

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

To: WILBURN L. CHESSER
ARENTFOX SCHIFF, LLP
1717 K STREET, N.W.
WASHINGTON, DC 20006-5344

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FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US 23/71998

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Applicant KPR U.S., 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
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion

29 November 2023 (29.11.2023)

Authorized officer

Kari Rodriguez

PCT Help Desk
Telephone No. 571-272-4300

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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(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.

b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)),



accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

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Box No. V Reasoned statement under Rule 43bis.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	None	YES
	Claims	1-24	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-24 lack an inventive step under PCT Article 33(3) as being obvious over US 2016/0045400 A1 to Covidien LP (hereinafter 'Covidien') in view of US 2022/0142982 A1 to MITSUBISHI TANABE PHARMA CORPORATION (hereinafter 'MITSUBISHI').

As to claims 1, 22, 23 and 24, Covidien discloses a method/feeding-pump/computer-readable medium/feeding-set off/for occlusion detection of a feeding pump, the method comprising (Abstract, flow control apparatus capable of detecting a downstream flow condition in a tube set mounted on the apparatus, para [0001], flow control apparatus adapted to load a feeding set having an upstream side and a downstream side - pumping device acts on the feeding set to produce fluid flow in the feeding set for delivery of fluid to a subject, para [0004]-[0011], method of operating a flow control apparatus can include a pumping device for detecting occlusions in fluid flow in a pump set acted upon by the flow control apparatus in a downstream portion of the pump set located downstream of the pumping device generally comprises receiving in a control circuit sensor signals from an ultrasonic sensor positioned to detect pressure in the downstream portion of the pump set. The received sensor signals are compared to a baseline stored in the control circuit, and the control circuit determines the presence of an occlusion in the downstream portion of the pump set using the comparison of the received sensor signals to the baseline, para [0012]-[0021], para [0041]-[0050], para [0051]-[0057]):

one or more memories; and instructions executable by one or more processors coupled with the one or more memories and configured, individually or in combination, to (para [0045]-[0050]):

a liquid, wherein the liquid is a feeding formula (tubing 11 provides a fluidic pathway between a bag 12 of nutritional liquid and a patient, para [0041]-[0044]);

and a feeding formula conduit, wherein the feeding pump is configured to advance a first amount of the feeding formula through the feeding formula conduit, and the first amount is a first volume of the liquid (tubing 11 provides a fluidic pathway between a bag 12 of nutritional liquid and a patient - cassette 9 and feeding set 5 may be broadly considered a conduit assembly - rotation of rotor 29 compresses the tubing 11 and provides a means for driving fluid from the upstream to the downstream side of the feeding set 5 for delivery to a patient, para [0041]-[0050]);

wherein the feeding pump is further configured to (pumping device acts on the feeding set to produce fluid flow in the feeding set for delivery of fluid to a subject, para [0004]-[0011], para [0041]-[0050]):

determining when a feeding set including a liquid is engaged in the feeding pump, wherein the liquid is a feeding formula (flow control apparatus 1 may comprise a housing 3 adapted for loading the feeding set 5 (broadly, "pump set") to the flow control apparatus 1 - tubing 11 provides a fluidic pathway between a bag 12 of nutritional liquid and a patient - rotation of rotor 29 compresses the tubing 11 and provides a means for driving fluid from the upstream to the downstream side of the feeding set 5 for delivery to a patient - In order for the sensor 32 to detect the change in pressure in the tubing 11 of the feeding set 5, the tubing may be engaged and retained within a sensor track 45 configured to receive the downstream side of the feeding set. Once the tubing 11 is engaged within the sensor track 45 and the remaining portions of the feeding set 5 are engaged to the apparatus 1, the flow monitoring system 16 may become operational, para [0041]-[0050], para [0051]-[0057]):

advancing a first amount of the feeding formula through the feeding pump via a feeding formula conduit (tubing 11 provides a fluidic pathway between a bag 12 of nutritional liquid and a patient - cassette 9 and feeding set 5 may be broadly considered a conduit assembly - rotation of rotor 29 compresses the tubing 11 and provides a means for driving fluid from the upstream to the downstream side of the feeding set 5 for delivery to a patient, para [0041]-[0050]);

acquiring a first pressure sensor reading of the feeding formula conduit (receiving in a control circuit sensor signals from an ultrasonic sensor positioned to detect pressure in the downstream portion of the pump set, para [0019]-[0024], sensor 32 may comprise an ultrasonic sensor for detecting a change in pressure in the downstream side of the feeding set 5 - ultrasonic signal may be responsive to the pressure in the tubing 11 such that an increase in pressure in the tubing will produce an increase in an amplitude of the signal, para [0041]-[0050]);

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V, 2. Citations and explanations:

advancing a second amount of the feeding formula through the feeding pump via the feeding formula conduit (tubing 11 provides a fluidic pathway between a bag 12 of nutritional liquid and a patient - cassette 9 and feeding set 5 may be broadly considered a conduit assembly - rotation of rotor 29 compresses the tubing 11 and provides a means for driving fluid from the upstream to the downstream side of the feeding set 5 for delivery to a patient, para [0041]-[0050]);

acquiring a second pressure sensor reading of the feeding formula conduit (receiving in a control circuit sensor signals from an ultrasonic sensor positioned to detect pressure in the downstream portion of the pump set, para [0019]-[0024], sensor 32 may comprise an ultrasonic sensor for detecting a change in pressure in the downstream side of the feeding set 5 - ultrasonic signal may be responsive to the pressure in the tubing 11 such that an increase in pressure in the tubing will produce an increase in an amplitude of the signal, para [0041]-[0050]);

acquiring a third pressure sensor reading of the feeding formula conduit (receiving in a control circuit sensor signals from an ultrasonic sensor positioned to detect pressure in the downstream portion of the pump set, para [0019]-[0024], sensor 32 may comprise an ultrasonic sensor for detecting a change in pressure in the downstream side of the feeding set 5 - ultrasonic signal may be responsive to the pressure in the tubing 11 such that an increase in pressure in the tubing will produce an increase in an amplitude of the signal, para [0041]-[0050]);

and detecting when an occlusion is present in the feeding formula conduit based on at least one of the first pressure sensor reading, the second pressure sensor reading and the third pressure sensor reading (receiving in a control circuit sensor signals from an ultrasonic sensor positioned to detect pressure in the downstream portion of the pump set. The received sensor signals are compared to a baseline stored in the control circuit, and the control circuit determines the presence of an occlusion in the downstream portion of the pump set using the comparison of the received sensor signals to the baseline, para [0016]-[0024], ultrasonic signal may be responsive to the pressure in the tubing 11 such that an increase in pressure in the tubing will produce an increase in an amplitude of the signal. In particular, the compressing the tubing 11 by the rotor 29 when an occlusion in the tubing is present may cause the tubing to swell and increase a coupling of the tubing to the sensor 32. Therefore, the strength of the signal will increase with increased pressure on the downstream side of the feeding set 5. Conversely, a decrease in pressure in the tubing 11 may cause a decrease in the amplitude of the ultrasonic signal - Software subsystem 36 may determine through a series of decision points and steps whether normal flow or abnormal flow conditions exist within tubing 11, and if an abnormal flow condition does exist, whether it is a downstream occlusion or a downstream air bubble in the tubing, para [0041]-[0050]) but fails to specifically disclose wherein the first/second amount is a first/second volume of the liquid.

However, MITSUBISHI in analogous art discloses wherein the first/second amount is a first/second volume of the liquid (Abstract, para [0005]-[0006], intragastric administration, for example, a tube such as a feeding tube can be used, para [0013]-[0018], suspension of the following composition has, for example, a total volume of 5 mL, an edaravone content of 105 mg, and a form of, for example, a liquid, para [0025]-[0035]. For the feeding tube, for example, a nasopharyngeal gastric tube (which may be referred to as an "NG tube") or a percutaneous endoscopic gastrostomy tube (which may be referred to as a "PEG tube") can be used, and the pharmaceutical composition is administered via this feeding tube, para [0060]-[0064], Formulas used in clinical studies - Study # 1 - Study #2 - Study #3 - amount - Edaravone - 200mg - 100mg -105mg, Table 1).

It would have been obvious to one of ordinary skill in the art to add MITSUBISHI's intragastric administration to Covidien's method/feeding-pump/computer-readable medium/feeding-set as it is used as a measure for a case where nutrition cannot be consumed through the mouth because of dysphagia or the like - in the intragastric administration, for example, the administration is intragastric administration via a tube (also referred to as transluminal administration or transluminal intragastric administration) as described above, and as a specific example, the administration may be administration via a percutaneous endoscopic gastrostomy tube (PEG tube), administration via a nasopharyngeal gastric tube (NG tube), a combination of both, or a change from one to the other (see para [0060]-[0064]).

As to claim 2, MITSUBISHI discloses a method wherein the feeding formula is rated as level 0-4 on an International Dysphagia Diet Standardization Initiative (IDDSI) framework (pharmaceutical composition - The form is, for example, a liquid, a gel, or a solid. The liquid is exemplified by solutions and suspensions, the gel is exemplified by jellies, and the solid is exemplified by tablets, capsules, powders, fine granules, and granules - the preferred form is a liquid, and in particular, a suspension is preferred, [0013]-[0018], nutrition cannot be consumed through the mouth because of dysphagia or the like - the administration is intragastric administration via a tube - via a percutaneous endoscopic gastrostomy tube (PEG tube) - via a nasopharyngeal gastric tube (NG tube), a combination of both, or a change from one to the other, para [0060]-[0064]).

As to claim 3, MITSUBISHI discloses a method wherein the feeding formula is further rated as level 2-4 on the IDDSI framework (pharmaceutical composition - The form is, for example, a liquid, a gel, or a solid. The liquid is exemplified by solutions and suspensions, the gel is exemplified by jellies, and the solid is exemplified by tablets, capsules, powders, fine granules, and granules - the preferred form is a liquid, and in particular, a suspension is preferred, [0013]-[0018], nutrition cannot be consumed through the mouth because of dysphagia or the like - the administration is intragastric administration via a tube - via a percutaneous endoscopic gastrostomy tube (PEG tube) - via a nasopharyngeal gastric tube (NG tube), a combination of both, or a change from one to the other, para [0060]-[0064]).

As to claim 4, Covidien discloses a method further comprising pausing the feeding pump for a predetermined period of time after advancing the first amount of the feeding formula, and before performing the acquiring of the first pressure sensor reading (control circuit can be configured to stop the pumping device at a predetermined position before receiving said new sensor signal readings or obtain new sensor signal readings while the pumping device is in operation, para [0004]-[0015], para [0041]-[0050], microprocessor 62 may instruct the flow control apparatus 1 to stop rotation of the rotor 29 at a "pressure release position." The pressure release position is a position of the rotor 29 that allows pressure in the tubing 11 to be released from the tube. At 298 the microprocessor 62 may instruct the sensor 32 to transmit an ultrasonic signal through the downstream portion of the tubing 11 to provide the microprocessor with a reading of the signal. At 300, the microprocessor may record the signal reading for a period of time, para [0051]-[0057]).

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

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Box V, 2. Citations and explanations:

As to claim 5, MITSUBISHI discloses a method wherein the predetermined period of time being 1-3 seconds ("first" and "second" in the "first time interval" and the "second time interval" are used to distinguish the two different time intervals, para [0013]-[0018], measuring the concentration of edaravone in plasma of a subject, for example, at a predetermined period before and after administration of the pharmaceutical composition containing edaravone, para [0037]-[0038]).

As to claim 6, Covidien discloses a method further comprising pausing the feeding pump for a second predetermined period of time after advancing the second amount of the feeding formula and before performing the acquiring of the third pressure sensor reading (control circuit can be configured to stop the pumping device at a predetermined position before receiving said new sensor signal readings or obtain new sensor signal readings while the pumping device is in operation, para [0004]-[0015], para [0041]-[0050], microprocessor 62 may instruct the flow control apparatus 1 to stop rotation of the rotor 29 at a "pressure release position." The pressure release position is a position of the rotor 29 that allows pressure in the tubing 11 to be released from the tube. At 298 the microprocessor 62 may instruct the sensor 32 to transmit an ultrasonic signal through the downstream portion of the tubing 11 to provide the microprocessor with a reading of the signal. At 300, the microprocessor may record the signal reading for a period of time, para [0051]-[0057]).

As to claim 7, Covidien discloses a method wherein the pausing of the feeding pump for the second predetermined period of time is after performing the acquiring of the second pressure sensor reading (control circuit can be configured to stop the pumping device at a predetermined position before receiving said new sensor signal readings or obtain new sensor signal readings while the pumping device is in operation, para [0004]-[0015], para [0041]-[0050], microprocessor 62 may instruct the flow control apparatus 1 to stop rotation of the rotor 29 at a "pressure release position." The pressure release position is a position of the rotor 29 that allows pressure in the tubing 11 to be released from the tube. At 298 the microprocessor 62 may instruct the sensor 32 to transmit an ultrasonic signal through the downstream portion of the tubing 11 to provide the microprocessor with a reading of the signal. At 300, the microprocessor may record the signal reading for a period of time, para [0051]-[0057]).

As to claims 8 and 11, MITSUBISHI discloses a method wherein the second predetermined period of time being 2-7 seconds ("first" and "second" in the "first time interval" and the "second time interval" are used to distinguish the two different time intervals, para [0013]-[0018], measuring the concentration of edaravone in plasma of a subject, for example, at a predetermined period before and after administration of the pharmaceutical composition containing edaravone, para [0037]-[0038]).

As to claim 9, Covidien discloses a method further comprising pausing the feeding pump for a predetermined period of time after advancing the second amount of the feeding formula and before performing the acquiring of the third pressure sensor reading (control circuit can be configured to stop the pumping device at a predetermined position before receiving said new sensor signal readings or obtain new sensor signal readings while the pumping device is in operation, para [0004]-[0015], para [0041]-[0050], microprocessor 62 may instruct the flow control apparatus 1 to stop rotation of the rotor 29 at a "pressure release position." The pressure release position is a position of the rotor 29 that allows pressure in the tubing 11 to be released from the tube. At 298 the microprocessor 62 may instruct the sensor 32 to transmit an ultrasonic signal through the downstream portion of the tubing 11 to provide the microprocessor with a reading of the signal. At 300, the microprocessor may record the signal reading for a period of time, para [0051]-[0057]).

As to claim 10, Covidien discloses a method wherein the pausing of the feeding pump for the predetermined period of time is after performing the acquiring of the second pressure sensor reading (control circuit can be configured to stop the pumping device at a predetermined position before receiving said new sensor signal readings or obtain new sensor signal readings while the pumping device is in operation, para [0004]-[0015], para [0041]-[0050], microprocessor 62 may instruct the flow control apparatus 1 to stop rotation of the rotor 29 at a "pressure release position." The pressure release position is a position of the rotor 29 that allows pressure in the tubing 11 to be released from the tube. At 298 the microprocessor 62 may instruct the sensor 32 to transmit an ultrasonic signal through the downstream portion of the tubing 11 to provide the microprocessor with a reading of the signal. At 300, the microprocessor may record the signal reading for a period of time, para [0051]-[0057]).

As to claim 12, Covidien discloses a method wherein the feeding formula conduit is a tube that is compressably engaged with a rotor of a feeding set (tubing 11 provides a fluidic pathway between a bag 12 of nutritional liquid and a patient - cassette 9 and feeding set 5 may be broadly considered a conduit assembly - rotation of rotor 29 compresses the tubing 11 and provides a means for driving fluid from the upstream to the downstream side of the feeding set 5 for delivery to a patient, para [0041]-[0050]).

As to claim 13, MITSUBISHI discloses a method wherein the first volume of the liquid and the second volume of the liquid is one aliquot (edaravone oral formulation was loaded into a syringe for catheter administration to give an edaravone amount of 105 mg, and the edaravone oral formulation was passed from the syringe to each of the catheters. Water at a predetermined temperature was then injected into the catheter to wash in the edaravone oral formulation. The edaravone oral formulation that passed through the catheter and the wash-in liquid were collected and mixed, and an amount of edaravone contained in the mixed liquid was measured, para [0121]-[0122]).

As to claim 14, MITSUBISHI discloses a method wherein advancing the first amount is priming the feeding set (edaravone oral formulation was loaded into a syringe for catheter administration to give an edaravone amount of 105 mg, and the edaravone oral formulation was passed from the syringe to each of the catheters. Water at a predetermined temperature was then injected into the catheter to wash in the edaravone oral formulation. The edaravone oral formulation that passed through the catheter and the wash-in liquid were collected and mixed, and an amount of edaravone contained in the mixed liquid was measured, para [0121]-[0122]).

As to claim 15, Covidien discloses a method further comprising when a difference between the third pressure sensor reading and the second pressure sensor reading is less than or equal to X pounds per square inch (PSI) the feeding formula conduit is not occluded (Software subsystem 36 may determine through a series of decision points and steps whether normal flow or abnormal flow conditions exist within tubing 11 - pressure of between about 3 and about 5 psi is produced in the tubing 11 during non-occluded operation of the pumping device, para [0045]-[0050]).

--(Continued in Supplemental Box)--

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V, 2. Citations and explanations:

As to claim 16, Covidien discloses a method further comprising when a difference between the third pressure sensor reading and the second pressure sensor reading is greater than X pounds per square inch, and when a difference between the third pressure sensor reading and the first pressure sensor reading is less than or equal to X2 pounds per square inch, the feeding formula conduit is occluded (Software subsystem 36 may determine through a series of decision points and steps whether normal flow or abnormal flow conditions exist within tubing 11 - FIG. 11 illustrates a typical pressure in an occluded feeding set along the length the feeding set. In the embodiment of FIG. 11, the pressure generally ranges from about 12 psi to about 15 psi when an occlusion is present in the feeding set, para [0045]-[0050]).

As to claim 17, Covidien discloses a method further comprising when a difference between the third pressure sensor reading and the second pressure sensor reading is greater than X PSI, and when a difference between the third d pressure sensor reading and the first pressure sensor reading is greater than X2 PSI, and when an average of a plurality of previous second pressure sensor readings is greater than or equal to X3, the feeding formula conduit is occluded (Software subsystem 36 may determine through a series of decision points and steps whether normal flow or abnormal flow conditions exist within tubing 11 - pressure of between about 3 and about 5 psi is produced in the tubing 11 during non-occluded operation of the pumping device - FIG. 11 illustrates a typical pressure in an occluded feeding set along the length the feeding set. In the embodiment of FIG. 11, the pressure generally ranges from about 12 psi to about 15 psi when an occlusion is present in the feeding set, para [0045]-[0050]).

As to claim 18, Covidien discloses a method wherein X is between -10 and 2 PSI, X2 is between 0 and 10 PSI, and X3 is between -6 and 8 PSI (Software subsystem 36 may determine through a series of decision points and steps whether normal flow or abnormal flow conditions exist within tubing 11 - pressure of between about 3 and about 5 psi is produced in the tubing 11 during non-occluded operation of the pumping device - FIG. 11 illustrates a typical pressure in an occluded feeding set along the length the feeding set. In the embodiment of FIG. 11, the pressure generally ranges from about 12 psi to about 15 psi when an occlusion is present in the feeding set, para [0045]-[0050]).

As to claim 19, Covidien discloses a method wherein X is between -6 and -2 PSI, X2 is between 4 and 8 PSI, and X3 is between -2 and 5 PSI (Software subsystem 36 may determine through a series of decision points and steps whether normal flow or abnormal flow conditions exist within tubing 11 - pressure of between about 3 and about 5 psi is produced in the tubing 11 during non-occluded operation of the pumping device - FIG. 11 illustrates a typical pressure in an occluded feeding set along the length the feeding set. In the embodiment of FIG. 11, the pressure generally ranges from about 12 psi to about 15 psi when an occlusion is present in the feeding set, para [0045]-[0050]).

As to claim 20, Covidien discloses a method wherein X is -4 PSI, X2 is 5 PSI, and X3 is 3 PSI (Software subsystem 36 may determine through a series of decision points and steps whether normal flow or abnormal flow conditions exist within tubing 11 - pressure of between about 3 and about 5 psi is produced in the tubing 11 during non-occluded operation of the pumping device - FIG. 11 illustrates a typical pressure in an occluded feeding set along the length the feeding set. In the embodiment of FIG. 11, the pressure generally ranges from about 12 psi to about 15 psi when an occlusion is present in the feeding set, para [0045]-[0050]).

As to claim 21, Covidien discloses a method wherein the plurality of previous second pressure sensor reading is less than or equal to 12 second pressure readings (received sensor signals are compared to a baseline stored in the control circuit, and the control circuit determines the presence of an occlusion in the downstream portion of the pump set using the comparison of the received sensor signals to the baseline, para [0016]-[0024], Software subsystem 36 may determine through a series of decision points and steps whether normal flow or abnormal flow conditions exist within tubing 11 - pressure of between about 3 and about 5 psi is produced in the tubing 11 during non-occluded operation of the pumping device - FIG. 11 illustrates a typical pressure in an occluded feeding set along the length the feeding set. In the embodiment of FIG. 11, the pressure generally ranges from about 12 psi to about 15 psi when an occlusion is present in the feeding set, para [0045]-[0050]).

Claims 1-24 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.