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D E C I S I O N
of 11 June 2003

Case Number: W 0005/03 - 3.2.2

Application Number: PCT/US02/18742

Publication Number: -

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Language of the proceedings: EN

Title of invention:

Apparatus and method for sculpting the surface of a joint

Applicant:

ENGH, Gerard

Opponent:

-

Headword:

Non-unity of invention

Relevant legal provisions:

PCT Art. 17

PCT R. 40

Keyword:

"Lack of unity (yes, in part)"

Decisions cited:

W 0005/85, G 0001/89

Catchword:

-



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Boards of Appeal

Chambres de recours

Case Number: W 0005/03 - 3.2.2
International Application No. PCT/US02/18742

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 11 June 2003

Applicant: ENGH, Gerard

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Subject of the Decision: Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 23 October 2002.

Composition of the Board:

Chairman: W. D. Weiß
Members: R. Ries
B. J. Schachenmann

Summary of Facts and Submissions

I. The applicant filed an international patent application PCT/US02/18742 with 144 claims. Independent claims 1, 59 and 81 read as follows:

"1. An apparatus for sculpting the articular surface of a first bone that normally articulates with a second bone, the apparatus comprising:

a bone-sculpting tool including an attachment portion for attaching the bone-sculpting tool to the second bone in a position for sculpting the articular surface of the first bone."

"59. An apparatus for replacing the surfaces of a joint between a first bone and a second bone, the first bone normally articulating in a predetermined manner with a second bone, the apparatus comprising:

a first bone implant made up of a plurality of components configured for mimicking and replacing a bearing surface of the first bone; and

a second bone baseplate configured for mimicking and replacing a bearing surface of the second bone;

wherein the components of the first bone implant and the second bone baseplate are joined within the confines of a joint cavity between the first bone and the second bone."

"81. An apparatus for imparting force between first and second adjacent bones to secure an implant, the apparatus comprising:

an impaction device including an attachment portion for attaching the impaction device to the second bone; and

an implant for securing to a first bone."

The independent claims 97, 116 and 134 related to a

- method for sculpting the articular surface of the first bone by engaging the bone-sculpting tool with the articular surface of the second bone (claim 97);
- a method for replacing the articular surfaces of a first bone by sculpting the articular surface of the first bone by engaging the bone-sculpting tool with the articular surface of the second bone; and providing an implant for replacing the articular surface of the first bone (claim 116); and
- a method of securing an implant to a second bone that articulates with a first bone, comprising the steps of:
 - providing an impaction device, attaching the impaction device to the first bone; placing an implant on the impaction device and aligning the implant with the second bone; and imparting force to the implant, the force being reacted with the second bone and the first bone (claim 134).

Claims 2 to 58 which were directly or indirectly dependent on claim 1 related to certain embodiments of the bone-sculpting apparatus.

Claims 60 to 80 which were directly or indirectly dependent on claim 59 related to preferred embodiments of the prosthetic apparatus replacing the surfaces of a joint.

Claims 82 to 96 were directly or indirectly dependent on claim 81 and related to certain embodiments of the impaction device.

Dependent claims 98 to 115 and 117 to 133 and 135 to 144 related to preferred embodiments of the method claimed in claims 97, 116, or 134, respectively.

II. On 23 October 2002, the EPO, acting as an International Search Authority (ISA) sent to the applicant an invitation to pay four (4) additional fees pursuant to Article 17(3) (a) and Rule 40.1 PCT.

In the invitation, the ISA identified five (5) groups of inventions:

1. claims 1 to 25, 27, 33 to 47
 - 1.1 claims 1 to 11, 21 to 25, 27, 33 to 45, 47: apparatus for attachment to one bone and sculpting another, where the sculpted bone may be the acetabulum;
 - 1.2 claims 12 to 20, 46: apparatus for attachment to one bone and sculpting another, where the sculpting tool is rotatable;
2. claim 26: apparatus for attachment to one bone and sculpting another, provided with a fluid filled distractor;
3. Claims 28 to 32: apparatus for attachment to one bone and sculpting another, where the sculpting tool is elongatable;
4. Claims 48 to 58, 81 to 96: apparatus for attachment to one bone and impacting an implant into another;
5. claims 59 to 80: joint prosthesis

The ISA remarked that the inventions 1.1 and 1.2, although not being linked by a common inventive concept, were searched without effort so that an additional fee was not justified.

The ISA further referred to the document US 4574794 A (D1). In the ISA's view, this document discloses an apparatus comprising a bone-sculpting tool including an attachment portion for attaching the bone-sculpting tool to the second bone in a position for sculpting the articular surface of the first bone, thus anticipating the subject matter of claims 1 to 6, 8, 9, 21, 23 to 25, 27, 33 to 37, 39 to 45 and 47.

With respect of the remaining claims of the six groups of inventions (group 1.1 and 1.2 and groups 2 to 5) and the technical features distinguishing these claims from the prior art D1, the ISA found that these features had nothing in common and solved different problems. Consequently, the requirement of unity pursuant to Rule 13.1 PCT was not met.

III. The applicant paid the additional fees under protest pursuant to Rule 40.2(c) PCT and requested that all or a portion of the additional fees should be refunded. In support of the protest the following arguments were submitted:

It is apparent from various parts of the specification that the unifying technical feature of the present invention is sculpting of the articular surface of the first bone with a bone sculpting tool as the second bone is articulated in a predetermined manner with respect to the first bone. In doing so, the articular bone surfaces are sculpted according to the individual physiology of each patient, and the natural junction of the joint is restored as much as possible. The

apparatus disclosed in US 4574794 A neither teaches nor suggests an apparatus comprising this technical feature. Enclosed with its protest the applicant submitted amended claims 1 to 11 comprising the above mentioned technical feature.

- IV. On 20 February 2003, the Review Panel of the ISA confirmed that the finding of lack of unity was justified and invited the applicant to pay a protest fee. The ISA further remarked that the objection "lack of unity" was raised with respect to the claims as originally filed. It was also noted that the allegedly common technical feature referred to by the applicant could not be found in the first group of inventions.
- V. On 17 March 2003, the applicant paid the required protest fee.

Reasons for the Decision

1. The protest is admissible.
2. As it is apparent from independent claims 97, 116 and 134 and various parts of the description, the present application essentially resides in providing a minimally invasive surgical method for replacing a joint (knee joint, hip joint) totally or in part. Thereby, accurate bone and soft tissue preparation, implant orientation and implant fixation through a limited surgical exposure is accomplished (cf. eg. description page 8, lines 20 to 24).

Following the provisions of PCT Rule 39.1(iv) in combination with PCT Article 17(2)(a)(i), the ISA correctly decided not to search the subject matter claimed in the claims 97 to 144 which related to

treatment of the human or animal body by surgery or therapy. It, therefore, has to be examined whether a technical relationship, involving one or more of the same or corresponding special technical features, exists between the subject matter claimed in the remaining independent claims 1, 59 and 81 as originally filed and whether these independent claims form a single general inventive concept so that the requirement of PCT Rule 13.1 is satisfied.

3. In its approach to the question of unity of invention, the ISA identified - in a first step - five different groups of inventions and the technical features addressed by each group. In this step, the IPEA did not base its considerations on a document or documents which were regarded as representing the closest prior art. Therefore, the objection is rated as being an "*a priori*" objection within the meaning of the PCT Preliminary Search Guidelines S-06/1998 VII-9 to VII-13.

In a second step, the ISA tried to identify in the five inventions those distinguishing technical features which were not anticipated by the prior art document D1 and to determine the problems solved by these features vis-à-vis this prior art. This approach is regarded as raising a non-unity objection "*a posteriori*".

4. *Non-unity "a priori"*

- 4.1 Following the Administrative Instructions under the PCT S-03/1998(E), Annex B, part 1, (c), unity of invention has to be considered in the first place only in relation to the independent claims of an international application and not to the dependent claims. According to the established case law of the Boards of Appeal, determining the unity of invention "*a priori*" requires as a mandatory pre-condition an

analysis of the technical problem (or problems) underlying the respective groups of inventions by starting from what is considered in the description of the application as having been achieved by the invention. It also has to be decided whether or not the subject matter claimed as a solution to such a problem represents a single general inventive concept.

4.2 In the Board's view, the first group of inventions (claim 1 ff.) provides an apparatus for sculpting the articular surface of a first bone that normally articulates in a predetermined manner with a second bone, e.g. a hip joint or knee joint. The apparatus comprises

- a bone sculpting tool,
- an adjustable attachment for attaching the sculpting tool to the second bone in a position for sculpting the surface of the first bone.

The problem solved by the first group of inventions resides in sculpting the corresponding articular surfaces of a joint (hip, knee) and preparing the bony structures so that, in the next step, proper alignment and orientation of the implant components with respect to each other is facilitated. Dependent claims 2 to 58 relate to preferred embodiments of the apparatus according to claim 1.

The second group of inventions (independent claim 59) relates to an implant apparatus comprising

- a first implant made up of a plurality of components for mimicking and replacing the bearing surface of the first bone and

- a second implant (bone base plate) replacing the bearing surface of the second bone.

The problem solved by the second group of inventions is to provide appropriate implants which are designed to fit through the minimally invasive incisions and to resurface the resected articular surfaces of the first and second bone. The implants which incorporate all combinations of fixed and mobile bearing inserts or parts are joined within the confines of the joint cavity. Dependent claims 60 to 80 relate to more preferred embodiments of the implant apparatus set out in claim 59.

The third group of inventions (independent claim 81) is concerned with an apparatus for imparting force to secure an implant. The apparatus comprises

- an impaction device (i.e. any suitable force generating mechanism, e.g. a pneumatic hammer, a hydraulic piston, a linear actuator, a spring activated device etc.) and
- an attachment portion for attaching the impaction device to the second bone so that the implant resurfacing the first bone can be secured to the first bone.

The problem solved by the third group of inventions is to provide an impaction device designed to be attachable directly or indirectly to the bone of a joint and to provide an impaction force to properly seat the implant.

4.3 As can be seen, the three different groups of inventions do not comprise the same or corresponding special technical features and each group of inventions

aims at solving a different problem. Moreover, the apparatuses claimed in each group of inventions can be used independently with no need for using the others. Based on these considerations it is, therefore, concluded that a technical relationship does not exist among all three groups of inventions, as required by Rule 13.2 PCT.

5. *Non unity "a posteriori"*

5.1 As stated in the decision G 1/89 (OJ EPO, 1991, 155), the ISA is empowered to raise an objection for lack of unity "a posteriori" i.e. after having taken the prior art into consideration. Decision G 1/89 makes also clear that an objection of this kind can only be based on a provisional opinion on novelty and inventive step which is in no way binding upon the authorities subsequently responsible for the substantive examination (cf. G 1/89, point 8.1 of the reasons). The Enlarged Board also held that charging of additional fees under Article 17(3)(a) PCT should be made only in clear cases.

5.2 Within the first group referred to above (claims 1 to 58) the ISA identified four different groups 1.1, 1.2, 2 and 3 and found that the subject matter of claims 1 to 6, 8, 9, 21, 23-25, 27, 33 to 37, 39 to 45 and 47 lacked novelty with respect to document D1 US 4574794 A. This document discloses a jig for mounting a bone-cutting device, e.g. an orthopaedic saw for use in resurfacing arthroplasty. The jig comprises, inter alia, a frame adjustably mounted on a baseplate and means to adjustably and releasably secure each of the patients tibia and femur to the frame in anatomical and planar parallel alignment (cf. D1, column 1, line 61 to column 2, line 18). The cutting device is slidably mounted on a slide bed which in turn is

slidably mounted on the parallel bars of the jig to provide three degrees of movement for the orthopaedic saw (cf. D1, column 3, lines 15 to 20).

- 5.3 The Board has verified the novelty objection in particular with respect to independent claim 1 finding that, in the light of the above teachings, such a bone-sculpting apparatus was already known from document D1. The respective statement of the ISA in the international search report is therefore not objectionable.
- 5.3 As set out in the PCT Guidelines for International Search S-06/1998(E) Annex B, Part 1, (c)(ii), lack of unity may become evident after having taken prior art into consideration, for instance a document showing that there is a lack of novelty of the subject matter of independent claim 1, and leaving two or more dependent claims without a single general inventive concept. It cannot, however, be deduced from Rule 13 PCT or from the corresponding part of the Guidelines for International Search or the Administrative Instructions under the PCT that the mere existence of such a document inevitably prejudices the unity of the invention of the remaining subject matter of the application. Faced with a non-unity objection "*a posteriori*" based on a prior disclosure resulting from an international search, the applicant has during the later substantive examination procedure according to PCT Chapter II various possibilities of restricting the claims without jeopardizing the unity of the invention. This restricted subject matter is normally defined on the basis of the dependent claims or the examples generally relating to preferred embodiments of the invention (see W 5/85 dated 21 March 1986, point 10 of the reasons).

5.4 This situation appears to apply to the present case. In its communication, the ISA rated the subject matter of at least the dependent claims 12, 15, 26, 28 to 32 and 48 to 58 as being novel and non-obvious vis-à-vis the prior art D1. In the later substantive examination procedure, the applicant could, for instance by including the subject matter of one or more dependent claims not covered by the prior art, formulate a revised independent claim 1 which would meet the requirements for novelty, inventive step and unity. If only a single independent claim 1 avoiding the prior art was drafted with dependent claims (similar to the originally filed claim 1 and dependent claims 2 to 58), the problem of unity would not arise, since unity has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. This could be achieved e.g. by providing the bone-cutting tool according to claim 1 with an axis of rotation or elongation as claimed in claims 12 or 30. By "dependent" claim is meant a claim which contains all the features of another claim and is of the same category as that other claim. In particular, it does not matter, if a dependent claim itself contains a further invention (see PCT Gazette Administrative Instructions, S-03/1998(E) Annex B, part 1, (c) (i)). Thus, it would not be of any consequence if a dependent claim related to a bone-sculpting apparatus comprising additional technical features like:

- a visualisation apparatus including a monitoring system (claim 50),
- an irrigation and suction apparatus (claim 53),
- a hydraulically actuated distraction device to support the bone-cutting tool during resection of the bone structures (claim 26),

- a drive mechanism comprising a hydraulic motor, a flexible drive shaft for connecting the drive mechanism to a motor and a gear box, (claims 43, 45, 39)

5.5 Thus, the ISA's statement in its communication that claims 1 to 58 (representing in the Board's view the first group of inventions) comprise at least four different inventions cannot be accepted as a sufficient reasoning in support of the finding of lack of unity of invention. In the Board's view, additional fees are only justified for the groups of inventions of claims 59 ff. and claims 81 ff. referred to above.

6. It follows from the above that the ISA's invitation to pay four (4) additional fees was only partly justified. Hence, two additional search fees should be reimbursed.

7. Moreover, the Board finds that the applicant's protest was only in part justified. Given this situation, the protest fee should not be refunded.

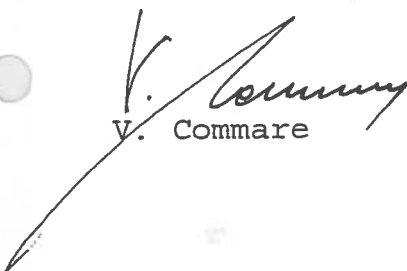
8. It is, however, noted that the Board's present assessment of unity of invention does not exclude the possibility that - in the later International Preliminary Examination under PCT Chapter II and based on other grounds - the issue of unity of invention may arise again with respect to parts of the application.

Order

For these reasons it is decided that:

Reimbursement of two additional search fees is ordered.

The Registrar:


V. Commare

The Chairman:


W. D. Weiss



