PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

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

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.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2008/080203	16.10.2008	16.10.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61F2/02 A61F2/00 A61F2/28 A61B17/80

Applicant
CORDIS CORPORATION

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 43*bis*.1(a)(i) with regard to novelty, inventive step or 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 notifed the International Bureau under Rule 66.1*bis*(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.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	see form PCT/ISA/210	Geuer, Melanie Telephone No. +31 70 340-4695

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/080203

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 and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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

1. Statement

Novelty (N)	Yes:	Claims	2,4-6,9-12,14,15,17-20
	No:	Claims	1,3,7,8,13,16
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-20
Industrial applicability (IA)	Yes:	Claims	1-20
	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 V.

1. Reference is made to the following documents:

D1: US 2004/143154 A1 (LAU LILIP [US] ET AL) 22 July 2004 (2004-07-22)
D2: EP-A-1 157 673 (VARIOMED AG [LI]) 28 November 2001 (2001-11-28)
D3: EP-A-1 523 959 (CORDIS CORP [US]) 20 April 2005 (2005-04-20)
D4: US 2005/172471 A1 (VIETMEIER KRISTOPHER H [US] VIETMEIER KRISTOPHER HENRY [US]) 11 August 2005 (2005-08-11)

2. INDEPENDENT CLAIMS 1, 8 AND 17

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

The document D1 discloses (cf. paragraphs 70, 90 and 93, figures 11 and 12):

A medical sheet (92) for implantation into a patient, the medical sheet comprising:
a) a planar member having a thickness, first and second expandable sides, first and second retractable sides and a longitudinal axis extending between the first and the second retractable sides, the planar member having a first smaller area position for insertion into the patient, and a second larger area position for implantation into the patient;
b) the planar member comprising a plurality of adjacent strips (36) extending parallel to each other along the longitudinal axis of the planar member, the strips comprising a plurality of longitudinal struts (34) and a plurality of loops connecting adjacent struts;
c) a plurality of bridges connecting the adjacent strips to one another at bridge-to-loop connection points, wherein the bridge-to-loop connection points for each bridge are separated angularly with respect to the longitudinal axis; and
d) a plurality of amorphic circles (94), wherein some of the amorphic circles are attached to at least some of the plurality of loops.

The medical sheet is made from Nitinol and insofar the circles are amorphic.

2.2 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 8, which therefore is also considered not new.

2.3 For the sake of completeness, it is pointed out that the objection of lack of novelty of claim 1 set out above could also have been substantiated, by using D2 (cf. paragraphs 2, 28 and 29, claim 6, figure 1).

2.4 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 17 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D3 is regarded as being the closest prior art to the subject-matter of claim 17, and discloses (cf. paragraphs 30-32, 44 and 54, figures 1, 2 and 9):

> A medical sheet (100) for implantation into a patient, the medical sheet comprising:
> a) a member made from a super elastic alloy comprising from about 50.5 percent to about 60 percent Nickel and the remainder comprising Titanium and having an A_f temperature between about 24 deg. to about 37 deg. Celsius (paragraphs 30, 44);
> b) the member having a thickness first and second expandable sides, first and second retractable sides and a longitudinal axis extending between the first and the second retractable sides, the planar member having a first smaller surface area position for insertion into the patient and a second larger surface area position for implantation into the patient;
> c) the member comprising a plurality of adjacent strips (108) parallel to each other along the longitudinal axis of the planar member, the strips comprising a plurality of longitudinal struts (110) and a plurality of loops (112) connecting adjacent struts; and
> d) a plurality of bridges (116) connecting adjacent strips to one another at bridge-to-loop connection points, wherein the number of bridge-to-loop connection points is less than the total number of loops on a hoop, wherein the bridge-to-loop connection points for each bridge are separated angularly with respect to the longitudinal axis, the bridges having a non-linear curved profile between the bridge-to-loop connection points; and
> e) a plurality of amorphic circles (802) that are attached to at least some of the

plurality of loops.

The circles are amorphic insofar as the circles are made from the same material as the medical sheet, namely Nitinol, and Nitinol is amorphic in martensite phase.

The subject-matter of claim 17 therefore differs from this known medical sheet in that the member is planar.

The problem to be solved by the present invention may therefore be regarded as providing a support for several different sorts of (planar) damaged tissue like hernias or broken bones.

The solution proposed in claim 17 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons. This feature has already been employed for the same purpose in a similar medical sheet, see document D2, paragraph 28. It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a medical sheet according to document D3, thereby arriving at a planar medical sheet according to claim 17.

3. DEPENDENT CLAIMS 2-7, 9-16 AND 18-20

3.1 Dependent claims 2-7, 9-16 and 18-20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents D1-D4 and the corresponding passages cited in the search report.

As far as some of the dependent claims are not covered by these documents these dependent claims just define constructional details which come within the scope of the customary practice followed by persons skilled in the art.

Re Item VII.

1. Independent claims need to be formulated in the two-part form in accordance with

Rule 6.3(b) PCT, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII.

1. Although claims 1, 8 and 17 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

2. Moreover, Claim 8 comprises all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).

3. Moreover, Claim 17 comprises all the features of claim 8 respectively claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).