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)*	03 DEC 2010

Applicant's or agent's file reference	FOR FURTHER ACTION
LVC-001PC	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/042540	20 July 2010	21 July 2009

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61M 25/01 (2010.01)
USPC - 604/516

Applicant COVELLO, LEONARD

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 or 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.

3. For further details, see notes to 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. 571-273-3201	24 November 2010	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 filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

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 in 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. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the appicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

See first Supplemental Box.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-6, 9-14 and 17-21

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

1. Statement

Novelty (N)	Claims	5, 17-21	YES
	Claims	1-4, 6, 9-14	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-6, 9-14, 17-21	NO
Industrial applicability (IA)	Claims	1-6, 9-14, 17-21	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-4, 6, 9-14 lack novelty under PCT Article 33(2) as being anticipated by Becker.

Regarding claim 1, Becker discloses a method of treating a congested maxillary sinus (Title and Abstract; para. 0048) comprising:
i. advancing an instrument (cutting forceps 67; Fig. 4) capable of making a perforation into the ethmoid infundibulum (24; Figs. 4 & 5; para. 0048);
ii. positioning the instrument (67) at the anterior and inferior attachment of the uncinate process (26; Fig. 4; para. 0048);
iii. making a perforation in the uncinate process (26; para. 0048 regarding sing cutting forceps 67 to remove part of the uncinate process 26; Fig. 4);
iv. inserting a dilator (balloon catheter 130 which includes balloon 134) through the perforation (Fig. 5; para. 0048);
v. positioning the dilator (balloon 134; Fig. 7) in the ethmoid infundibulum (24; Fig. 5; para. 0048 regarding balloon catheter 130 is then pushed through the maxillary ostium 41 (which is in ethmoid infundibulum 24)); and
vi. dilating the ethmoid infundibulum (24) by expanding the dilator (134; Fig. 5; para. 0048 describes the dilation).

Regarding claim 2, Becker discloses the method of claim 1, and Becker further discloses
vii. advancing the dilator (134) into the natural ostium of the maxillary sinus (Fig. 5; para. 0048 regarding balloon catheter 130 is then pushed through the maxillary ostium 41 (which is in ethmoid infundibulum 24) into the maxillary sinus 21); and
viii. dilating the natural ostium (41) of the maxillary sinus (21) by expanding the dilator (134; Fig. 5; para. 0048).

Regarding claim 3, Becker discloses the method of claim 2, and Becker further discloses
ix. advancing the dilator (134) to the site of the perforation (Figs. 6 & 8 show examples of advancing the balloon catheter 1340 to a perforation site on the nasal wall 44; para. 0049-0050); and
x. dilating the perforation (Figs. 7 & 9 show dilation of the perforation, which is capable of occurring at locations shown in Figs. 4 & 5; para. 0049-0050 describes the dilation).

Regarding claim 4, Becker discloses the method of claim 1, and Becker further discloses wherein the dilator (134) is a guide-free dilator (Fig. 1 shows a closed distal tip 184 that forms a guide-free dilator, which is a dilator that does not use a guide wire to position it; para. 0040).

Regarding claim 6, Becker discloses the method of claim 1, and Becker further discloses wherein the skeletal support structure of the uncinate process (26) is maintained after making the perforation (para. 0048, 0051 both describe removing a portion of the uncinate process 26 to form the perforation; as no additional permanent components are placed in the area, only dilation occurs, we are capable of assuming the structural support of the uncinate process remains in place; Figs. 4 & 10).

Regarding claim 9, Becker discloses a method of treating a congested maxillary sinus (Title and Abstract; para. 0048) comprising:
i. retracting the middle turbinate (para. 0048 regarding the middle turbinate 20 is retracted medially; Fig. 4);
ii. advancing an instrument (cutting forceps 67) capable of making a perforation into the ethmoid infundibulum (24; Figs. 4 & 5; para. 0048);
iii. positioning the instrument (67) at the anterior and inferior attachment of the uncinate process (26; Fig. 4; para. 0048);
iv. making a perforation in the uncinate process (26; para. 0048 regarding sing cutting forceps 67 to remove part of the uncinate process 26; Fig. 4);
v. inserting a dilator (balloon catheter 130 which includes balloon 134) through the perforation (Fig. 5; para. 0048);
vi. positioning the dilator (134) in the ethmoid infundibulum (24; Fig. 5; para. 0048 regarding balloon catheter 130 is then pushed through the maxillary ostium 41 (which is in ethmoid infundibulum 24)); and
vii. dilating the ethmoid infundibulum (24) by expanding the dilator (130; Fig. 5; para. 0048 describes the dilation).

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
Box IV, part 3

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-6, 9-14 and 17-21 are drawn to a method of treating a congested maxillary sinus.

Group II, claims 22-27 are drawn to a method of delivering a drug to a congested maxillary sinus.

Group III, claims 28 and 29 are drawn to a method of retracting the middle turbinate prior to a sinus procedure.

Group IV, claims 30-34 are drawn to a middle turbinate retractor.

Group V, claim 35 is drawn to a middle turbinate retractor.

Group VI, claims 36-41 are drawn to a hole punch capable of making a perforation in the uncinate process.

Group VII, claims 42-58 are drawn to a guide-free dilator.

Group VIII, claims 59-62 are drawn to a drug insertion device.

Group IX, claims 63 and 64 are drawn to a device for controlled delivery of a drug into a sinus.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I, advancing an instrument capable of making a perforation; making a perforation; inserting a dilator through the perforation; dilating by expanding the dilator, are not present in Groups II-IX; the special technical features of Group II, advancing a drug insertion instrument device through the perforation; and releasing a drug or drug delivery device in the maxillary sinus, are not present in Groups I or III-IX; the special technical features of Group III, advancing a middle turbinate retractor in a compressed state into the axilla of the middle meatus between the middle turbinate and the lateral wall of the nose; and expanding the middle turbinate retractor to reveal the relevant anatomy around an obstructed sinus cavity, are not present in Groups I, II or IV-IX; the special technical features of Group IV, an expandable frame having two parallel sides and a rounded portion between the two sides, said expandable frame approximating a V-shape or a U-shape; an intervening pliable metal or plastic frame between the two sides of the expandable frame which enables expansion and compression of the frame; and a pair of forceps on the inner portion of both sides of the expandable frame, are not present in Groups I-III or V-IX; the special technical features of Group V, two parallel arms that are capable of being expanded or compressed with respect to each other; a pair of expansion receptacles at the lower portion of each arm; a ratchet arm connected at the upper portion of each parallel arm, are not present in Groups I-IV or VI-IX; the special technical features of Group VI, a shaft; a stationary platform mounted on said shaft; a blade attached to one end of the stationary platform; a mobile tapered flange, are not present in Groups I-V or VII-IX; the special technical features of Group VII, a rigid shaft with a bottom portion and a top portion; a rigid handle mounted at the bottom portion of the rigid shaft; and a dilator segment mounted at the top portion of the rigid shaft, are not present in Groups I-VI, VIII or IX; the special technical features of Group VIII, a rigid shaft containing a lumen, said rigid shaft angled distally at an angle between about 55 degrees and about 60 degrees; a piston slidedly connected to said lumen of said rigid shaft; a receptacle for holding a drug or drug delivery device, are not present in Groups I-VII or IX; and the special technical features of Group IX, a drug containing matrix; and a degradable framework having a spine and a series of coplanar ribs protruding radially from the spine, the tips of the ribs protruding past the outer surface of the drug containing matrix, wherein the drug containing matrix degrades at a rate faster than the degradable framework, are not present in Groups I-VIII.

Since none of the special technical features of the Groups I-IX inventions is found in more than one of the inventions, unity is lacking.

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Supplemental Box

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

Regarding claim 10, Becker discloses a method of treating a congested anterior ethmoid sinus (Title and Abstract; para. 0051) comprising:
i. dilating the hiatus semilunaris superior (para. 0027 describes how the ethmoid infundibulum and semilunar hiatus are next to each other; para. 0048 describes dilating the ethmoid infundibulum region, shown in Figs. 4 & 5, which includes a portion of the hiatus semilunaris);
ii. making a perforation in the anterior wall (30) of the ethmoid bulla (28; Fig. 10; para. 0051 regarding fine cutting forceps 66 is used to remove the anterior wall 30 of the ethmoid bulla 28);
iii. advancing a dilator (balloon catheter 230 which includes balloon 234) through the perforation until it reaches the ethmoid bulla ostium (at the anterior ethmoid air cells 29 in Fig. 12; para. 0051); and
iv. dilating the ethmoid bulla ostium (Fig. 12; para. 0051 describes a second dilation).

Regarding claim 11, Becker discloses a method of treating a congested anterior ethmoid sinus (Title and Abstract; para.0051) comprising:
i. dilating the hiatus semilunaris superior (para. 0027 describes how the ethmoid infundibulum and semilunar hiatus are next to each other; para. 0048 describes dilating the ethmoid infundibulum region, shown in Figs. 4 & 5, which includes a portion of the hiatus semilunaris);
ii. making a perforation in the anterior wall (30) of the ethmoid bulla (28; Fig. 10; para. 0051 regarding fine cutting forceps 66 is used to remove the anterior wall 30 of the ethmoid bulla 28);
iii. dilating the perforation (Fig. 11; para. 0051 describes dilation via a balloon catheter 230);
iv. advancing a dilator (30) through the perforation until it reaches the ethmoid bulla ostium (at the anterior ethmoid air cells 29 in Fig. 12; para. 0051); and
v. dilating the ethmoid bulla ostium (Fig. 12; para. 0051 describes a second dilation).

Regarding claim 12, Becker discloses the method of claim 11, and Becker further discloses wherein the dilator (230) is a guide-free dilator (Fig. 1 shows a closed distal tip 184 that forms a guide-free dilator, which is a dilator that does not use a guide wire to position it; para. 0040).

Regarding claim 13, Becker discloses the method of claim 11, and Becker further discloses retracting the middle turbinate (para. 0048, 0051 both describe how the middle turbinate 20 is retracted medially; Fig. 4 & 5) prior to dilating the hiatus semilunaris superior (para. 0027 describes how the ethmoid infundibulum and semilunar hiatus are next to each other; para. 0048 describes dilating the ethmoid infundibulum region, shown in Figs. 4 & 5, which includes a portion of the hiatus semilunaris).

Regarding claim 14, Becker discloses a method of treating a congested anterior ethmoid sinus (Title and Abstract; para.0051) comprising:
i. retracting the middle turbinate (para. 0048, 0051 both describe how the middle turbinate 20 is retracted medially; Fig. 4 & 5) ;
ii. dilating the hiatus semilunaris superior (para. 0027 describes how the ethmoid infundibulum and semilunar hiatus are next to each other; para. 0048 describes dilating the ethmoid infundibulum region, shown in Figs. 4 & 5, which includes a portion of the hiatus semilunaris);
iii. making a perforation in the anterior wall (30) of the ethmoid bulla (28; Fig. 10; para. 0051 regarding fine cutting forceps 66 is used to remove the anterior wall 30 of the ethmoid bulla 28);
iv. advancing a dilator (balloon catheter 230) through the perforation until it reaches the ethmoid bulla ostium (at the anterior ethmoid air cells 29 in Fig. 12; para. 0051); and
v. dilating the ethmoid bulla ostium (Fig. 12; para. 0051 describes a second dilation).

Claim 5 lacks an inventive step under PCT Article 33(3) as being obvious over Becker in view of Doble.
Regarding claim 5, Becker discloses the method of claim 1, and Becker further discloses wherein the instrument (cutting forceps 67 is one instrument shown in Fig. 4; a Blakesely punch 60, shown in Fig. 6, is another instrument that could be used to create a perforation) capable of making a perforation is a hole punch (Figs. 4 & 6; para. 0049 describes the upbiting Blakesely punch 60; para. 0027).
Becker fails to explicitly disclose a backbiting instrument.
Doble teaches of a backbiting surgical instrument, comprising a backbiting instrument (Fig. 1; col. 2, lns. 9-14 describes a backbiting surgical instrument; col. 1, lns. 29-52 describes using the instrument on the uncinate process).
It would have been obvious to one of skill in the art at the time of invention to modify the invention of Becker to include a backbiting surgical instrument as taught by Doble as this can create the necessary perforation in the uncinate process of the patient's sinus.

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

Claim 17-19 lacks an inventive step under PCT Article 33(3) as being obvious over Becker in view of Muni et al. (hereafter Muni).
Regarding claim 17, Becker discloses a method of treating a congested anterior ethmoid sinus (Title and Abstract; para.0051) comprising:
i. advancing an instrument (balloon catheter) into the antrum of the ethmoid bulla (para. 0051 describes how the catheter is the cavity of the ethmoid bulla 28; Fig. 11);
ii. engaging the ethmoid bulla ostium with the instrument (Figs. 11 & 12 show openings on the ethmoid bulla being engaged by the distal end 237 of the balloon catheter 230; para. 0051);
iv. advancing a dilator (230) into the antrum of the ethmoid bulla (at the anterior ethmoid air cells 29 in Fig. 12; para. 0051); and
v. dilating the ethmoid bulla ostium (Fig. 12; para. 0051 describes a second dilation in the region of the ethmoid bulla ostium).
Becker fails to explicitly disclose iii. stretching the ethmoid bulla medially and anteriorly.
Muni teaches of methods for treating sinusitis, comprising iii. stretching a ethmoid bulla (EB) medially and anteriorly (para. 0134 describes positioning a member in a natural opening of the ethmoid bulla, which can expand to stretch the opening in medial and anterior directions, among other directions).
It would have been obvious to one of skill in the art at the time of invention to modify the invention of Becker to include stretching the ethmoid bulla as taught by Muni as this may provide sinus relief.

Regarding claim 18, Becker discloses the method of claim 17, and Becker further discloses dilating the hiatus semilunaris superior (para. 0027 describes how the ethmoid infundibulum and semilunar hiatus are next to each other; para. 0048 describes dilating the ethmoid infundibulum region, shown in Figs. 4 & 5, which includes a portion of the hiatus semilunaris).

Regarding claim 19, Becker discloses the method of claim 17, and Becker further discloses retracting the middle turbinate (para. 0048, 0051 both describe how the middle turbinate 20 is retracted medially; Fig. 4 & 5) prior to advancing the instrument into the antrum of the ethmoid bulla (28; para. 0051 describes the retracting prior before the ethmoid bulla is reached).

Claims 20, 21 lack an inventive step under PCT Article 33(3) as being obvious over Becker in view of Chang et al. (hereafter Chang).
Regarding claim 20, Becker discloses a method of treating a congested frontal sinus (Title and Abstract; para. 0054) comprising:
i. positioning a device into the middle meatus (para. 0054 describes using a device for performing an anterior ethmoidectomy, which retracts the middle turbinate to gain access to the middle meatus 22 as described in para. 0051; Figs. 4 & 16);
ii. advancing a guide-free dilator (balloon cathter 130) into the frontal ostium (para. 0054 describes bringing the catheter 130 into the frontnasal duct 36, which is part of the frontal ostium; Fig. 16); and
iii. dilating the frontal ostium (para. 0054 describes dilating the frontnasal duct 36; Fig. 16). Becker fails to explicitly disclose a device for performing procedures in the sinuses, wherein the device is an endoscope.
Chang teaches of a device for performing procedures in the sinuses, wherein the device is an endoscope (para. 0110 describes positioning an endoscope 84 in the medial meatus).
It would have been obvious to one of skill in the art at the time of invention to modify the invention of Becker to include using an endoscope as taught by Chang as this allows the surgeon to better see the area in question.

Regarding claim 21, Becker discloses a method of treating a congested frontal sinus (Title and Abstract; para. 0054) comprising:
i. retracting the middle turbinate (para. 0054 describes performing an anterior ethmoidectomy, which retracts the middle turbinate to gain access to the middle meatus 22 as described in para. 0051; Figs. 4 & 16);
ii. positioning a device into the middle meatus (para. 0054 describes using a device for performing an anterior ethmoidectomy, which retracts the middle turbinate to gain access to the middle meatus 22 as described in para. 0051; Figs. 4 & 16);
iii. advancing a guide-free dilator (balloon cathter 130) into the frontal ostium (para. 0054 describes bringing the catheter 130 into the frontnasal duct 36, which is part of the frontal ostium; Fig. 16); and
iv. dilating the frontal ostium (para. 0054 describes dilating the frontnasal duct 36; Fig. 16). Becker fails to explicitly disclose a device for performing procedures in the sinuses, wherein the device is an endoscope.
Chang teaches of a device for performing procedures in the sinuses, wherein the device is an endoscope (para. 0110 describes positioning an endoscope 84 in the medial meatus).
It would have been obvious to one of skill in the art at the time of invention to modify the invention of Becker to include using an endoscope as taught by Chang as this allows the surgeon to better see the area in question.

Claims 1-6, 9-14, 17-21 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.