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/US2006/008232	08.03.2006	17.03.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/70

Applicant
ABBOTT LABORATORIES

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	Macaire, S Telephone No. +31 70 340-3115

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. 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.

3. ☐ 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.

4. 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	10, 19-21
	No:	Claims	1-9,11-18
Inventive step (IS)	Yes:	Claims	10
	No:	Claims	1-9,11-21
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

see form 210

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

Re Item V.

1 Reference is made to the following documents:
D1 : US 2003/191470 A1 (RITLAND STEPHEN) 9 October 2003 (2003-10-09)
D2: EP-A-1 281 361 (LAFITT, S.A) 5 February 2003 (2003-02-05)

2 INDEPENDENT CLAIMS 1, 11

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.
Document D1 discloses (the references in parentheses applying to this document) an implant (figs. 9,10), comprising:
a first rod (10,30), comprising a non-helical, multi-curve flexible portion coupled to a respective rigid portion (12,16) at each end; and
a plurality of fasteners (20) coupled to the first rod, the plurality of fasteners configured to fasten the first rod to the vertebrae.

2.2 The implant disclosed in D1 is used to support vertebral bodies in a spine and the non-helical portion is a serpentine spring portion (figs. 9,10).
Thus, the subject-matter of claim 11 is not new in the sense of Article 33(2) PCT.

2.3 The document D2 also discloses an implant according to claim 1. In this implant the cable (13) can form multiple curves (fig. 6).

3 INDEPENDENT CLAIM 19

3.1 The solution proposed in claim 19 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons.

The implant rod comprising a multi-curve flexible portion coupled to first and second rigid portions disclosed in document D1 can be made of titanium or titanium alloy (paragraphs [0065-0066]).
The use of a machined block of material to manufacture an implant made of titanium

alloy is generally known to the person skilled in the art.
It would therefore be obvious to the person skilled in the art, to apply this known method of producing an implant to produce the implant disclosed in document D1.

4 DEPENDENT CLAIMS 2-9, 12-18, 20, 21
Dependent claims 2-9, 12-18, 20, 21 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 (Article 33(2) and (3) PCT).

4.1 [claims 2,8,12-18,21] Document D1 discloses the pedicle screws (20), the limitation of the movements and the rigid portions extending outwardly (figs. 9,10), the two rigid portions coupled to the two pedicle screws, the transition portions (figs. 9-10) and the multi-level implant. In this document the form of the rod (figs. 8a-8h and 11a-11f) can be considered as an orientation mechanism.

Additionally, claims 8, 12-13 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The functional statements in these claims do not enable the skilled person to determine which technical features are necessary to perform the stated functions.

4.2 [claims 3] Claim 3 only refers to the use of the implant and no specific feature is required to achieve these functions.

4.3 [claims 4-7] The implant according to D2 discloses three additional rods: a second flexible rod (13) and two rigid rods. This document also discloses a sleeve (11) to couple two rods.

Additionally, the skilled person would regard it a normal design procedure to replace the flexible rod in the implant disclosed in document D2 by the flexible rod disclosed in document D1.

4.4 The implant according to document D1 can be made of titanium alloy ([0065-0066]). The choice of titanium Beta C would therefore be one of several straightforward possibilities from which the skilled person would select, in accordance with

circumstances.

6 DEPENDENT CLAIM 10

The combination of the features of dependent claim 10 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:
The rigid portions extending inwardly from the flexible portion is not disclosed in the documents cited in the search report.

Additionally, claim 10 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The adverb "inwardly" should refer to the centre or the interior of the flexible portion, but this direction is not properly disclosed in the claim and can only be understood in view of figs. 10 and 11 of the present application.

Re Item VI
Certain documents cited

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 2005/030066	2005-04-07	29-09-2003	
US 2005/203511	2005-09-15	02-03-2004	
EP-A-1 658 815	2006-05-24	27-10-2005	17-11-2004
WO 2006/066053	2006-06-22	15-12-2005	15-12-2004

Re Item VII
Certain defects in the international application

The application as filed comprises two claims 20. The last claim was considered as claim 21.