(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 February 2004 (19.02.2004)

PCT

(10) International Publication Number
WO 2004/014471 A1

(51) International Patent Classification[7]: A61M 16/04, A61B 1/01

(21) International Application Number: PCT/US2003/025000

(22) International Filing Date: 7 August 2003 (07.08.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/217,266 8 August 2002 (08.08.2002) US

(71) Applicant: **SCIMED LIFE SYSTEMS, INC.** [US/US]; One Scimed Place, Maple Grove, MN 55311-1566 (US).

(72) Inventor: **SCOPTON, Paul**; 145 Cambridge Street, Winchester, MA 01890 (US).

(74) Agent: **TULLETT, Rodney, C.**; Christensen O'Connor Johnson & Kindness PLLC, 1420 Fifth Avenue, Suite 2800, Seattle, WA 98101 (US).

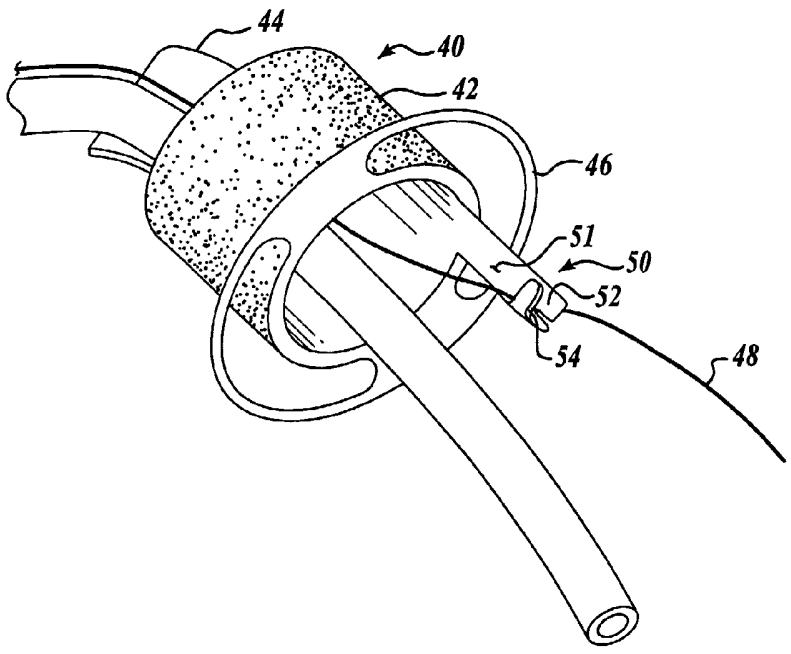
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MOUTHGUARD HAVING DEVICE SECURING TAB



(57) Abstract: A mouthguard for allowing medical instruments to be passed into a patient includes an integrally formed or removable locking device. The locking device includes y one or more mechanisms for preventing the movement of a guidewire or other medical devices during a surgical procedure.

WO 2004/014471 A1

MOUTHGUARD HAVING DEVICE SECURING TAB

FIELD OF THE INVENTION

The present invention relates to medical devices and in particular to minimally invasive medical devices.

BACKGROUND OF THE INVENTION

As an alternative to conventional surgical techniques, many new minimally invasive techniques are being developed to access and treat internal body tissue. These minimally invasive techniques are generally less traumatic to the patient and heal faster than conventional surgeries.

In many minimally invasive surgical procedures, it is necessary for an endoscopist to route a guidewire from a position outside the patient's body to the position of the tissue to be treated. With the guidewire in place, catheters or devices can be advanced over the guidewire in order to position them adjacent the tissue in question.

For example, in treating the digestive tract, an endoscope is first routed through a patient's alimentary canal and a guidewire is then routed through a lumen in the endoscope in order to position it near the tissue in question. The endoscope is then removed over the guidewire thereby leaving the guidewire at the desired location. Other devices or catheters can then be routed over the guidewire in order to perform a treatment operation. Typically, the proximal end of the guidewire extends out the patient's mouth. In order to avoid having to reposition the guidewire, it is important that the guidewire not be moved during the surgical procedure.

SUMMARY OF THE INVENTION

To aid in securing the position of a guidewire or other medical device that extends out of a patient's mouth during a medical procedure, the present invention is a mouthguard having a tube through which medical devices may be passed. A flange on the tube prevents the mouthguard from being swallowed, and a locking device is either integrally formed or removably secured to the mouthguard. The locking device has mechanisms for securing one or more of the medical devices in position during a medical procedure.

In one embodiment of the invention, the locking device comprises a tab having a slot into which a guidewire or other medical device can be held with a friction fit.

Alternatively, the mechanisms can comprise clips, tabs, hook and loop tape or other mechanisms that prevent a guidewire or other device from being moved during surgery.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 illustrates a patient undergoing a catheter-based surgical procedure with a conventional catheter and guidewire;

FIGURE 2 illustrates a patient undergoing a catheter-based surgical procedure using a rapid exchange-type catheter;

FIGURE 3 illustrates a mouthguard having a locking device in accordance with one embodiment of the present invention; and

FIGURE 4 illustrates a mouthguard having a locking device according to a second embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGURES 1 and 2 illustrate a patient undergoing a minimally invasive surgical procedure that uses a guidewire. In FIGURE 1, a guidewire 10 is positioned with its distal tip adjacent a tissue area to be treated within the patient's body. Typically, the guidewire 10 is routed through a lumen in an endoscope (not shown) such that the physician can see where the guidewire is to be placed. Once the guidewire is in the appropriate location, the physician removes the endoscope over the guidewire, thereby leaving the guidewire with its distal tip at the desired location. With the guidewire in the appropriate position, a catheter 20 can be routed over the guidewire in order to deliver a surgical device or treatment to the tissue in question. Such surgical devices can include balloons, stents, electro- or laser tissue cutting devices, aspirators or therapeutic delivery mechanisms, etc.

If the catheter 20 is a conventional type, it contains a lumen along it entire length through which the proximal end of the guidewire 10 is routed. In order to advance the catheter 20 into the patient, the guidewire10 must have a length that is at least as long as the catheter 20 such that the physician can grasp the proximal end of the guidewire while advancing the catheter 20 into the patient. With this arrangement, it will be appreciated that the length of the guidewire that extends out of the patient may interfere with the

physician's movements and make it more likely that the guidewire may be moved or dislodged and will have to be repositioned.

FIGURE 2 shows a patient undergoing a minimally invasive surgical procedure using a "rapid exchange" type catheter that is fitted over a guidewire. In this embodiment, a guidewire 22 is positioned in the patient with its distal tip at a region of interest. Again, the guidewire is most often routed through a lumen in an endoscope to the desired position. The endoscope is then removed over the guidewire leaving the guidewire in place. A catheter 24 is then routed over the guidewire 22. A rapid exchange catheter has a guidewire lumen extends only along a portion of the length of the catheter. To route the catheter 24 over the catheter, the guidewire 22 is inserted through the shorter lumen and the proximal end of the guidewire 22 held securely in order to advance the catheter 24 into the patient. The advantage of the rapid exchange type catheter 24 is that the length of the guidewire 22 can be made significantly shorter than the type required for use with conventional catheters.

Regardless of what type of catheter is used, it is important that the position of the guidewire remain substantially fixed as the physician is operating on the patient. FIGURE 3 illustrates one embodiment of the present invention which is used to secure the position of a guidewire or other medical device that is inserted into the patient. A mouthguard 40 has a tube 42 that is positioned in the patient's mouth to provide access into the patient's alimentary or bronchial canals. The mouthguard may include a curved tongue 44 that extends distally from the tube 42 and operates to aid the passage of a catheter or endoscope into the patient's esophagus or trachea. In some embodiments, the outer surface of the tube 42 may be covered with a foam or other compressible material to protect the patient's teeth as surgical devices are inserted into the patient. Alternatively, the tube itself may be formed of a relatively soft material. A flange 46 is positioned at the proximal end of the tube 42 and has a diameter larger than the patient's mouth such that the mouthguard 40 cannot be accidentally swallowed by the patient.

To secure the position of a guidewire positioned in a patient, the mouthguard 40 includes a locking device 50 that is integrally formed with the mouthguard 40. The locking device 50 comprises a tab 51 that extends proximally from the opening of the tube 42. The tab 51 includes a slot 52 having a diameter that narrows to a width that is smaller than the diameter of the guidewire. The guidewire 48 can be secured in the slot 52 with a friction fit. Additionally, the locking device may include a tab 54 under

which the guidewire can be passed in order to further secure the guidewire 48 to the locking device 50. The locking device 50 is not limited to securing guidewires but may contain other tabs or slots for securing the position of catheters or other medical devices placed into the patient's body. Other locking mechanisms may include clips, slots, hook and loop-type fasteners, or other mechanisms for securing the position of a medical device to the locking device.

FIGURE 4 shows another embodiment of the mouthguard according to the present invention. A mouthguard 40' includes a tube 42' preferably covered with a compressible material such as foam. Extending from the distal end of the tube 42' is a curved tongue 44'. A flange 46' has a diameter that is larger than the patient's mouth and extends outwardly from the proximal end of the tube 42' such that the mouthguard 40' cannot be swallowed by a patient.

In this embodiment, the mouthguard includes a locking device 50' that is removably secured to the tube 42'. The locking device 50' has a slot 52' into which a guidewire 48 can be secured. In addition, the locking device may include a tab 54' under which the guidewire 48 may be passed in order to secure it to the locking device. The locking device 50' may include other mechanisms for securing the position of a number of medical devices passed through the mouthguard as indicated above. These other mechanisms may be in addition to or in lieu of the slot 52'.

In one embodiment of the invention, the locking device 50' is secured to the mouthguard using tabs positioned on the tube 42' and corresponding holes or slots positioned on the locking device 50' or vice versa. Alternatively, the locking device 50' could be secured to the mouthguard 40' using screws, interlocking channels, clips or other mechanisms for removably securing the two devices together.

While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the scope of the invention. The scope of the invention is therefore to be determined from the following claims and equivalents thereof.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A mouthguard comprising:

a tube that is insertable into a patient's mouth and through which medical devices may be passed;

a flange extending outwardly from the tube to prevent the mouthguard from being swallowed; and

a locking device integrally formed with the mouthguard for securing the position of a medical device passing through the tube.

2. The mouthguard of Claim 1, wherein the locking device comprises a tab having a slot disposed therein into which the medical device can be held with a friction fit.

3. The mouthguard of Claim 1, wherein the locking device includes mechanisms for securing the position of two or more medical devices.

4. The mouthguard of Claim 1, further comprising a compressible material surrounding the tube.

5. The mouthguard of Claim 1, further comprising a tongue extending distally from the tube.

6. The mouthguard of Claim 1, wherein the locking device comprises a tab having one or more clips disposed thereon into which one or more medical devices may be secured.

7. The mouthguard of Claim 1, wherein the medical device is a catheter.

8. The mouthguard of Claim 1, wherein the medical device is a guidewire.

9. A mouthguard comprising:

a tube through which medical devices may be passed;

a flange extending outwardly from the tube to prevent the mouthguard from being swallowed;

a locking device removably secured to the mouthguard for securing the position of a medical device passing through the tube.

10. The mouthguard of Claim 9, wherein the locking device comprises a tab having one or more mechanisms for securing a medical device to the locking device.

11. The mouthguard of Claim 10, wherein the tab includes a slot into which the medical device can be held with a friction fit.

12. The mouthguard of Claim 10, wherein the tab includes mechanisms for securing the position of two or more medical devices.

13. The mouthguard of Claim 9, wherein the medical device is a catheter.

14. The mouthguard of Claim 9, wherein the medical device is a guidewire.

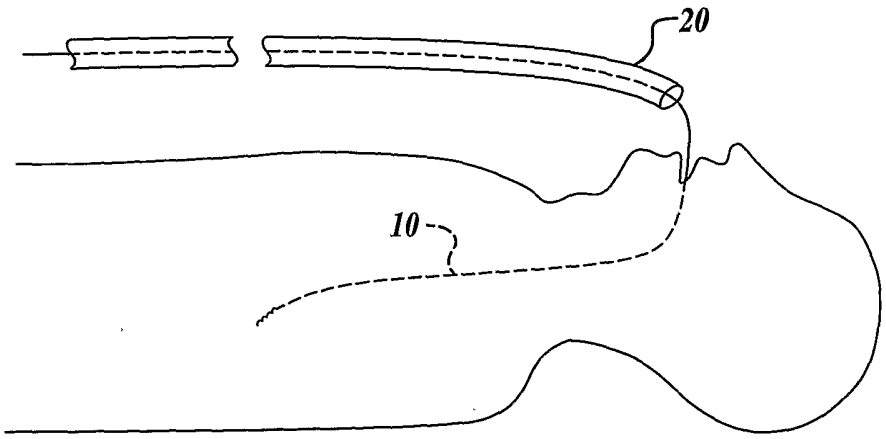


Fig. 1.

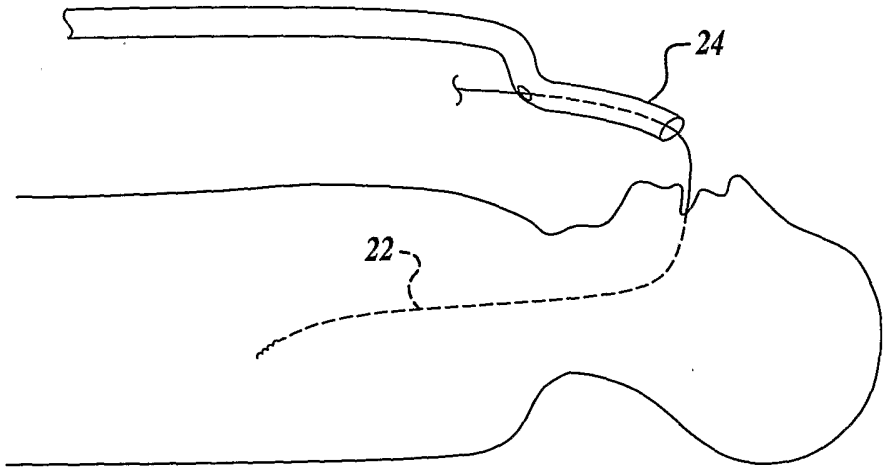


Fig. 2.

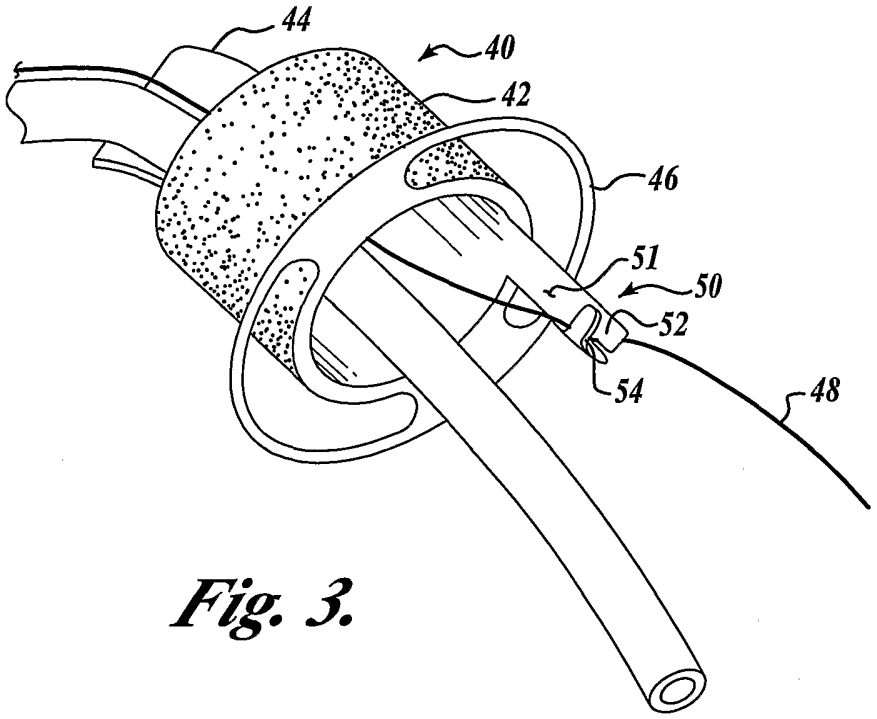


Fig. 3.

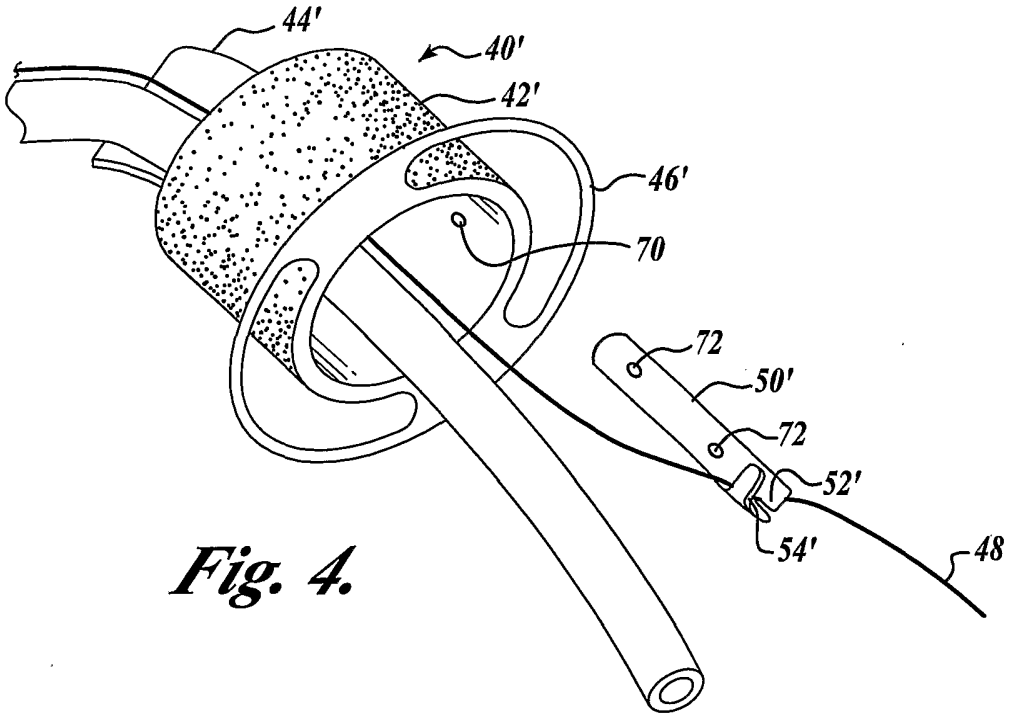


Fig. 4.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/25000

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M16/04 A61B1/01

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 02 076541 A (CURON MEDICAL INC) 3 October 2002 (2002-10-03) page 9, line 17 -page 10, line 23; figures 20,22	1,6,7,9, 10,13
X	US 6 408 850 B1 (SUDGE MICHAEL) 25 June 2002 (2002-06-25)	9,13
A	column 4, line 36 - line 47; figure 3	1-7, 10-12,14
X	US 4 185 639 A (LINDER GERALD S) 29 January 1980 (1980-01-29) column 2, line 19 - line 26	1,8
X	US 5 009 227 A (NIEUWSTAD PETER P) 23 April 1991 (1991-04-23) column 3, line 67 -column 4, line 1	9,13
A	column 4, line 12 - line 16; figure 1	1,3,4,12

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 December 2003	18/12/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Knüpling, M

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/25000

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 62325 A (U S ARMY INST OF SURGICAL RES; BERTOCH TODD M (US); GINGRICH TED F) 30 August 2001 (2001-08-30) page 6, line 9 - line 17	1,3,7
A	page 9, line 3 - line 4; figure 3	9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/25000

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 02076541	A	03-10-2002	US	2002162555 A1	07-11-2002
			US	2002151871 A1	17-10-2002
			WO	02076541 A1	03-10-2002
US 6408850	B1	25-06-2002	NONE		
US 4185639	A	29-01-1980	CA	1112973 A1	24-11-1981
			DE	2911227 A1	11-10-1979
			GB	2017504 A ,B	10-10-1979
			JP	1118864 C	28-10-1982
			JP	54161787 A	21-12-1979
			JP	57009827 B	23-02-1982
			NL	7902276 A	01-10-1979
US 5009227	A	23-04-1991	NONE		
WO 0162325	A	30-08-2001	AU	4320601 A	03-09-2001
			WO	0162325 A1	30-08-2001
			US	2002092526 A1	18-07-2002