

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: BETSY K. DOWD
 GOODWIN PROCTER LLP
 THE NEW YORK TIMES BUILDING
 620 EIGHTH AVENUE
 NEW YORK, NEW YORK 10018

PCT

INVITATION TO PAY ADDITIONAL FEES
 AND, WHERE APPLICABLE, PROTEST FEE

(PCT Article 17(3)(a) and Rules 40.1 and 40.2(e))

| | | | |
|--|--|---|---|
| | | Date of mailing (day/month/year) | 20 SEP 2010 |
| Applicant's or agent's file reference LVC=001PC | | PAYMENT DUE | within ONE MONTH from the above date of mailing |
| International application No. PCT/US2010-42540 | | International filing date (day/month/year) | 20 JULY 2010 |
| Applicant COVELLO, LEONARD V. | | | |

1. This International Searching Authority

(i) considers that there are 9 (number of) inventions claimed in the international application covered by the claims indicated below/on an extra sheet:
 See Extra Sheet

(ii) therefore considers that **the international application does not comply with the requirement of unity of invention** (Rules 13.1, 13.2 and 13.3) for the reasons indicated below/on an extra sheet:
 See Extra Sheet

(iii) has carried out a partial international search (see Annex) will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:
 claims 1-6, 9-14, 17-21

(iv) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid.

2. Consequently, the applicant is hereby **invited to pay**, within the time limit indicated above, additional fees in the amount indicated below:

$$\frac{\$ 2,080.00}{\text{Fee per additional invention}} \times \frac{8}{\text{number of additional inventions}} = \frac{\$ 16,640.00}{\text{total amount of additional fees/currency}}$$

3. The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fees may be made under protest**, that is, a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fees is excessive, where applicable, subject to the payment of a protest fee.
 Where the applicant pays additional fees under protest, the applicant is hereby invited, within the time limit indicated above, to pay a protest fee (Rule 40.2(e)) in the amount of _____ (amount/currency)
 Where the applicant has not, within the time limit indicated above, paid the required protest fee, the protest will be considered not to have been made and the International Searching Authority will so declare.

4. Claim(s) Nos. 7, 8, 15 and 16 have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

| | |
|---|--|
| 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. 571-273-3201 | Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774 |
|---|--|

INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE

International application No.

PCT/US2010-42540

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 uncinat 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 slidably 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.