

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/PT2018/050023

International filing date (day/month/year)
07.06.2018

Priority date (day/month/year)
07.06.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61F5/01

Applicant
UNIVERSIDADE DO ALGARVE

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 43bis.1(a)(i) with regard to novelty, inventive step and 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 usually 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 66.1bis(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.

Name and mailing address of the ISA:




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Date of completion of this opinion

see form PCT/ISA/210

Authorized Officer

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Box No. I Basis of the 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 43bis.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:
 - a. forming part of the international application as filed:
 - in the form of an Annex C/ST.25 text file.
 - on paper or in the form of an image file.
 - b. furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. furnished subsequent to the international filing date for the purposes of international search only:
 - in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
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 forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- the entire international application
- claims Nos. 11-14(completely); 1-10(partially)

because:

- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):
- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):
- no international search report has been established for the whole application or for said claims Nos. 11-14(completely); 1-10(partially)
- a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
 - furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
 - pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).
- See Supplemental Box for further details

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 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 separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- all parts.
 - the parts relating to claims Nos. 1-10(partially)

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

1. Statement

Novelty (N)	Yes: Claims	<u>3-10(partially)</u>
	No: Claims	<u>1, 2(partially)</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-10(partially)</u>
Industrial applicability (IA)	Yes: Claims	<u>1-10(partially)</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

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:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 1 Claim 14 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT) which are also not searched, see Rule 39.1(iv) PCT (method for treatment of the human, in this case a method of treating a drop foot of a patient).

Re Item IV

Lack of unity of invention

- 2 Initially it is noted that claim 1 contains two alternatives:
- 1A: an orthosis with an upper portion and an instep - with a pneumatic cylinder assembled therebetween, and
- 1B an orthosis with two pneumatic cylinders mounted laterally from the centre of the malleoli,
- As the two alternatives are non-unitary, claim 1 de facto comprises two independent claims – hereinafter designated claims 1A and 1B – and is hence treated as such.
- 3 Accordingly, this Authority considers that the application does not meet the requirements of unity of invention and there are three inventions covered by the claims as indicated:
- 3.1 Claims 1A-10 (partially): an orthosis with an upper portion and an instep - with a pneumatic cylinder assembled therebetween,
solving the problem of providing actuation between an upper portion and an instep.
- 3.2 Claims 1B-10 (partially): an orthosis with two pneumatic cylinders mounted laterally from the centre of the malleoli,
solving the problem of providing an orthosis with a larger pneumatic force.
- 3.3 Claims 11-13: A process for manufacturing an ankle-foot orthosis comprising a high-density thermoplastic and a pneumatic cylinder with an electro-mechanically actuated valve,

solving the problem of controlling a pneumatic cylinder.

- 4 The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:
- 5 A complete search of the a priori first potential invention claimed, namely the subject-matter of independent claim 1, revealed US 2014/0257521 (D1) as the most pertinent state of the art with respect to claim 1.
- 6 The common subject-matter between independent claims 1A, 1B and 11, is thus a orthosis with an actuator which is not new (Art. 33(2) PCT) since D1 discloses such orthosis with an actuator.
- 7 The subject-matter of these groups of claims is not so linked as to form a single inventive concept (Rule 13.1 PCT), since there is apparently no technical relationship in the sense of Rule 13.2 PCT between these groups of special technical features and the corresponding technical problems which they solve.

Re Item V

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

- 8 Reference is made to the following documents:
- D1 US 2014/257521 A1 (FLAVEN THIERRY [FR] ET AL) 11 September 2014 (2014-09-11)
- 9 The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1A is not new.
- D1 discloses a semiautomatic anterior ankle foot orthosis, comprising at least one pneumatic cylinder (*D1: actuation component 130*) controlled by an electronic circuit wherein the at least one pneumatic cylinder is centrally assembled from the upper portion (*D1: first prosthetic component 302*) of the orthosis corresponding to the leg to the instep (*D1: second prosthetic component 304*) of the orthosis.
- Accordingly, claim 1A is not novel in view of D1.
- 10 The combination of the features of dependent claims 2-10 as dependent on claim 1A is neither known from, nor rendered obvious by, the available prior art.

Re Item VII

Certain defects in the international application

- 11 The cited prior art has not been identified in the description (Rule 5.1(a)ii PCT).
- 12 The features of the claims are not provided with reference signs placed in parentheses to increase the intelligibility of claims (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

- 13 Claim 4 is unclear in that the terms "L16" and "B25" cannot be understood.
- 14 The category of claim 6 is unclear in that the phrase "electrical circuit is controlled through a mobile application via Bluetooth[®] Low technology" indicates use of the device although the claim relates to an apparatus. Accordingly, it is not clear whether the claim relates to an apparatus or to a method. One way of overcoming this clarity objection is to amend "is" with "is adapted to" .
- 15 The category of claim 10 is unclear in that the phrase "the ankle foot orthosis is connected to the foot and leg" indicates use of the device although the claim relates to an apparatus. Accordingly, it is not clear whether the claim relates to an apparatus or to a method. One way of overcoming this clarity objection is to amend "is" with "is adapted to" .
- 16 The applicant is kindly asked to review the claims dependencies as it seems that an error has been made.
- 16.1 Especially it is noted that claim 12 refers back to claim 9. It is believed that the intention of the applicant was to refer back to claim 11 - as only claim 11 contains a method step "a)".
- 16.2 Similarly, it is noted that claim 13 refers back to claims 9-10. It is believed that the intention of the applicant was to refer back to claims 11-12 as the method step "b)" is defined in claim 11.