

# PATENT COOPERATION TREATY

# PCT

From the INTERNATIONAL SEARCHING AUTHORITY

To:  
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INVITATION TO PAY ADDITIONAL FEES  
 AND, WHERE APPLICABLE, PROTEST FEE  
 (PCT Article 17(3)(a) and Rule 40.1 and 40.2(e))

	Date of mailing (day/month/year) <span style="float: right;">25 February 2020 (25-02-2020)</span>
Applicant's or agent's file reference 1676884P/PCT	<b>PAYMENT DUE</b> within <b>ONE MONTH</b> from the above date of mailing
International application No. PCT/EP2019/082282	International filing date (day/month/year) <span style="float: right;">22 November 2019 (22-11-2019)</span>
Applicant  KAPITEX HEALTHCARE LIMITED	

1. This International Searching Authority

(i) considers that there are 2 (number of) inventions claimed in the international application covered by the claims indicated on an extra sheet:

(ii) therefore considers that **the international application does not comply with the requirements of unity of invention** (Rules 13.1, 13.2 and 13.3) for the reasons indicated on an 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.:  
**see extra sheet**

(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, the amount indicated below:

<u>EUR 1.775,00</u>	x	<u>1</u>	=	<u>EUR 1.775,00</u>
Fee per additional invention		number of additional inventions		currency/total amount of additional fees

3. The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fee may be made under protest**, i.e., 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 fee 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 EUR 875,00 (currency/amount)

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. \_\_\_\_\_ 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 International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	Authorized officer STAUBER, Regina Tel: +49 (0)89 2399-5654
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This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-8

A speaking valve to allow inspiration and controllable expiration

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2. claims: 9-14

A valve element suitable for use in a speaking valve

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Invention 1: claims:

1-8

A speaking valve to allow inspiration and controllable expiration through a tracheostoma.

Invention 2: claims:

9-14

A valve element suitable for use in a speaking valve according to claims 1 to 8, said valve element comprising a bistable diaphragm.

There is lack of unity between the independent claims 1 and 9, since there is no link between said claims as to form a general inventive concept. (Rule 13 PCT). The valve element of claim 9, is of general use and not specially adapted for a speaking valve.

The above identified inventions could only fulfil the unity requirements of the PCT (Rule 13) in the event that they were linked by as to form a single general inventive concept according to Article 3 (4)iii and Rule 13.2 PCT, i.e., that there were a technical relationship among them involving one or more of the same or corresponding special technical features in the sense of Rule 13.1 PCT.

In the present case the only conceivable unifying concept could reside in a valve element suitable for use in a speaking valve, see for example W00189618.

However this concept was known in the prior art, see W00189618, to the effective date of the present application.

This document (page 6 (second paragraph)) describes a speaking valve containing a membrane 19 that can be curled to have the opening 18 unobstructed or closed, whereby the membrane is rolled out and closes the openings 18.

In view of the prior art, the underlying problem can be formulated as the provision of an alternative speaking valve or valve element.

This problem is solved individually by each above-identified invention, which are hence not considered to comply with the unity requirements of the PCT.

In order to avoid any misunderstandings on the subject-matter to be searched, the applicant is asked to provide the exact subject matter for which a search is requested and the corresponding fees are paid.

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
- see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/89618 A1 (ATOS MEDICAL AB [SE]; PERSSON JAN OVE [SE]) 29 November 2001 (2001-11-29) abstract; claims 1-14; figures 1-3 page 6, paragraph 2 - page 8, paragraph 1 -----	1-8
A	WO 2010/114372 A2 (UNIV GRONINGEN [NL]; GRONINGEN ACAD ZIEKENHUIS [NL] ET AL.) 7 October 2010 (2010-10-07) the whole document -----	1-8
A	DE 299 13 116 U1 (HITTEL JENS PETER [DE]) 27 January 2000 (2000-01-27) the whole document -----	1-8
A	EP 0 222 509 A2 (HANSA MEDICAL PRODUCTS INC [US]) 20 May 1987 (1987-05-20) the whole document -----	1-8
A	US 2017/319813 A1 (VOLGYESI GEORGE [CA]) 9 November 2017 (2017-11-09) the whole document -----	1-8

Further documents are listed in the continuation of box C.

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

# Patent Family Annex

Information on patent family members

International Application No

PCT/EP2019/082282

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
WO 0189618	A1	29-11-2001	AT 280608 T	15-11-2004
			AU 5899601 A	03-12-2001
			DE 60106751 T2	17-03-2005
			EP 1282455 A1	12-02-2003
			JP 4220157 B2	04-02-2009
			JP 2004507286 A	11-03-2004
			WO 0189618 A1	29-11-2001
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WO 2010114372	A2	07-10-2010	CN 102427843 A	25-04-2012
			CN 104436395 A	25-03-2015
			EP 2236165 A1	06-10-2010
			EP 2414016 A2	08-02-2012
			US 2012090621 A1	19-04-2012
			US 2015128955 A1	14-05-2015
			WO 2010114372 A2	07-10-2010
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DE 29913116	U1	27-01-2000	NONE	
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EP 0222509	A2	20-05-1987	NONE	
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US 2017319813	A1	09-11-2017	NONE	
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Application no:  
Demande n°: PCT/EP2019/082282  
Anmelde-Nr:

#### DISCLAIMER

The attached provisional opinion on the patentability of the first invention searched serves only as information.  
A reply addressing the points raised in the opinion is **not** required and will **not** be taken into account when issuing the final search report and opinion on patentability.

#### AVERTISSEMENT

L'avis provisoire ci-joint sur la brevetabilité de la première invention recherchée ne sert qu'à titre d'information.  
Une réponse abordant les points soulevés dans l'avis n'est **pas** nécessaire et ne sera **pas** prise en compte lors de l'établissement du rapport final de la recherche et de l'avis sur la brevetabilité.

#### DISCLAIMER

Die beigefügte vorläufige Stellungnahme zur Patentierbarkeit der ersten geprüften Erfindung dient lediglich zur Information.  
Eine Antwort auf die erhobenen Punkte in der Stellungnahme ist **nicht** erforderlich und bleibt bei der Erstellung des endgültigen Recherchenberichts und der Stellungnahme zur Patentierbarkeit **unberücksichtigt**.

The following documents (D) are referred to in this opinion; the numbering will be adhered to the rest of the procedure:

D1: WO01/89618

### **SECTION III**

The present applicant contains unsearched subject matter, see section IV

### **SECTION IV**

The present application contains two inventions:

Invention 1: claims: 1-8

A speaking valve to allow inspiration and controllable expiration through a tracheostoma.

Invention 2: claims: 9-14

A valve element suitable for use in a speaking valve according to claims 1 to 8, said valve element comprising a bistable diaphragm.

### **SECTION V**

#### **1. Novelty (Article 33(2) PCT)**

Claims 1-8 are anticipated by D1

D1 (abstract, page 6 (second paragraph) to page 8 (first paragraph); claims 1 to 14; figures 1-3) describes a tracheostoma valve ("speaking valve" according to claim 1) that can be in an open position and can be used for inspiration/expiration ("first configuration" according to claim 1) and a closed position, when the expiration air flow rate exceeds a predetermined value. The valve is then closed for expiration ("second configuration" according to claim 1) and the air flow will pass through a voice prosthesis. For a new inspiration phase the membrane opens again ("transition back into said first configuration" according to claim 1). The cover 26 is a cough valve member ("increasing the pressure difference", "third configuration" according to claim 1) of the valve and will open at a certain cough pressure and after pressure reduction it will close again. Permanent magnets 24 and 25 will keep the membrane in a closed position and the magnetic force is overcome at a new inhalation phase. Magnets 33 and 34 keep the cover 26 in a closed position, if the attraction force is overcome, the cover can move to an open position and air can escape from the housing to the ambient atmosphere ("allowed to be returned", "adjustable"; "biasing mechanism" according to claims 3-8).

### **SECTION VII**

## **2. Rule 6 PCT**

### **2.1 Rule 6.3 PCT**

Independent claim 1 is not in the two-part form, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble and the remaining features being included in the characterising part.

### **2.2 Rule 6.2 PCT**

The features of the preamble of the claims should also be provided with reference signs in parentheses.