment elements, shown in FIGS. 3a, 3b and 5a, 5c, are secured within or on the catheter connection tip to provide the desired positioning or alignment of the catheter tip with respect to a second guide 40, which may be a guide wire or catheter, also having a magnetic connection tip 42 and providing for delivery or receiving of energy at the tip.").

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Regarding Claim 13, Grantham discloses a small-diameter tube (guide 32, Fig 2a-2b) comprising: an elongated body (guide 32 has elongated body section shown in Figs 2a-2b); a distal tip (magnetic connection tip 36, see Figs 2a-2b and para [0023]); an inner lumen that extends the length of the tube (guide 32 includes an inner lumen, see para [0023]: "The device 30 includes a first guide 32, which may be a catheter including a central lumen 34 capable of facilitating passage of another catheter or guide wire, or a guide wire"); and a magnetic element associated with the distal tip that generates a strong focal magnetic field (para [0023]: "a magnetic connection tip 36 to provide for delivery of energy at the tip...One or more magnets or magnetic alignment elements, shown in FIGS. 3a, 3b and 5a, 5c, are secured within or on the catheter connection tip"). Grantham fails to explicitly disclose the magnetic element attracting ferromagnetic materials, though it discloses the magnetic element attracting another magnet on a wire element (distal tip 42 has a magnetic element, as described in para [0023]: "One or more magnets or magnetic alignment elements, shown in FIGS. 3a, 3b and 5a, 5c, are secured within or on the catheter connection tip to provide the desired positioning or alignment of the catheter tip with respect to a second guide 40, which may be a guide wire or catheter, also having a magnetic connection tip 42 and providing for delivery or receiving of energy at the tip."). Tejani teaches a a crossing wire distal tip utilizing a ferromagnetic element which is attracted to a magnetic capture element (Tejani: Fig 5a-5b includes recanalization wire 508 and ferromagnetic tip 524, see para [0028]: "FIGS. 5A and 5B illustrate partial cutaway views of a peripheral artery in which another embodiment of a distal or retrograde approach to traversing a CTO is carried out, wherein a wire is advanced from the distal cap of the CTO through the proximal cap (FIG. 5A), where it is then captured by a capture wire using a neodymium magnet (FIG. 5B), in accordance with various embodiments"..."In various embodiments, the recanalization wire 508 may include a ferromagnetic tip 524."). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Tejani for the purpose of enhancing the magnetic bonding strength to enable a more snug connection between the crossing wire and capture device, as recognized in para [0029] of Tejani, and ensure proper alignment between the tube and wire as recognized in Grantham para [0023].

Regarding Claim 20, Grantham discloses a method for treating total occlusion of an artery of a patient (Abstract), the method comprising: positioning a small-diameter tube (Figs 2a-2b, para [0023]: "The device 30 includes a first guide 32, which may be a catheter", catheter 32 has tip 36) on a first side of an arterial plaque causing the total occlusion (para [0024]: "The tips 36, 42 of each device may be proximal or distal to the CTO"), the small-diameter tube having an elongated body (catheter 32 has an elongated body shown in Figs 2a-2b), a distal tip (Fig 2a-2b, distal tip 36), and an inner lumen that extends the length of the tube (guide 32 includes an inner lumen, see para [0023]: "The device 30 includes a first guide 32, which may be a catheter including a central lumen 34 capable of facilitating passage of another catheter or guide wire, or a guide wire"), the distal tip including a magnetic element that generates a strong focal magnetic field (para [0023]: "a magnetic connection tip 36 to provide for delivery of energy at the tip...One or more magnets or magnetic alignment elements, shown in FIGS. 3a, 3b and 5a, 5c, are secured within or on the catheter connection tip"); positioning a crossing wire (Fig 2a-2b, wire element 40 with tip element 42, para [0023]: "second guide 40, which may be a guide wire") on a second side of the arterial plaque (para [0024]: "The tips 36, 42 of each device may be proximal or distal to the CTO"), the crossing wire having an elongated body (Fig 2a-2b, wire element 40 has an elongated body) and a distal tip (Fig 2a-2b, distal tip 42), the distal tip of the crossing wire including a magnetic element (para [0024]: "Each of the guide wires or catheters 32, 40 include a magnetic connection tip"); advancing the crossing wire through or around the arterial plaque toward the small-diameter tube so as to position the distal tip of the crossing wire proximate to the distal tip of the small-diameter tube (para [0024] describes keeping one element stationary while moving another element to enable connection, "In the embodiment shown in FIGS. 2a, 2b and 6c, 6d, one device 32 or 40 is positioned within the true lumen TL of the vessel and the other device 40 or 32 inside the wall VW of the vessel, the latter position, which is referred to as subintimal. The tips 36, 42 of each device may be proximal or distal to the CTO. It is possible, as shown in FIGS. 6a, 6b and 6c, 6d, that one tip 36 or 42 is within the arterial occlusion or plaque and the other connection tip 42 or 36 is adjacent to it or within the subintimal space. Providing increased connection locations offers the medical practitioner flexibility in positioning each guide 32, 40 in order to make the connection."), wherein the distal tip of the crossing wire is drawn to the distal tip of the small-diameter tube due to magnetic attraction (para [0023]: "One or more magnets or magnetic alignment elements, shown in FIGS. 3a, 3b and 5a, 5c, are secured within or on the catheter connection tip to provide the desired positioning or alignment of the catheter tip with respect to a second guide 40, which may be a guide wire or catheter, also having a magnetic connection tip 42 and providing for delivery or receiving of energy at the tip."); and continuing to advance the crossing wire toward the small-diameter tube until the crossing wire is drawn into the inner lumen of the small-diameter tube under the effects of the magnetic attraction (para [0023]: "One or more magnets or magnetic alignment elements, shown in FIGS. 3a, 3b and 5a, 5c, are secured within or on the catheter connection tip to provide the desired positioning or alignment of the catheter tip with respect to a second guide 40, which may be a guide wire or catheter, also having a magnetic connection tip 42 and providing for delivery or receiving of energy at the tip."). Grantham fails to explicitly teach the crossing wire including a ferromagnetic material, though Grantham does describe the crossing wire including a magnetic material - as discussed above. Tejani teaches a system utilizing a crossing wire distal tip utilizing a ferromagnetic element which is attracted to a magnetic capture element (Tejani: Fig 5a-5b includes recanalization wire 508 and ferromagnetic tip 524, see para [0028]: "FIGS. 5A and 5B illustrate partial cutaway views of a peripheral artery in which another embodiment of a distal or retrograde approach to traversing a CTO is carried out, wherein a wire is advanced from the distal cap of the CTO through the proximal cap (FIG. 5A), where it is then captured by a capture wire using a neodymium magnet (FIG. 5B), in accordance with various embodiments"..."In various embodiments, the recanalization wire 508 may include a ferromagnetic tip 524."). It would have been obvious to combine Grantham's magnetic crossing-wire and small-diameter tube/catheter system with the ferromagnetic distal tip crossing wire of Tejani for the purposes of enhancing the magnetic bonding strength to enable a more snug connection between the crossing wire and capture device, as recognized in para [0029] of Tejani, and ensure proper alignment between the tube and wire as recognized in Grantham para [0023].

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Claims 2-5 and 14-16 lack an inventive step under PCT Article 33(3) as being obvious over Grantham et al. (hereinafter Grantham) in view of Tejani and Berg et al. (hereinafter Berg).

Regarding Claim 2, modified Grantham discloses the system of claim 1, but Grantham fails to explicitly disclose wherein the small-diameter tube has an outer diameter no greater than 7 mm. Berg teaches a small diameter-tube/catheter having an outer diameter no greater than 7 mm (Berg: col 5 lines 5-15, largest sample outer diameter of 0.039 inches is equivalent to 0.99 millimeters which is under 7 mm). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Berg for the purpose of facilitating passage of an array of wire sizes within the catheter/small diameter tube and ensure a snug connection between the wire and catheter/small diameter tube, as recognized in para [0024] of Grantham, and ensure proper alignment between the tube and wire as recognized in Grantham para [0023].

Regarding Claim 3, modified Grantham discloses the system of claim 1, but Grantham fails to explicitly disclose wherein the inner lumen of the small-diameter tube has a diameter no greater than 1 mm. Berg teaches a small diameter-tube/catheter having an inner lumen diameter no greater than 1 mm (Berg: col 5 lines 5-15, inner lumen diameter of 0.023 inches inches is equivalent to 0.58 millimeters which is under 1 mm). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Berg for the purpose of facilitating passage of an array of wire sizes within the catheter/small diameter tube and ensure a snug connection between the wire and catheter/small diameter tube, as recognized in para [0024] of Grantham, and ensure proper alignment between the tube and wire as recognized in Grantham para [0023].

Regarding Claim 4, modified Grantham discloses the system of claim 1, but Grantham fails to explicitly disclose wherein the small-diameter tube is a microcatheter (though Grantham does teach the small-diameter tube as a catheter, as previously described in Grantham para [0023]). Berg teaches a small-diameter tube which is a microcatheter used for medical procedures (Berg: Abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Berg for the purpose of facilitating passage of an array of wire sizes within the catheter/small diameter tube and ensure a snug connection between the wire and catheter/small diameter tube, as recognized in para [0024] of Grantham, and ensure proper alignment between the tube and wire as recognized in Grantham para [0023].

Regarding Claim 5, modified Grantham discloses the system of claim 4, but Grantham fails to explicitly disclose wherein the microcatheter comprises an inner strengthening member and a polymeric outer layer. Berg teaches a microcatheter (Berg: Abstract) comprising an inner strengthening member (Berg: Fig 1 inner structural section 170 provides rigidity, see col 3 lines 54-55) and a polymeric outer layer (Berg: Fig 1 sections 120-160 extend longitudinally across distinct segments of the microcatheter and sit outside structural section 170, and comprise a polymer as desribed in col 3 lines 44-45). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Berg for the purpose of enhancing the structural strength of the catheter to ensure a snug connection between the wire and catheter/small diameter tube, as recognized in Grantham: para [0024] and Berg: col 1 lines 40-44.

Regarding Claim 14, modified Grantham discloses the small-diameter tube of claim 13, but does not explicitly disclose wherein the small-diameter tube has an outer diameter no greater than 7 mm. Berg teaches a small diameter-tube/catheter having an outer diameter no greater than 7 mm (Berg: col 5 lines 5-15, largest sample outer diameter of 0.039 inches is equivalent to 0.99 millimeters which is under 7 mm). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Berg for the purpose of facilitating passage of an array of wire sizes within the catheter/small diameter tube and ensure a snug connection between the wire and catheter/small diameter tube, as recognized in para [0024] of Grantham, and ensure proper alignment between the tube and wire as recognized in Grantham para [0023].

Regarding Claim 15, modified Grantham discloses the small-diameter tube of claim 13, but fails to explicitly disclose wherein the inner lumen of the small-diameter tube has a diameter no greater than 1 mm. Berg teaches a small diameter-tube/catheter having an inner lumen diameter no greater than 1 mm (Berg: col 5 lines 5-15, inner lumen diameter of 0.023 inches is equivalent to 0.58 millimeters which is under 1 mm). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Berg for the purpose of facilitating passage of an array of wire sizes within the catheter/small diameter tube and ensure a snug connection between the wire and catheter/small diameter tube, as recognized in para [0024] of Grantham, and ensure proper alignment between the tube and wire as recognized in Grantham para [0023].

Regarding Claim 16, modified Grantham discloses the small-diameter tube of claim 13, but fails to disclose wherein the small-diameter tube is a microcatheter having an inner strengthening member and a polymeric outer layer. Berg teaches a microcatheter (Berg: Abstract) comprising an inner strengthening member (Berg: Fig 1 inner structural section 170 provides rigidity, see col 3 lines 54-55) and a polymeric outer layer (Berg: Fig 1 sections 120-160 extend longitudinally across distinct segments of the microcatheter and sit outside structural section 170, and comprise a polymer as desribed in col 3 lines 44-45). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Berg for the purpose of enhancing the structural strength of the catheter to ensure a snug connection between the wire and catheter/small diameter tube, as recognized in Grantham: para [0024] and Berg: col 1 lines 40-44.

Claims 6, 7, and 17 lack an inventive step under PCT Article 33(3) as being obvious over Grantham et al. (hereinafter Grantham) in view of Tejani and Levine et al. (hereinafter Levine).

Regarding Claim 6, modified Grantham discloses the system of claim 1, but Grantham fails to explicitly disclose wherein the small-diameter tube is a dilator. Levine teaches a dilator that can be used in medical procedures for placement over a medical wire (Levine: Abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Levine for the purpose of ensuring a snug connection between the wire and small diameter tube and flexibility in the type of procedure being conducted, as recognized in Grantham: para [0024] and para [0007].

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Regarding Claim 7, modified Grantham discloses the system of claim 6, but Grantham fails to explicitly disclose wherein the dilator is configured as a solid polymeric tube having an inner lumen and a tapered distal tip. Levine teaches a dilator that can be used in medical procedures for placement over a medical wire (Levine: Abstract) configured as a solid polymeric tube (Levine: para [0010]) having an inner lumen (Fig 3c opening 312, lumen is configured to allow passage of a wire as described in Levine para [0033]) and a tapered distal tip (Levine: Fig 3a-3b, tapered distal tip 310). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Levine for the purpose of ensuring a snug connection between the wire and small diameter tube and flexibility in the type of procedure being conducted, as recognized in Grantham: para [0024] and para [0007].

Regarding Claim 17, modified Grantham discloses the small-diameter tube of claim 13, but fails to explicitly disclose wherein the small-diameter tube is a dilator configured as a solid polymeric tube having an inner lumen and a tapered distal tip. Levine teaches a dilator that can be used in medical procedures for placement over a medical wire (Levine: Abstract) configured as a solid polymeric tube (Levine: para [0010]) having an inner lumen (Fig 3c opening 312, lumen is configured to allow passage of a wire as described in Levine para [0033]) and a tapered distal tip (Levine: Fig 3a-3b, tapered distal tip 310). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Levine for the purpose of ensuring a snug connection between the wire and small diameter tube and flexibility in the type of procedure being conducted, as recognized in Grantham: para [0024] and para [0007].

Claims 8, 9, 18, and 19 lack an inventive step under PCT Article 33(3) as being obvious over Grantham et al. (hereinafter Grantham) in view of Tejani and Pinsky et al. (hereinafter Pinsky).

Regarding Claim 8, modified Grantham discloses the system of claim 1, but Grantham fails to explicitly disclose wherein the magnetic element comprises a single-crystal magnet. Pinsky teaches a medical system utilizing a neck brace utilizing a magnetic element used to help attract and position a catheter (Pinsky: Abstract) where the magnetic element utilizes a single crystal magnet (Pinsky, para [0040]: "A neodymium magnet (also known as NdFeB, NIB, or Neo magnet), a type of rare-earth magnet, is a permanent magnet ...to form the Nd2Fe14B tetragonal crystalline structure. TMs material is currently the strongest type of permanent magnet."). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify Grantham with the teaching of Pinsky, whereby the tube magnet of modified Grantham (which attracts the wire magnet) further utilizes the single crystal magnet of Pinsky for the purpose of enhancing the strength of the magnetic connection as recognized by Pinsky: para [0040], and for the purpose of ensuring a snug connection between the wire and small diameter tube, as recognized in Grantham: para [0024].

Regarding Claim 9, modified Grantham discloses the system of claim 8, wherein the single-crystal magnet is made of a rare-earth metal. Grantham fails to explicitly disclose the single crystal magnet being made of a rare-earth metal. Pinsky teaches a medical system utilizing a neck brace utilizing a magnetic element used to help attract and position a catheter , where the magnetic element is a rare earth metal (Pinsky, para [0040]: "A neodymium magnet (also known as NdFeB, NIB, or Neo magnet), a type of rare-earth magnet"). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify Grantham with the teaching of Pinsky, whereby the single crystal tube magnet of modified Grantham (which attracts the wire magnet) further utilizes the rare earth metal of Pinsky for the purpose of enhancing the strength of the magnetic connection as recognized by Pinsky: para [0040], and for the purpose of ensuring a snug connection between the wire and small diameter tube, as recognized in Grantham: para [0024].

Regarding Claim 18, modified Grantham discloses the small-diameter tube of claim 13, but Grantham fails to explicitly disclose wherein the magnetic element comprises a single-crystal magnet. Pinsky teaches a medical system utilizing a neck brace utilizing a magnetic element used to help attract and position a catheter (Pinsky: Abstract) where the magnetic element utilizes a single crystal magnet (Pinsky, para [0040]: "A neodymium magnet (also known as NdFeB, NIB, or Neo magnet), a type of rare-earth magnet, is a permanent magnet ...to form the Nd2Fe14B tetragonal crystalline structure. TMs material is currently the strongest type of permanent magnet.") It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify Grantham with the teaching of Pinsky, whereby the tube magnet of modified Grantham (which attracts the wire magnet) further utilizes the single crystal magnet of Pinsky for the purpose of enhancing the strength of the magnetic connection as recognized by Pinsky: para [0040], and for the purpose of ensuring a snug connection between the wire and small diameter tube, as recognized in Grantham: para [0024].

Regarding Claim 19, modified Grantham discloses the small-diameter tube of claim 18, but fails to explicitly teach wherein the single-crystal magnet is made of a rare-earth metal. Pinsky teaches a medical system utilizing a neck brace utilizing a magnetic element used to help attract and position a catheter , where the magnetic element is a rare earth metal (Pinsky, para [0040]: "A neodymium magnet (also known as NdFeB, NIB, or Neo magnet), a type of rare-earth magnet"). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify Grantham with the teaching of Pinsky, whereby the single crystal tube magnet of modified Grantham (which attracts the wire magnet) further utilizes the rare earth metal of Pinsky for the purpose of enhancing the strength of the magnetic connection as recognized by Pinsky: para [0040], and for the purpose of ensuring a snug connection between the wire and small diameter tube, as recognized in Grantham: para [0024].

Claim 12 lacks an inventive step under PCT Article 33(3) as being obvious over Grantham et al. (hereinafter Grantham) in view of Tejani and Vascular Solutions, Inc..

Regarding Claim 12, modified Grantham discloses the system of claim 1, but Grantham fails to explicitly disclose wherein a stiffness of the crossing wire gradually increases near its distal tip. Vascular Solutions, Inc. teaches a crossing wire used to cross a vessel occlusion (Abstract) where a stiffness of the crossing wire gradually increases near its distal tip (see para [0011] and [0017], distal tip includes a first segment and more distal second segment, where second segment is stiffer than first segment). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Grantham with the teaching of Vascular Solutions, Inc. for the purpose of enhancing the ability of the crossing wire to cross the occlusion, as recognized in para [0007] of Vascular Solutions, Inc. and para [0005] of Grantham.

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Claims 21-24 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest:

Regarding claim 21, the prior art of record, individually or in combination, does not teach or fairly suggest the method of claim 20, further comprising advancing the crossing wire thorough the inner lumen of the small-diameter tube until the distal tip of the crossing wire is positioned outside of the patient's body.

Regarding claim 22, the prior art of record, individually or in combination, does not teach or fairly suggest the method of claim 21, further comprising removing the smalldiameter tube from the patient.

Regarding claim 23, the prior art of record, individually or in combination, does not teach or fairly suggest the method of claim 22, further comprising advancing a stent over the crossing wire and positioning the stent within the artery at the location of the plaque.

Regarding claim 24, the prior art of record, individually or in combination, does not teach or fairly suggest the method of claim 23, further comprising deploying the stent at the location of the plaque to restore patency to the artery.

Claims 1-24 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.