

# WIPO



PCT/MIA/9/5

ORIGINAL: English only

DATE: July 9, 2003

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WORLD INTELLECTUAL PROPERTY ORGANIZATION  
GENEVA

INTERNATIONAL PATENT COOPERATION UNION  
(PCT UNION)

MEETING OF INTERNATIONAL AUTHORITIES  
UNDER THE PCT

Ninth Session  
Geneva, July 21 to 25, 2003

FORMAT OF REPORTS AND WRITTEN OPINIONS  
UNDER PCT CHAPTERS I AND II

*Document prepared by the International Bureau*

1. Certain proposed new and modified Forms were the subject of consultation via WIPO Circular C. PCT 916, dated April 25, 2003. The Annexes to the present document contain proposals submitted by the European Patent Office to the International Bureau concerning the format of reports and written opinions under PCT Chapters I and II:

Annex I: International Search Report;

Annex II: Written Opinion of the International Searching Authority;

Annex III: Written Opinion of the International Preliminary Examining Authority;

Annex IV: International Preliminary Report on Patentability (Chapter II).

2. *The Meeting of International Authorities is invited to consider the proposed formats of the Forms appearing in Annexes I to IV.*

[Annex I follows]

ANNEX I

**PATENT COOPERATION TREATY (PCT)  
INTERNATIONAL SEARCH REPORT (ISR) - PART 1**  
(PCT Article 18 and Rules 43 and 44) - (Form PCT/ISA/210)

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**FOR FURTHER ACTION** See Notification of Transmittal of ISR (Form PCT/ISA/220) as well as, where applicable, abstract information below

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Applicant's or agent's file reference:	AGGR/01/01
International application No:	PCT/EP01/98989
International filing date:	01 April 2001 (01/04/2001)
(Earliest) priority date:	02 April 2000 (02/04/2000)
Applicant:	Heath Robinson

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This report has been prepared by this International Searching Authority (ISA) and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

It consists of two parts: Part 1 contains comments on the international application. Part 2 contains the results of the search, the subject matter classification and the fields searched.

It is also accompanied by a copy of each prior art document cited in the report.

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**(1) Basis of the report**

With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed.

With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing: not applicable.

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**(2) Certain claims were found unsearchable**

This report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

Claim(s) No(s): 1,2

because they relate to subject matter not required to be searched by this Authority:

*Claims 1,2 directed to an instruction manual with particular wording are considered to be mere presentations of information and is subject matter the ISA is not required to search under Article 17(2)(a)(i) and Rule 39.1(v).*

**PATENT COOPERATION TREATY (PCT)**  
**INTERNATIONAL SEARCH REPORT (ISR) - PART 1**  
(PCT Article 18 and Rules 43 and 44) - (Form PCT/ISA/210)

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**(3) Unity of invention is lacking**

This Authority found multiple inventions in this international application, as follows:

- *Claims 1 - 18 directed to a sealing body and an instruction manual for its use*
- *Claim 19 - 28 directed to an apparatus, but not limited to an apparatus comprising the sealing body of claims 3 - 18*

No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos. 3-18

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**(4) Title**

The text is approved as submitted by the applicant.

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**(5) Abstract**

The text is approved as submitted by the applicant.

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**(6) Drawings**

The figure of the drawings to be published with the abstract is Figure No: **1** as suggested by the applicant.

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**\*\* End of Part 1 of the ISR \*\***

**PATENT COOPERATION TREATY (PCT)**  
**INTERNATIONAL SEARCH REPORT (ISR) - PART 2**  
(PCT Article 18 and Rules 43 and 44) - (Form PCT/ISA/210)

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(21) **International application No.:** PCT/EP01/98989

(51) **CLASSIFICATION OF SUBJECT MATTER**

**IPC<sup>7</sup>:** G06K11/14

(58) **FIELDS SEARCHED**

**Minimum documentation searched:**

**IPC<sup>7</sup>:** G06K

**Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched:**

Not applicable

**Electronic database consulted during the international search:**

EPO-Internal, PAJ, WPI Data

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**DOCUMENTS CONSIDERED TO BE RELEVANT**

(Citation of document, with indication, where appropriate, of the relevant passage(\*), followed by category and claim(s) No(s))

(1) US 5 332 238 A (BORUCKI G) 26 July 1994; cited in the application

*\*column 2, line 1-27; figures 4,5\**

Category: **Y** Claims: **1,6,7,9**

*\*column 7, line 32-55\**

Category: **X** Claims: **18**

(2) US 5 784 054 A (KENT JOEL C ET AL) 21 July 1998; cited in the application

*\*column 6, line 61-65; figures 1,2,4,8, column 7, line 35-65\**

Category: **X** Claims: **1,6,7,14,15,18**

(3) US 4 816 811 A (BOGATIN ERIC L ET AL) 28 March 1989

*\*column 4, line 57,58; figures 2-4\**

Category: **A** Claims: **1,9**

(4) EP 0 740 264 A (GORE & ASS) 30 October 1996

*\*column 8, line 7-10; figure 1; column 9, line 18-column 13, line 8\**

Category: **Y** Claims: **1,6,7,9**

Category: **A** Claims: **2, 18**

**PATENT COOPERATION TREATY (PCT)**  
**INTERNATIONAL SEARCH REPORT (ISR) - PART 2**  
(PCT Article 18 and Rules 43 and 44) - (Form PCT/ISA/210)

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- (5) WO 98 52184 A (ELO TOUCHSYSTEMS INC) 19 November 1998  
*\*page 21, line 9-1; figures 5,6\**  
Category: **A**      Claims: **1, 18**
- (6) US 5 852 433 A (TODA KOHJI) 22 December 1998  
*\*column 6, line 20-28; figure 1\**  
Category: **A**      Claims: **1, 18**
- 

Special categories of cited documents:

- A: document defining the general state of the art which is not considered to be of particular relevance.
- X: The claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone.
- Y: 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.
- 

**Patent family information**

\* **US 4 816 811 A:**

EP 0 196 186	A,B	01.10.1986
JP 61223932	A	04.10.1986
US 4 816 811	A	28.03.1989
CA 1 270 309	A	12.06.1990
DE 3 682 927	D	30.01.1992
KR 9 309 671	B	08.10.1993

\* **EP 0 740 264 A:**

JP 9044291	A	14.02.1997
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**PATENT COOPERATION TREATY (PCT)**  
**INTERNATIONAL SEARCH REPORT (ISR) - PART 2**  
(PCT Article 18 and Rules 43 and 44) - (Form PCT/ISA/210)

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\* **WO 98 52184 A:**

AU 7 151 098	A	08.12.1998
JP 11065765	A	09.03.1999
EP 1 019 897	A	19.07.2000
BR 9 809 121	A	01.08.2000
CN 1 269 043	T	04.10.2000
AU 732877	B	03.05.2001
US 6 236 391	B	22.05.2001

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**ISA/Examiner:** European Patent Office  
SPIGARELLI, Alfred  
PB 5818, Patentlaan 2  
NL 2280 HV Rijswijk  
Tel. +31 - 70 340 2040  
Fax. +31 - 70 340 3016

Search completed: 24 July 2001  
ISR mailed: 28 July 2001

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**\*\* End of the ISR \*\***

[Annex II follows]

## ANNEX II

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1) - (Form PCT/ISA/237)

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**FOR FURTHER ACTION** If a demand for international preliminary examination is made, this Written Opinion shall, under Rule 66.1bis(a) but subject to Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority for the purposes of Rule 66.2(a). Should such a demand be made, the applicant is hereby invited to submit to the International Preliminary Examining Authority, before expiry of the time limit under Rule 54bis.1(a), a written reply together, where appropriate, with amendments.

International application No: PCT/EP01/98989

International filing date: 01 April 2001 (01/04/2001)

Priority date: 02 April 2000 (02/04/2000)

International Patent Classification (IPC)  
or national classification and IPC: G06K11/14

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**This opinion contains indications relating to:**

- Basis of the opinion
  - Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
  - Lack of unity of invention
  - Reasoned statement with regard to novelty, inventive step or industrial applicability
- 

**(1) Basis of the opinion**

This opinion has been drawn up on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments):*

The description, pages  
1-21 as originally filed

The claims, Nos.  
1-28 as originally filed

The drawings, sheets/figs.  
1/2-2/2 as originally filed

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**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**  
(PCT Rule 43*bis*.1) - (Form PCT/ISA/237)

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**(3) Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question whether the claimed invention appears to be novel, to involve an inventive step or to be industrially applicable have not been examined in respect of claims Nos. 1, 2 because:

No ISR has been established in respect of the claim(s).

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**(4) Lack of unity of invention**

The requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the reasons given in the ISR. In response to the invitation to pay additional fees due for searching under Article 17(3)(a), the applicant has not paid additional fees. Consequently, the parts of the international application relating to claims 3- 18 were the subject of this opinion.

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**(5) Novelty, Inventive step and industrial applicability**

Novelty (N):	Claim(s) 3-17	Yes
	Claim(s) 18	No
Inventive Step (IS):	Claim(s) 8, 10-12	Yes
	Claim(s) 3-7, 9, 14-18	No
Industrial Applicability (IA):	Claim(s) 3-18	Yes

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**INDEPENDENT CLAIM 3**

Document US-A-5 332 238, which is considered to represent the most relevant state of the art, discloses (cf. relevant passages indicated in the ISR) a device from which the subject-matter of independent claim 3 differs in that the elongate sealing body is an elongate gel body.

The problem to be solved by the present invention may therefore be regarded as finding a suitable material for making the elongate sealing body.

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

EP-A-0 740 264 (cf. relevant passages indicated in the ISR), discloses such a sealing body comprising a silicone elastomer, namely a sealing body made of a composition comprising a gel.



**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**  
(PCT Rule 43*bis*.1) - (Form PCT/ISA/237)

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**INDEPENDENT CLAIM 18**

Document US-A-5 332 238 (cf. relevant passages indicated in the ISR) discloses in combination all the features defined in independent claim 18.

Therefore the subject matter of this claim is not new (Article 33(2) PCT).

**DEPENDENT CLAIMS**

The following dependent claims 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:

The additional features of claims 4, 5 and 9 are known from document EP-A-0 740264 (cf. relevant parts indicated in the ISR);

the additional features of claims 6 and 7 are already disclosed in US-A-5 332 238 (cf. relevant passages indicated in the ISR);

dependent claims 14-17 define slight constructional details of the arrangement of the independent claim to which they refer.

The additional features of dependent claims 8 and 10-12 are neither disclosed nor suggested by any one of the available prior art documents. Therefore, a combination of at least one of these claims with the claims to which they refer could be considered as novel and inventive.

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**ISA**                      European Patent Office  
D-80298 Munich  
Tel: +49 89 2399-0  
Fax: +49 89 2399-4465

**Examiner:**              Twist, Oliver

Date of completion of this written opinion:

30 August 2001

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**\*\* End of the Written Opinion\*\***

[Annex III follows]

**PATENT COOPERATION TREATY  
WRITTEN OPINION**

(PCT Rule 66) - (Form PCT/IPEA/408)

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Date of mailing (*day/month/year*) 15/03/2001

**REPLY DUE** within 2 months from the above date of mailing

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Applicant's or agent's file reference: AGGR/01/94

International application No: PCT/EP01/98989

International filing date: 01 April 2001 (01/04/2001)

Priority date: 02 April 2000 (02/04/2000)

International Patent Classification (IPC)  
or national classification and IPC: G01N33/569

Applicant: Heath Robinson

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This written opinion is the first additional opinion drawn up by this International Preliminary Examining Authority under Rule 66.4(a).

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**This opinion contains indications relating to:**

- Basis of the opinion
  - Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
  - Lack of unity of invention
  - Reasoned statement with regard to novelty, inventive step or industrial applicability
- 

The applicant is hereby **invited to reply** to this opinion.

**When?** See the time limit indicated above. The applicant, may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments according to Rule 66.3. For the form and language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*. For an informal communication with the examiner, see Rule 66.6.

**If no reply is filed**, the international preliminary examination report will be established on the basis of this opinion

**PATENT COOPERATION TREATY**  
**WRITTEN OPINION**  
(PCT Rule 66) - (Form PCT/IPEA/408)

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The final date by which the international preliminary examination report must be established according to Rule 69.2 is:

**02 August 2002.**

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**(1) Basis of the opinion**

This report has been drawn up on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments)*:

The description, pages

1-15, 17-21

16

as originally filed

as filed with the demand

The claims, Nos.

1-11

12-16

as originally filed

as filed with the demand

The drawings, sheets/figs.

1/2-2/2

as originally filed

This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

The following amendments are contrary to the provisions of Article 34(2)(b):

- (i) The range of values given on page 16 for the length of the cutting edge was not disclosed in the application as filed;
- (ii) An essential feature of the invention, present in all the originally filed independent claims, relating to the gripping part of the knife, has been omitted from the latest filed claims.

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**(3) Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question 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 claims Nos. 1, 2 because:

The subject-matter of claims 1, 2 does not require an international preliminary examination with respect to industrial applicability as it is directed to a method of treatment by surgery (Article 34(4)(a)(i), Rule 67.1 (iv)).

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**PATENT COOPERATION TREATY**  
**WRITTEN OPINION**  
(PCT Rule 66) - (Form PCT/IPEA/408)

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**(4) Lack of unity of invention**

The applicant has paid additional fees in response to the invitation to restrict or pay additional fees.

This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:

- (i) Claims 3-8 relate to a surgical knife.
- (ii) Claims 9, 10 relate to a method of sharpening knives and are not restricted to the type of knife claimed in Claim 3.

Consequently, the parts of the international application relating to claims 3 - 8 were the subject of international preliminary examination in establishing this report.

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**(5) Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Novelty (N):	Claim(s) 4, 5, 6-8, 9-10 Claim(s) 3	Yes No
Inventive Step (IS):	Claim(s) 5, 6-8, 9-10 Claim(s) 3, 4	Yes No
Industrial Applicability (IA):	Claims 3-10	Yes

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A surgical knife for use in making incisions is disclosed in US-A-9 999 999 (hereinafter referred to as document 1) comprising the following features:

A, B, C - see column 1, lines 20-55 and Figures 2,3.

D, E - see column 3, lines 70-110 and Figure 4.

The subject-matter of Claim 3 does not therefore meet the requirements of Article 33 (2) of the PCT.

The additional features of Claim 4 are already known from DE-A-0 000 000 (document 2). Moreover the reasons why those features are used in the knife disclosed in that document are identical to the present application. The adoption of these features in the knife disclosed in document 1 is therefore obvious for the skilled man. The subject-matter of Claim 4 is accordingly lacking inventive step contrary to Article 33 (3) PCT.

None of the available prior art discloses the features claimed in Claim 5. Moreover, these features achieve the result of achieving a more precise incision than was hitherto possible using existing knives.

**PATENT COOPERATION TREATY**  
**WRITTEN OPINION**  
(PCT Rule 66) - (Form PCT/IPEA/408)

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The subject-matter of Claim 5 in combination with that of Claim 3 would therefore appear to meet the requirements of Articles 33(2) and 33(3) PCT.

Claims 6-8 contain modifications of the inventive idea embodied in the combination of Claims 3 and 5 and also meet the requirements of Articles 33 (2) and 33 (3) PCT.

The method of sharpening knives claimed in Claim 9 is based on US-A-1 111 111 as nearest prior art. Compared with this known method the angle of the grinding wheel is controlled between limits by a control unit which measures various parameters during the grinding operation. No prior art document gives a lead to these features: Claim 10 contains a minor modification of the inventive idea of Claim 9.

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**IPEA**                      European Patent Office  
D-80298 Munich  
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Fax: +49 89 2399-4465

**Examiner:**              Twist, Oliver

Date of submission of the demand:                      30 November 2001

Date of completion of this report:                      12 March 2002

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**\*\* End of the Written Opinion \*\***

*[Comments:*

- 1. Should an address box be maintained on the first page?*
- 2. Wording of information given on first, second etc. Written Opinion changed in the light of Rule 66.1bis*
- 3. Under "When?", reference changed to new Rule 66.2(e)]*

[Annex IV follows]

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(CHAPTER II OF THE PCT)**

International Preliminary Examination Report (IPER) established by the International Preliminary Examining Authority  
(PCT Article 36 and Rule 70) - (Form PCT/IPEA/409)

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**FOR FURTHER ACTION** See Notification of Transmittal of IPER (Form PCT/IPEA/416)

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Applicant's or agent's file reference:	AGGR/01/94
International application No:	PCT/EP01/98989
International filing date:	01 April 2001 (01/04/2001)
Priority date:	02 April 2000 (02/04/2000)
International Patent Classification (IPC) or national classification and IPC:	G01N33/569
Applicant:	Heath Robinson

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This international preliminary examination report has been prepared by this International Preliminary Examining Authority (IPEA) and is transmitted to the applicant according to Article 36.

This report is accompanied by 4 sheets of annexes, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

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**This report contains indications relating to:**

- Basis of the report
  - Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
  - Lack of unity of invention
  - Reasoned statement with regard to novelty, inventive step or industrial applicability
-

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(CHAPTER II OF THE PCT)**

International Preliminary Examination Report (IPER) established by the International Preliminary Examining Authority  
(PCT Article 36 and Rule 70) - (Form PCT/IPEA/409)

---

**(1) Basis of the report**

This report has been drawn up on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as *A*originally filed $\cong$  and are not annexed to the report since they do not contain amendments)*:

The description, pages		
1-15, 17-21		as originally filed
16		as filed with the demand
The claims, Nos.		
1-11		as originally filed
12-16		as filed with the demand
The drawings, sheets/figs.		
1/2-2/2		as originally filed

---

This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

The following amendments are contrary to the provisions of Article 34(2)(b):

- (i) The range of values given on page 16 for the length of the cutting edge was not disclosed in the application as filed;
  - (ii) An essential feature of the invention, present in all the originally filed independent claims, relating to the gripping part of the knife, has been omitted from the latest filed claims.
- 

**(3) Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question 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 claims Nos. 1, 2 because:

The subject-matter of claims 1, 2 does not require an international preliminary examination with respect to industrial applicability as it is directed to a method of treatment by surgery (Article 34(4)(a)(i), Rule 67.1 (iv)).

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**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(CHAPTER II OF THE PCT)**

International Preliminary Examination Report (IPER) established by the International Preliminary Examining Authority  
(PCT Article 36 and Rule 70) - (Form PCT/IPEA/409)

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**(4) Lack of unity of invention**

The applicant has paid additional fees in response to the invitation to restrict or pay additional fees.

This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:

- (i) Claims 3-8 relate to a surgical knife.
- (ii) Claims 9, 10 relate to a method of sharpening knives and are not restricted to the type of knife claimed in Claim 3.

Consequently, the parts of the international application relating to claims 3 - 8 were the subject of international preliminary examination in establishing this report.

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**(5) Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Novelty (N):	Claim(s) 4, 5, 6-8, 9-10	Yes
	Claim(s) 3	No
Inventive Step (IS):	Claim(s) 5, 6-8, 9-10	Yes
	Claim(s) 3, 4	No
Industrial Applicability (IA):	Claims 3-10	Yes

---

A surgical knife for use in making incisions is disclosed in US-A-9 999 999 (hereinafter referred to as document 1) comprising the following features:

A, B, C - see column 1, lines 20-55 and Figures 2,3.

D, E - see column 3, lines 70-110 and Figure 4.

The subject-matter of Claim 3 does not therefore meet the requirements of Article 33 (2) of the PCT.

The additional features of Claim 4 are already known from DE-A-0 000 000 (document 2). Moreover the reasons why those features are used in the knife disclosed in that document are identical to the present application. The adoption of these features in the knife disclosed in document 1 is therefore obvious for the skilled man. The subject-matter of Claim 4 is accordingly lacking inventive step contrary to Article 33 (3) PCT.

None of the available prior art discloses the features claimed in Claim 5. Moreover, these features achieve the result of achieving a more precise incision than was hitherto possible using existing knives.



**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(CHAPTER II OF THE PCT)**

International Preliminary Examination Report (IPER) established by the International Preliminary Examining Authority  
(PCT Article 36 and Rule 70) - (Form PCT/IPEA/409)

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The subject-matter of Claim 5 in combination with that of Claim 3 would therefore appear to meet the requirements of Articles 33(2) and 33(3) PCT.

Claims 6-8 contain modifications of the inventive idea embodied in the combination of Claims 3 and 5 and also meet the requirements of Articles 33 (2) and 33 (3) PCT.

The method of sharpening knives claimed in Claim 9 is based on US-A-1 111 111 as nearest prior art. Compared with this known method the angle of the grinding wheel is controlled between limits by a control unit which measures various parameters during the grinding operation. No prior art document gives a lead to these features: Claim 10 contains a minor modification of the inventive idea of Claim 9.

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**IPEA**                      European Patent Office  
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                                  Fax: +49 89 2399-4465

**Examiner:**              Twist, Oliver

Date of submission of the demand:                      30 November 2001

Date of completion of this report:                      12 March 2002

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**\*\* End of the IPER \*\***

[End of Annex IV and of document]