PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: BOUNDY, David E. Potomac Law Group, PLLC 1300 Pennsylvania Avenue, NW, Suite 700 Washington D.C. 20004 United States of America		PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43 <i>bis</i> .1)		
		Date of mailir (day/month/ye	g 19 Dec 2022	
Applicant's or agent's file reference 4082-0008WO10		FOR FURTHER ACTION See paragraph 2 below		
International application No.	International filing date	(day/month/year) Priority date (day/month/year)		
PCT/IB2022/058030	26 Aug	2022	27 Aug 2021	
International Patent Classification (IPC) or both national classification and IPC IPC (20220101) A61B 1/00 A61B 1/05 A61B 17/34 CPC (20130101) A61B 1/00066 A61B 1/00101 A61B 1/00105 A61B 1/00121 A61B 1/05 A61B 17/34 Applicant PSIP2 LLC				
1. This opinion contains indications relating to the following items: Image: Second				
Name and mailing address of the ISA: Israel Patent Office		Date of completion of	Authorized officer SEGAL Liviu	
Technology Park, Bldg.5, Malcha, Jerusa	lem, 9695101, Israel	this opinion		
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International	application No.	

PCT/IB2022/058030

Box	No. I	Basis of this opinion
1.	With re	egard to the language, this opinion has been established on the basis of:
	X	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 <i>bis</i> .1(b))
3.	With re establis	egard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been shed 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 13 <i>ter</i> .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.	Addition	al comments:
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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 applicable time limit:
paid additional face under protect and where applicable, the protect face
noid additional fees under protest and, where applicable, the protest fee.
not paid additional fees.
2. X 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.
X not complied with for the following reasons:
The following separate inventions have been identified:
Invention 1: Claims 1-7, which refer to an endoscope, wherein the handle and its components being formed of biocompatible material and designed with no metal fasteners, no adhesives, and no detachable parts small enough to travel though fluid passages of the insertion shaft. Invention 2: Claims 8-12, which refer to an endoscope, wherein the handle is formed of inner and outer shells concentric
with each other. Invention 3: Claims 13-18, which refer to an endoscope set comprising an endoscope, cannula and obturator.
The common matter between said inventions is an endoscope having a handle and an insertion shaft with a camera at its distal end, the handle having retained within a circuit board for control of and receipt signals from the camera. Devices showing these features are, however, well-known in the field (see for example, documents D1-D4). In conclusion, the claimed inventions are not linked by common or corresponding special technical features and define 3 different inventions not linked by a single inventive concept. Consequently, the requirement of unity is not fulfilled, according to Rules 13 PCT.
4. Consequently, this opinion has been established in respect of the following parts of the international application:
X all parts.
the parts relating to claims Nos.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORIT

Reasoned statement under Rule 43 <i>bis</i> .1(a)(i) with regard to novelty, i citations and explanations supporting such statement	inventive step and industrial applicability;	
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	citations and explanations supporting such statement			
1.	Statement			
	Novelty (N)	Claims	2,3,5,7-12,15,18	YES
		Claims	1,4,6,13,14,16,17	NO
	Inventive step (IS)	Claims	2,3,8-12,15	YES
		Claims	1,4-7,13,14,16-18	NO
	Industrial applicability (IA)	Claims	1-18	YFS
		Claims		NO

2. Citations and explanations:

Box No. V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2.1 Reference is made to the following documents:

D1 US 2019/0328217 A1 (Deka Products Ltd. Partnership [US]) 31 October 2019 D2 US 2018/0168442 A1 (Cook Medical Technologies [US]) 21 June 2018 D3 US 2019/0374095 A1 (Pristine Surgical LLC [US]) 12 December 2019 D4 US 2020/0397232 A1 (Karl Storz Se & Co. KG [DE]) 24 December 2020

Novelty and Inventive step

2.2 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 1 is not new in the sense of Article 33(2) PCT.

2.2.1 Document D1 discloses (the references in parentheses applying to this document):

An endoscope (endoscope 10, see fig. 3B; see also Abstract), comprising:

a handle (section 16) and an insertion shaft (insertion shaft/section 14), the insertion shaft having at its distal end a solid state camera (camera assembly 350, see par. [0246] and fig. 23), the handle having retained within a circuit board with circuitry (enclosed circuit board 431, see fig. 9B) for control of and receipt of signals from the camera (see e.g. par. [0080]); the handle and its components being formed of biocompatible material (see par. [0136], last six lines "rubber or other elastomer"), and designed with no metal fasteners, no adhesives, and no detachable parts small enough to travel though fluid passages of the insertion shaft, except those encapsulated by overmolding or melt-fusing to prevent dislodgement (e.g. the handle section 16 may be manufactured as two separate parts and coupled together by any suitable means, e.g. snap-fit, see e.g. figs. 4 and 9B).

Consequently and when taking into consideration the lack of clarity of claim 1 mentioned at Box VIII below, the subject-matter of independent claim 1 is not new in view of the disclosure of D1.

2.2.2 Similarly, document **D2** discloses all the technical features of claim 1, as follows (the references in parentheses applying to this document):

An endoscope (device 10, see fig. 1; see also Abstract), comprising:

a handle (14) and an insertion shaft (elongate member 12, see also par. [0070]), the insertion shaft having at its distal end a solid state camera (imaging device 18 in fig. 2, see also par. [0123] "solid states imaging device"), the handle having retained within a circuit board with circuitry (control board body 162, see fig. 4) for control of and receipt of signals from the camera (see e.g. par. [0105]); the handle and its components being formed of biocompatible material (see par. [0091]), and designed with no metal fasteners, no adhesives, and no detachable parts small enough to travel though fluid passages of the insertion shaft, except those encapsulated by overmolding or melt-fusing to prevent dislodgement (e.g. as implicitly results from figs. 4, 7 and 8 and pars. [0091], [0101]).

2.2.3 For reasons of completeness it is noted that the subject-matter of claim 1 is also anticipated by documents **D3** (see in particular, endoscope 100 in fig. 1a comprising handle 114+112 including within circuit board 422 - see fig. 4c and shaft 110 with distal camera- see par. [0027]; see also par. [0015]) and **D4** (see in particular, endoscope 10 in fig. 1 comprising handle 12 including within circuit board 35 and shaft 18 with distal camera 50; see also pars. [0059], [0063]).

2.3 INDEPENDENT CLAIM 13

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 13 is not new in the sense of Article 33(2) PCT.

Document **D1** discloses (the references in parentheses applying to this document):

An endoscope set, comprising:

an endoscope (10, see fig. 3B), cannula (trocar or cannula 318, see fig. 16A-B) and obturator (319, see fig. 19); the endoscope having a handle (section 16) and an insertion shaft (insertion shaft/section 14), the insertion shaft having at its distal end a solid state camera (camera assembly 350, see par. [0246] and fig. 23), the handle having retained within a circuit board with circuitry (enclosed circuit board 431, see fig. 9B) for control of and receipt of signals from the camera (see e.g. par. [0080]); the obturator designed to pierce tissue (via pointed end 323) for introduction of the endoscope (see par. [0237]); the cannula being a tube (see fig. 16) to accept passage of the endoscope insertion shaft and to offer structural protection to the insertion shaft (see e.g. par. [0229]); the cannula having a connector and locking features of the obturator (via base portion 325, see par. [0237]) and the endoscope (via handle section 30, see pars. [0230], [0234] and fig. 18), both successively.

Therefore, the subject-matter of claim 13 is considered to be known from document D1.

2.4 INDEPENDENT CLAIM 8

The subject-matter of claim 8 seems to meet the requirements of Article 33(2) and 33(3) PCT with respect to novelty and inventive step.

None of the available prior art (taking into account document **D1**, see in particular pars. [0143], [0154] and fig. 3B, as representing the closest prior art) appears to disclose or suggest, individually or in combination, an endoscope comprising a handle being formed of inner and outer shells concentric with each other, wherein rotation of the shells relative to each other is controlled via one or more resilient components frictionally engaged between the respective shells.

It is maintained, that employing an inner and outer handle shells, configured to rotate relative to each other, allows a surgeon to rotate the two handle components to adjust the endoscope's field of view, using the magnetic Hall effect sensors disposed within the handle.

Therefore, the subject-matter of claim 8 meets the requirements of PCT Article 33(2) and (3) with respect to novelty and inventive step.

2.5 DEPENDENT CLAIMS 4-7, 14, 16-18

Dependent claims 4-7, 14, 16-18 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, to meet the requirements of Article 33 PCT, in respect of novelty and/or inventive step, due to the following reasons:

2.5.1 Regarding claim 4, document D1 further discloses a cannula (trocar or cannula 318, see fig. 16A-B) and obturator (319, see fig. 19), the obturator designed to pierce tissue (via pointed end 323) for introduction of the endoscope (see par. [0237]); the cannula being a tube (see fig. 16) to accept passage of the endoscope insertion shaft and to offer structural protection to the insertion shaft (see e.g. par. [0229]); the cannula having a connector and locking feature (e.g. cannula mount 300, see figs. 16, 17) designed to engage with the mating connectors and locking features of the obturator (via base portion 325, see par. [0237]) and the endoscope (via handle section 30, see pars. [0230], [0234] and fig. 18), both successively. Therefore, the subject-matter of claim 4 is not new.

2.5.2 Regarding claim 6, document D1 further discloses that the circuit board is overmolded by plastic that encapsulates the circuit board from contact with water (implied by e.g. par. [0180] "... the PCB may be encased in a water resistant material"). Therefore, the subject-matter of claim 6 is not new.

2.5.3 Regarding claim 14, document D1 further discloses that the handle and its components being formed of biocompatible material (see par. [0136], last six lines "rubber or other elastomer"), and designed with no metal fasteners, no adhesives, and no detachable parts small enough to travel though fluid passages of the insertion shaft, except those encapsulated by overmolding or melt-fusing to prevent dislodgement (e.g. the handle section 16 may be manufactured as two separate parts and coupled together by any suitable means, e.g. snap-fit, see e.g. figs. 4 and 9B).Therefore, the subject-matter of claim 14 is not new.

2.5.4 Regarding claims 16 and 17, document D1 further discloses that the locking features of the obturator and endoscope being engageable by twisting of the endoscope relative to the cannula, wherein the connectors of the endoscope and cannula being watertight, for an interference seal without O-rings (implied by pars. [0234], [0235], [0237] and figs. 17, 18). Therefore, the subject-matter of these claims is not new.

2.5.5 The additional features defined by claims 5, 7 and 18 are considered, in light of the disclosure of documents D1-D4, merely slight constructional changes or matters of design choice which a person skilled in the art would contemplate without applying any inventive effort and without providing any special/surprising technical effect in respect to the problem posed. Consequently, the subject-matter of these claims cannot be regarded as involving an inventive step.

2.6 DEPENDENT CLAIMS 2, 3, 9-12, 15

2.6.1 The subject-matter of claims 2, 3 and 15 specifies the same new and inventive concept of claim 8 and therefore, it is also considered to meet the requirements of the PCT with respect to novelty and inventive step.

2.6.2 Claims 9-12 are dependent on independent claim 8, and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Industrial Applicability

The invention defined in the claims 1-18 is considered to meet the requirements of industrial applicability under Article 33(4) of the PCT.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The present application does not meet the requirements of Article 6 PCT, due to the following reasons:

Although claims 1 and 8 have been drafted as separate independent device claims, they appear to relate effectively to the SAME subject-matter and to differ from each other only with the regard to the definition of the subject-matter for which protection is sought. Therefore, the present set of claims lack conciseness.

Claim 1 is not clear defined. Thus, the term "no" used in this claim is a negative limitation. A claim's subject-matter has to be defined in terms of positive features indicating that certain technical elements are present. Also, the term "small enough" used in this claim is unclear, since it is a relative term with no well-defining meaning in the technical field. The same objections above, apply to the subject-matter of claims 10 and 14.

The limitation "its components" used in claim 1 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of claim 1 unclear.

Claim 3 makes reference to "the inner and outer shells", while no "inner and outer shells" is mentioned in claim 1 to which this claim refers, thus rendering the subject-matter of claim 3 unclear. Therefore, for the purposes of this search and opinion, it is assumed that claim 3 is dependent ONLY on claim 2.

Dependent claims 4 and 11 (which are dependent on claims 1 and 8, respectively) define the device (endoscope) comprising several components (cannula, obturator). Therefore, the subject-matter of claims 1 and 8 should be amended to an endoscope set. This should be clarified.

Claim 8 is missing essential features which are necessary for adequately define the invention, such as to achieve the intended scope as reflected from the description (such as, Hall effect magnet sensors, rotation collar).

The preamble of dependent claims 14-18 should be reformulated "The endoscope SET", according to the formulation in dependent claim 13.