PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: FREDERICK S. BURKHART
GARDNER LINN BURKHART & ONDERSMA LLP
2900 CHARLEVOIX DR. SE SUITE 300
GRAND RAPIDS, MI 49546

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	15 JUL 2020

Applicant's or agent's file reference	FOR FURTHER ACTION
BAK04FP129WO	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB 20/52169	11 March 2020 (11.03.2020)	11 March 2019 (11.03.2019)

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

IPC - A61F 2/04; A61F 5/00; A61H 9/00; A61B 1/018; A61B 1/273 (2020.01)

CPC - A61F2/04; A61F 5/0079; A61F 5/0083; A61F 5/0086; A61H 9/0078; A61B17/0401; A61B 1/273; A61F 2/95; A61F 5/0089

Applicant BFKW, LLC

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, Virginia 22313-1450 Facsimile No. 571-273-8300	29 June 2020	Lee Young PCT Help Desk Telephone No. 571-272-4300

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB 20/52169

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(b)).

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:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB 20/52169

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	3-6, (7-8)/(3-6), 9-17, 20-22, (24-25)/(20-22) and 26-37	YES
	Claims	1-2, (7-8)/(1-2), 18-19, 23, and (24-25)/(19,23)	NO
Inventive step (IS)	Claims	3-6, (7-8)/(3-6), 9-11, 20-22, (24-25)/(20-22) and 26-28	YES
	Claims	1-2, (7-8)/(1-2), 12-19, 23 and (24-25)/(19,23), and 29-37	NO
Industrial applicability (IA)	Claims	1-37	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-2, (7-8)/(1-2), 18-19, 23 and (24-25)/(19,23) lack novelty as per PCT Article 33(2) as being anticipated by US 2004/0092892 A1 to Kagan et al. (hereinafter 'KAGAN').

As per claim 1, KAGAN discloses an intraluminal device (400, Figs 24A, 24D; para [0282]), comprising:
a body having a wall defining a surface (432, 420, 423 Fig 24A, 24D - see the body of the device 432 which is a part of the entire device 400 having tissue contacting surfaces 420 and 423; para [0282], para [0286]), said surface configured to a portion of a lumen (Fig 24A, 24D - see device 400 with surfaces 420 and 423 in contact with tissue 425 attached at the gastroesophageal (GE) junction; para [0282]); and
an anchor system (427, 426 Figs 24A, 24D - see anchor apertures 427 through which the fastener 426 passes through to secure the tissue fold 425; para [0282], [0284], [0286]), said anchor system configured to fix said body to an inner wall of the lumen in a manner that said surface is adapted to apply at least intermittent pressure to the inner wall of the lumen (Fig 24D; para [0282], [0284], [0286] - intended use the device is capable of, see fastener 426 attaching the tissue fold 425 to the body 432 and the surfaces 420 and 432 are transferring pressure to the compressed tissue therebetween); and
a tissue fold that is adjacent the wall (425, Fig 24D - see folded tissue 425 between surfaces 420 and 423; para [0286]), said tissue fold transmitting a force between the inner wall of the lumen and said body (Fig 24D; para [0286] - intended use the device is capable of, see anchors consists of compressing tissue lumen wall against body surface and thus transferring force therebetween).

As per claim 2, KAGAN discloses the device as claimed in claim 1 wherein said anchor system comprises a plurality of anchors (Fig 24D - see plurality of anchors along the circumference of the device; para [0284], [0286]), each comprising a fastener that is adapted to retain said wall with the tissue fold of the lumen that is adjacent the wall (426, Fig 24D; para [0286]).

As per claim 7/(1-2), KAGAN discloses the device as claimed in claims 1 and 2, wherein said anchor is adapted to be disabled in order to explant the body from the lumen (para [0282], [0284], [0286]; see para [0032], [0374],[0390],[0391]).

As per claim 8/(1-2), KAGAN discloses the device as claimed in claim 7/(1-2), wherein said anchor is adapted to be disabled by cutting the fastener (426, Fig 24D; para [0286] - intended use, see para [0032], [0374],[0390],[0391]).

As per claim 18, KAGAN discloses a method of deploying an intraluminal device in a portion of a lumen (para [0022]; 400, Figs 24A, 24D; para [0282]), said method comprising:
said device having a body with a wall defining a surface (432, 420, 423 Fig 24A, 24D - see the the body of the device 432 which is a part of the entire device 400 having tissue contacting surfaces 420 and 423; para [0282], para [0286]), said surface configured to a portion of a lumen (Fig 24A, 24D - see device 400 with surfaces 420 and 423 in contact with tissue 425 attached at the gastroesophageal (GE) junction; para [0282]);
an anchor system (427, 426 Figs 24A, 24D - see anchor apertures 427 through which the fastener 426 passes through to secure the tissue fold 425; para [0282], [0284], [0286]);
fixing said body to an inner wall of the lumen with said anchor system (para [0022]; Fig 24A, 24D - see entirety of device attached to the lumen using the anchor system; para [0282],[0284],[0286]) and applying at least intermittent pressure with said surface to the inner wall of the lumen (para [0022], Fig 24D; para [0282], [0284], [0286] - see fastener 426 attaching the tissue fold 425 to the body 432 and the surfaces 420 and 432 are transferring pressure to the compressed tissue therebetween); and
forming a tissue fold of the inner wall of the lumen (para [0022]; 425, Fig 24D - see folded tissue 425 between surfaces 420 and 423; para [0286]), the tissue fold being adjacent the body wall, said tissue fold transmitting a force between the inner wall of the lumen and said body (Fig 24D; para [0286] - see anchors consists of compressing tissue lumen wall against body surface and thus transferring force therebetween).

-*- Continued in supplemental box -*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB 20/52169

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 4: The term "said at least one opening" is confusing and lacks proper antecedent basis on claim 2, from which claim 4 is dependent. For purposes of this opinion, claim 4 is interpreted as being dependent from claim 3, which provides proper antecedent basis

Claim 9: The term "said crossbar" is confusing and lacks proper antecedent basis on claims 7/(1-2) of 7/(1-6), from which claim 9 is dependent. For purposes of this opinion, claim 9 is interpreted as being dependent only from claims 7/(3-6), which provides proper antecedent basis.

Claim 21: The term "said at least one opening" is confusing and lacks proper antecedent basis on claim 19 from which claim 21 is dependent. For purposes of this opinion, claim 21 is interpreted as being dependent from claim 20, which provides proper antecedent basis.

Claim 26: The term "said crossbar" is confusing and lacks proper antecedent basis on claims 24/(19, 23) of 26/(19-23), from which claim 26 is dependent. For purposes of this opinion, claim 26 is interpreted as being dependent only from claims 24/(20-22), which provides proper antecedent basis.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB 20/52169

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*-Box V.2 - Citations and Explanations-*-

As per claim 19, KAGAN discloses the method as claimed in claim 18 wherein said anchor system comprises a plurality of anchors (Fig 24D - see plurality of anchors along the circumference of the device; para [0284], [0286]), said fixing including retaining said wall with the tissue fold of the lumen (para [0022]; Fig 24D; para [0286] - see tissue fold being placed within the wall of the device and fixed using fastener 426).

As per claim 23, KAGAN discloses the method as claimed in claim 19 wherein said wall has a central opening (402, Fig 24D - see opening 402 present in the center of both the the tissue contacting surfaces 420 and 423 and connecting to the intraluminal device 400; para [0282],[0286]) and a peripheral edge (Fig 24D - see the edge of the device contacting the tissue in both upper and lower tissue contacting surfaces 423 and 420 respectively; para [0286]) and wherein said anchors are spaced from both said central opening and said peripheral edge (Fig 24D - see entirety of the anchor system with all the apertures for the fasteners placed almost equidistant from the edge and the central opening; para [0286]).

As per claim 24/(19,23), KAGAN discloses the method as claimed in claims 19 and 23 including disabling said anchors in order to explant the body from the lumen (para [0032], [0374],[0390],[0391]).

As per claim 25/(19,23), KAGAN discloses the method as claimed in claim 24/(19,23) including disabling said anchor by cutting the fastener (para [0032], [0374],[0390],[0391]).

Claims 1, 12-14, 18-19, 29-32 lack an inventive step as per PCT Article 33(2) as being obvious over US 2016/0151233 A1 to BFKW, LLC (hereinafter 'BFKW 1233') in view of KAGAN.

As per claim 1, BFKW 1233 discloses an intraluminal device (220, Fig 4; para [0045]), comprising:
a body having a wall defining a surface (230, Fig 4; para [0045]), said surface configured to a portion of a lumen (230, Fig 4 - see cardiac member 230 which is similar to cardiac member 30 in Fig 2 where the bariatric device is attached in the lumen of the gastroesophageal (GE) junction; para [0036],[0045]); and
an anchor system (228b, Fig 4 - mucosal capture anchor system; para [0045]), said anchor system configured to fix said body to an inner wall of the lumen in a manner that said surface is adapted to apply at least intermittent pressure to the inner wall of the lumen (228b, Fig 4 - see mucosal capture anchor system on the cardiac member which captures the mucosal tissue and the device is capable to provide the intermittent pressure; para [0045]). BFKW 1233, however does not further disclose a tissue fold that is adjacent the wall said tissue fold transmitting a force between the inner wall of the lumen and said body. KAGAN, however, discloses a bariatric device (400, Figs 24A; para [0282]) having an anchor system (427, 426 Figs 24A, 24D - see anchor apertures 427 through which the fastener 426 passes through to secure the tissue fold 425; para [0282], [0284], [0286]), said anchor system creating a tissue fold that is adjacent the wall (425, Fig 24D - see folded tissue; para [0286]), said tissue fold transmitting a force between the inner wall of the lumen and said body (Fig 24D; para [0286] - intended use the device is capable of, see anchors consists of compressing tissue lumen wall against body surface and thus transferring force therebetween). BFKW 1233 further discloses that the bariatric device can incorporate different anchoring techniques (para [0037]). Incorporating different anchoring systems to secure a bariatric device in the GI tract lumen is within the scope of ordinary skill in the art. Accordingly, it would have been obvious to a person having ordinary skill in the art to have utilized the tissue fold anchor system taught by KAGAN in the bariatric device of BFKW 1233 to have a tissue fold formed which leads to an enhanced securement system of the device in the lumen of the patient.

As per claim 12, BFKW 1233 in view of KAGAN discloses the device as claimed in claim 1, wherein said surface is adapted to apply an adjustable pressure to the inner wall of the lumen (para [0046]).

As per claim 13, BFKW 1233 in view of KAGAN discloses the device as claimed in claim 12 wherein the surface is moveable with an inner bladder (242a, 242b, Fig 4; para [0045]) and a control system adjusting inflation of said inner bladder (236, 238, Fig 4; para [0045]).

As per claim 14, BFKW 1233 in view of KAGAN discloses the device as claimed in claim 13 wherein said control system includes a controller (236, 238, Fig 4; para [0045]) and an outer bladder on an opposite side of said wall (244a, 244b, Fig 4; para [0045]), said controller exchanging a fluid between said bladders in order to move said surface (para [0045]).

-*-Continued in next Supplemental Box-*-

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB 20/52169

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

As per claim 18, BFKW 1233 discloses a method of deploying an intraluminal device in a portion of a lumen (220, Fig 4; para [0045]), said method comprising:
said device having a body with a wall defining a surface (230, Fig 4; para [0045]), said surface configured to a portion of a lumen (230, Fig 4 - see cardiac member 230 which is similar to cardiac member 30 in Fig 2 where the bariatric device is attached in the lumen of the gastroesophageal (GE) junction; para [0036],[0045]);
an anchor system (228b, Fig 4 - mucosal capture anchor system; para [0045]);
fixing said body to an inner wall of the lumen with said anchor system and applying at least intermittent pressure with said surface to the inner wall of the lumen (228b, Fig 4 - see mucosal capture anchor system on the cardiac member which captures the mucosal tissue and the device provides the intermittent pressure with the surface 230 against the wall of the lumen; para [0045]). While BFKW 1233 does not disclose the method further comprising forming a tissue fold of the inner wall of the lumen, the tissue fold being adjacent the body wall, said tissue fold transmitting a force between the inner wall of the lumen and said body. KAGAN, however, discloses a bariatric device (400, Figs 24A; para [0282]) having an anchor system (427, 426 Figs 24A, 24D - see anchor apertures 427 through which the fastener 426 passes through to secure the tissue fold 425; para [0282], [0284], [0286]), said anchor system forming a tissue fold of the inner wall of the lumen (425, Fig 24D - see folded tissue; para [0286]), the tissue fold being adjacent the body wall, said tissue fold transmitting a force between the inner wall of the lumen and said body (Fig 24D; para [0286] - see anchors consists of compressing tissue lumen wall against body surface and thus transferring force therebetween which is an inherent property). BFKW 1233 further discloses that the bariatric device can incorporate different anchoring techniques (para [0037]). Incorporating different anchoring systems to secure a bariatric device in the GI tract lumen is within the scope of ordinary skill in the art. While BFKW 1233 in view of KAGAN do not explicitly disclose the positive recitation of a method, BFKW 1233 's device in view of KAGAN's bariatric device having a tissue fold is inherently used to perform the claimed method - BFKW 1233 in view of KAGAN teach the structure of the bariatric device and further teach how it anchors in the lumen of the GE junction. Furthermore, KAGAN discloses a method (para[0022]). Accordingly, it would have been obvious to a person having ordinary skill in the art to have utilized the bariatric device of BFKW 1233 in view of KAGAN and their teachings as a whole, effectively providing a method of using the bariatric device at the GE junction for combating weight loss and also metabolic diseases.

As per claim 19, BFKW 1233 in view of KAGAN discloses the method as claimed in claim 18. KAGAN further discloses the method wherein said anchor system comprises a plurality of anchors (Fig 24D - see plurality of anchors along the circumference of the device; para [0284], [0286]), said fixing including retaining said wall with the tissue fold of the lumen (Fig 24D; para [0286] - see tissue fold being placed within the wall of the device and fixed using fastener 426).

As per claim 29, BFKW 1233 in view of KAGAN discloses the method as claimed in any of claim 18. BFKW 1233 further discloses the device including applying an adjustable pressure with said surface to the inner wall of the lumen (para [0046]).

As per claim 30, BFKW 1233 in view of KAGAN discloses the method as claimed in claim 29 wherein applying an adjustable pressure includes the surface being moveable with an inner bladder (242a, 242b, Fig 4; para [0045]) and a control system adjusting inflation of said inner bladder (236, 238, Fig 4; para [0045]).

As per claim 31, BFKW 1233 in view of KAGAN discloses the method as claimed in claim 30 wherein said control system includes a controller (236, 238, Fig 4; para [0045]) and an outer bladder on an opposite side of said wall (244a, 244b, Fig 4; para [0045]), said controller exchanging a fluid between said bladders in order to move said surface (para [0045]).

As per claim 32, BFKW 1233 in view of KAGAN discloses the method as claimed in any of claim 18. BFKW 1233 further discloses wherein said wall is shaped to the cardiac portion of the stomach (230, Fig 4; para [0045]) and having a central opening (unlabeled, Fig 4; para [0045] - central opening of embodiment in Fig 4 is same as the central opening 31 in Fig 2; para [0036]).

Claims 15-17 and 35-37 lack an inventive step as per PCT Article 33(3) as being obvious over BFKW 1233 in view of KAGAN and US 2009/0018389 A1 to Laufer et al. (hereinafter 'LAUFER').

As per claim 15, BFKW 1233 in view of KAGAN disclose the device as claimed in claim 12. BFKW 1233 further discloses in a similar embodiment wherein said anchor system includes another body (122, Fig 3; para [0042]) that is connected with said body (122, 126, 130, Fig 3 - see esophageal member connected to cardiac member 130 which is similar to the cardiac member 230 in Fig 4; para [0040],[0042]). BFKW 1233 and KAGAN however do not disclose the device wherein the tissue fold connected with a controller on said wall with a filament. LAUFER, however discloses a tissue fold system (1500, Fig 15A; para [0054]) wherein a plurality of tissue folds is connected to a controller (1506, 1508, 1514, Fig 15A; para [0054]) via a filament (1516, 1518, Fig 15A; para [0054]). BFKW 1233 further discloses that the bariatric device can incorporate different anchoring techniques (para [0037]). Placement of a controlling system to dynamically alter the tensioning of suture elements to affect overall anchoring capability is within the scope of ordinary skill in the art. Accordingly, it would have been obvious to a person having ordinary skill in the art to have utilized the tissue fold control system taught by LAUFER in the device of BFKW 1233 in view of KAGAN to have a dynamically controlled tissue folding anchoring system to enable efficient securement of the device at the GE junction which has a dynamic environment due to numerous factors such as peristalsis.

-*-Continued in next Supplemental Box-*-

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB 20/52169

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

As per claim 16, BFKW 1233 in view of KAGAN and LAUFER disclose the device as claimed in claim 15. BFKW 1233 further discloses the device wherein said body is configured to the cardiac portion of the stomach (130, Fig 3; para [0042]) and said anchor system comprises said another body adapted to be fixed to a distal portion of the esophagus (122, Fig 3; para [0042]).

As per claim 17, BFKW 1233 in view of KAGAN and LAUFER disclose the device as claimed in claim 15 and claim 16. LAUFER further discloses wherein said control system includes a controller (1514, Fig 15A; para [0054]) on said wall that is connected with the tissue fold with a filament (1506, 1508, 1516, 1518, Fig 15A; para [0054]) to transmit a force between said tissue fold and said wall (para [0054]), said controller adapted to adjust a length of said filament (para [0054]) to adjust a force between said body and said tissue fold to adjust pressure applied by the surface to the inner wall of the lumen (para [0054]).

As per claim 35, BFKW 1233 in view of KAGAN disclose the method as claimed in claim 19. BFKW 1233 further discloses in a similar embodiment wherein said anchor system includes another body (122, Fig 3; para [0042]) that is connected with said body (122, 126, 130, Fig 3 - see esophageal member connected to cardiac member 130 which is similar to the cardiac member 230 in Fig 4; para [0040],[0042]). BFKW 1233 and KAGAN however do not disclose the device wherein the tissue fold connected with a controller on said wall with a filament. LAUFER, however discloses a tissue fold system (1500, Fig 15A; para [0054]) wherein a plurality of tissue folds is connected to a controller (1506, 1508, 1514, Fig 15A; para [0054]) via a filament (1516, 1518, Fig 15A; para [0054]). BFKW 1233 further discloses that the bariatric device can incorporate different anchoring techniques (para [0037]). Placement of a controlling system to dynamically alter the tensioning of suture elements to affect overall anchoring capability is within the scope of ordinary skill in the art. While BFKW 1233 in view of KAGAN and LAUFER do not explicitly disclose the positive recitation of a method, BFKW 1233 's device in view of KAGAN's bariatric device having a tissue fold and LAUFER's anchoring system with a controller inherently used to perform the claimed method - BFKW 1233 in view of KAGAN and LAUFER teach the device having an another esophageal body and a controller system connected to the plurality of tissue folds. Accordingly, it would have been obvious to a person having ordinary skill in the art to have utilized the bariatric device of BFKW 1233 in view of KAGAN and LAUFER and their teachings as a whole, effectively providing a method of using the bariatric device having an esophageal member and a control system to dynamically alter the tissue folding capability of the device in accordance to the dynamic environment at the GE junction.

As per claim 36, BFKW 1233 in view of KAGAN and LAUFER disclose the method as claimed in claim 35. BFKW 1233 further discloses wherein said body is configured to the cardiac portion of the stomach (130, Fig 3; para [0042]) and said anchor system comprises fixing said another body to a distal portion of the esophagus (122, Fig 3; para [0042]).

As per claim 37, BFKW 1233 in view of KAGAN and LAUFER disclose the method as claimed in claim 35 and claim 36. LAUFER further discloses wherein said control system includes a controller (1514, Fig 15A; para [0054]) on said wall that is connected with the tissue fold with a filament (1506, 1508, 1516, 1518, Fig 15A; para [0054]) to transmit a force between said tissue fold and said wall (para [0054]), said controller adjusting a length of said filament thereby adjusting a force between said body and said tissue fold thereby adjusting pressure applied by the surface to the inner wall of the lumen (para [0054]).

Claims 33-34 lack an inventive step as per PCT Article 33(3) as being obvious over BFKW 1233 in view of KAGAN and US 2015/0025313 A1 to BFKW, LLC (hereinafter 'BFKW 5313').

As per claim 33, BFKW 1233 in view of KAGAN discloses the method as claimed in claim 32. While BFKW 1233 in view of KAGAN do not disclose the method including deploying said wall with a deployment device and aligning said central opening with the esophageal gastric junction using said deployment device. BFKW 5313 discloses a method of deploying a similar bariatric device (Fig 9 - see entirety of bariatric device being deployed using endoscope 16; para [0004], para [0045]) with a deployment device (16, Fig 9; para [0045]) and aligning said central opening with the esophageal gastric junction using said deployment device (para [0044]). Using an endoscopic delivery system to achieve a non-invasive delivery of a bariatric device is within the scope of obvious skill in the art. Accordingly, it would have been obvious to a person having ordinary skill in the art to have utilized the method taught by BFKW 5313 in the combined device of BFKW 1233 in view of KAGAN to accurately deploy the device at the GE junction of the patient.

As per claim 34, BFKW 1233 in view of KAGAN discloses the method as claimed in claim 32. While BFKW 1233 in view of KAGAN do not disclose the method including retention filaments extending from said wall to external the recipient of the device and retaining said wall to the cardiac portion of the stomach of the recipient during said deployment. BFKW 5313 discloses a method of deploying a similar bariatric device (Fig 9 - see entirety of bariatric device being deployed using endoscope 16; para [0004], para [0045]) further comprising retention filaments attached to esophageal member (58, Fig 9; para [0045]). BFKW 5313 further discloses the retention filaments can also be attached to the cardiac member to assist during deployment (para [0045]). Utilizing attachment filaments during a non-invasive deployment is within the scope of ordinary skill in the art. Accordingly, it would have been obvious to a person having ordinary skill in the art to have utilized the method of deployment having retention filaments of BFKW 5313 in combined device of BFKW 1233 in view of KAGAN to accurately deploy the device at the GE junction of the patient.

-*-Continued in next Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB 20/52169

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

Claims 3-6, (7-8)/(3-6), 9-11, 20-22, and (24-25)/(20-22), 26-28 meet the requirements under PCT Articles 33(2) and 33(3) because the prior art does not teach or fairly suggest the claimed limitations. (Note: See Box VIII)

The prior art is exemplified by (1) US 2004/0092892 A1 to Kagan et al. (hereinafter 'KAGAN') and (2) US 2016/0151233 A1 to BFKW 1233, LLC (hereinafter 'BFKW 1233'). (1) KAGAN teaches a bariatric device (400, Figs 24A; para [0282]) having an anchor (421, 424, 427, 426 Figs 24A, 24D - see entirety of anchor system; para [0282], [0284], [0286]) and a tissue fold (425, Fig 24D - see folded tissue; para [0286]) placed at the GE junction (Fig 24A). (2) BFKW 1233 teaches a bariatric device (220, Fig 4; para [0045]) having a cardiac member (230, Fig 4; para [0045]) with a control system (236, 238, Fig 4; para [0045]) and an anchor system (228b, Fig 4 - mucosal capture anchor system; para [0045]).

As per claim 3, KAGAN discloses the device as claimed in claim 2 wherein each of said anchors comprises at least one opening in said wall (427, Fig 24D - see aperture 427 of anchor at the edge of the device close to the lumen; para [0284], [0286]) but fails to describe a crossbar at an edge portion of said at least one opening, the tissue fold positioned in said at least one opening.

As per claim 5, KAGAN discloses the device as claimed in claim 2 but fails to describe wherein each of said anchors comprises an opening traversed by a crossbar, with a tissue fold of the lumen extending into the opening on opposite sides of the crossbar and said fastener adapted to couple the tissue folds in a manner that retains the crossbar between the tissue folds.

As per claims 4, 6, and (7-8)/(3-6), 9-11 the prior art does not teach or fairly suggest the crossbar and the interconnected crossbar assembly as claimed since they are dependent upon claims 3 and 5.

As per claim 20, BFKW 1233 in view of KAGAN disclose the method as claimed in claim 19 (Second treatment). KAGAN further discloses wherein each of said anchors comprises at least one opening in said wall (427, Fig 24D - see aperture 427 of anchor at the edge of the device close to the lumen; para [0284], [0286]) but BFKW 1233 in view of KAGAN fail to describe a crossbar at an edge portion of said at least one opening, including forming the tissue fold in said at least one opening,

As per claim 22, BFKW 1233 in view of KAGAN disclose the method as claimed in claim 19 (Second treatment). BFKW 1233 in view of KAGAN however fail to describe wherein each of said anchors comprises an opening traversed by a crossbar, including forming at least two tissue folds of the lumen each extending into said opening on opposite sides of said crossbar and coupling the tissue folds with a fastener in a manner that retains the crossbar between the tissue folds.

As per claims 21, and (24-25)/(20-22), 26-28 the prior art does not teach or fairly suggest the crossbar and the interconnected crossbar assembly as claimed since they are dependent upon claims 20 and 22.

Claims 1-37 have industrial applicability as per PCT Article 33(4) because the subject matter can be made or used in industry.