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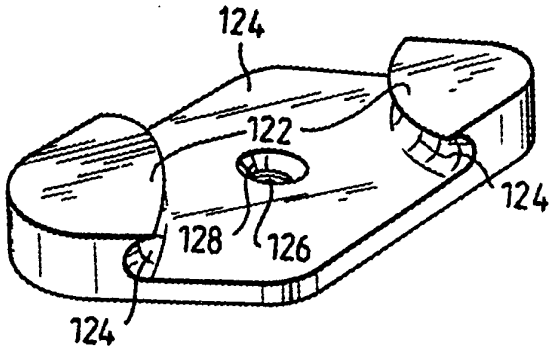
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: BONE FIXATION SYSTEM

(57) Abstract

Cable engagement elements are provided for use in surgical techniques in which cerclage cable is used to hold together a bone portion and a second portion (which may be bone or, for example, a hip implant). An element is used to vary the path of a cable, permitting a simpler fixing process, using a lesser number of cables. An element may be a cleat, with two D-shaped projections (22) rising from a baseplate (20). The projections (22) have opposed concave arcuate portions (24) defining cable paths. They may be closely spaced so that cable portions following the two paths are in mutual contact. The base plate may have an aperture (126) for a fixing screw. Alternative forms of element include half-cleat (320-326), closed cleat (220-232), and pulley-form (450).



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Bone Fixation System

Technical Field

The present invention relates to components for use in surgical techniques of bone fixation; to kits of parts for use in such techniques; to use of cable engagement elements (particularly cleats and pulleys) in manufacturing such kits; and to surgical techniques employing cable engagement elements.

Background Art

Figs. 1 and 2 illustrate prior art techniques of trochanteric fixation. Standard trochanteric fixation uses proximal (10) and distal (12) cables passed through a trochanteric grip 14 that loops medially as indicated in figure 1. Vertical fixation is also known, using cables 16 and a sleeve 18 as shown in figure 2. Generally the prior art techniques require the use of two cables and two sleeves.

Disclosure of Invention

Broadly the present invention provides, as surgical components, cable engagement elements that can permit more efficient bone fixation techniques. Preferred embodiments may make possible techniques requiring less components and/or enabling quicker and/or less skilled surgical operations. A cable engagement element is a body having portions defining a path for engaging a cable. Generally the portions will be radiused, at least in part, to facilitate smooth cable passage. They may be shaped, e.g.

grooved, so that a cable is positively located. An element may have fixation means (e.g. a screw-engaging opening) for fixation to bone. An element may comprise a cleat and/or a pulley. An element may have opposed portions defining paths for two cables (or two portions of the same cable), possibly arranged to define a pinch in which there will be cable-cable contact in use.

A kit of parts may comprise one or more cable engagement elements, and cable. These may be one or more other components e.g. selected from implant components cable crimps and bone engagement elements such as grips, screw plates and cerclage plates.

A surgical technique may involve locating one or more cables around a bone region (possibly embracing non-bone components such a plates and/or implant components), the path(s) of the cable(s) being affected by engagement with one or more engagement elements. The surgical technique may be hip replacement (by trochanteric fixation or otherwise) or any other technique in which cerclage cables may be applied, e.g. repair of fractures.

A cable engagement element may be a cleat, providing two cable-engaging portions which may be used to react cable tension against itself. An element (which may be a half-cleat providing a single engaging portion, or a pulley) which has means for fixation to a bone may be used to create a reaction

point.

Any surgically suitable materials may be used, e.g. stainless steels, cobalt chrome, titanium alloy, and/or plastics.

Some embodiments of the invention will now be described in more detail with reference to the accompanying drawings.

Brief Description of Drawings

Figs. 1 and 2 illustrate prior art methods of trochanteric fixation;

Fig. 3 is a perspective view of a first embodiment of the invention which is an open cleat;

Fig. 4 is a like view showing a second embodiment which is an open cleat with a screw-hole;

Fig. 5 is a like view showing a third embodiment which is a closed cleat;

Fig. 6 is a like view showing a fourth embodiment which is a half-cleat;

Fig. 7 is a like view showing a fifth embodiment which is a cable pulley;

Figs. 8 and 9 are lateral and frontal views showing the use of the fifth embodiment in trochanteric fixation; and

Figs. 10 and 11 are views showing two applications of the invention to treatment of bone fractures.

Modes for Carrying Out the Invention

Fig. 3 shows an open cleat having a base plate 20

from the top side of which rise two symmetrically-disposed projections 22. In plan, these are generally D-shaped with their curved edges projecting towards one another. In profile, these curved edges delimit rounded channels 24. The projections 22 approach quite close to one another, so that a pair of cables (or cable portions) extending around the grooves of respective projections 22 may be in frictional contact at the narrow region.

Figure 4 shows another form of open cleat having a base plate 124 and two projections 122 having opposing curved faces delimiting channels 124. However the projections 122 are relatively widely spaced and, in the space between them, the plate 124 is penetrated by a screw-hole 126 with an enlarged, countersunk opening 128.

Fig. 5 shows a closed cleat. This is a body that has approximately the shape of a flat cuboid with one pair of major faces 220 and a pair of minor faces 230. The remaining pair of faces 232 are long and narrow and have concave curves (so that they approach one another in the middle). Furthermore there is a large elongate opening 234 extending between them. The edges 224 of this opening correspond to the channels 24, 124 of the previously described embodiments, and are similarly formed.

Fig. 6 shows a half cleat. This is similar to the cleat shown in Fig. 4, with the removal of one end

region of the plate 124 with its projection 122. Thus there is a plate 320 with a single projection 322 which defines a curved channel 324. The plate has a countersunk screw hole 326.

Fig. 7 shows a different, though related, form of cable engagement element, in the form of a pulley 450. This is equivalent to a projection 22 as shown in Fig. 3, for example, but with a groove 424 extending fully around it. Furthermore there is a central countersunk screw hole 426.

Figs. 8 and 9 show a femur 400 in which an implant 402 has been mounted by trochanteric fixation employing a single cerclage cable 404, a single crimp sleeve 406, and a single closed cleat 408, which is generally as shown in Fig. 5. The procedure was as follows.

The cerclage cable 404 was threaded through the cleat 408 which was then positioned half-way along the cable. Two 1/8 inch (3mm) drill holes 410 were made through the lateral cortex of the femur approximately 30mm distal to the trochanteric osteotomy surface. The two ends of the cable were passed through respective holes 410 into the reamed femoral canal in a proximal direction to exit through the neck cut. The ends of the cable were pulled proximal to remove all slack so that a short loop formed in the middle of the cable, with the cleat on the lateral surface of the femur. The stem of the implant 402 was then

inserted. One cable end was kept anterior and the other posterior as they exit from the lateral aspect of the neck cut.

After insertion of the prosthetic stem, the hip was reduced and the trochanter held by means of trochanter-holding forceps. Using a trochanteric cable passer, the anterior portion of cable was crossed over and passed over the posterior corner of the top of the trochanter. The posterior cable portion was then crossed over to pass over the anterior corner of the top of the trochanter. (This crossover is advisable to avoid the cable slipping off the front or the back of the trochanter.)

One of the ends of the cable was passed through the cleat 408 and it and the other end were passed through a crimp sleeve 406. This can be positioned anteriorly or posteriorly depending on the surgeon's preference. The trochanter-holding forceps were removed, slack in the cables was taken up by hand, and the trochanter was positioned. (This may be done manually or, especially if the trochanter is to be advanced, with the help of a bone hook over the top.) A tensioner was used to tension the cable suitably. This was carried out by an assistant while the surgeon maintained the desired position of the trochanter. (It is important that excessive tension is not applied.) Finally, the crimp sleeve 406 was crimped and the ends of the cable 404 were cut off.

Fig. 10 shows the application of an embodiment of the invention in treating a butterfly fracture in a long bone, e.g. a femur 500. In this example, there are two cerclage cable portions 504, 505 disposed to pull outer bone portions 506, 507 and the central bone portion 508 together, in the correct anatomical alignment. A cleat 510 generally as shown in Fig. 5 is centrally located on the central fragment 508, and the cables 504, 505 extend away from it, to engage different ones of the outer bone portions 506, 507. In the illustration, one outer bone portion 506 has been drilled to provide an anchorage hole 512 for one cable 504. The other outer bone portion 507 has a half cleat 514, generally as shown in Fig. 6, secured by a screw 516. There is a crimp sleeve 518 holding together the ends of a cable 505. (In fact, the cables 504, 505 are preferably portions of a single cable that loops around the bone.)

Fig. 11 shows the application of an embodiment of the invention to a supracondylar fracture. A separated bone portion 600 has been drilled to provide two anchorage holes 602,604 for cables 606,608. One is a loop which extends under tension around the bone 610, its ends being held by a crimp sleeve 612. The other cable 606 cannot easily engage the bone, and therefore an engagement element embodying the invention is provided. In this case this is a pulley 614 generally as shown in Fig. 7, secured to the bone

by a screw 616. The use of a pulley 614 assists in directing cable force. Once again the ends of the cable 606 are held in a crimp sleeve 618.

CLAIMS

1. A cable engagement element (20-24; 122-128; 220-232; 320-326; 450) for implantation into the human or animal body for engaging a cerclage cable, said element consisting of surgically acceptable material(s) and comprising a body having a portion (24; 124; 224; 324; 424) defining a cable path.

2. An element according to claim 1 wherein the body has a plate portion (20; 124; 220; 320) and a projection (22; 122; 230; 322) rising from the plate portion; said projection having a peripheral edge portion (24; 124; 224; 324; 424) which is shaped to define a cable path extending at least partly around the projection.

3. An element according to claim 2 wherein said peripheral edge portion (24; 124; 224; 324; 424) is convexly curved along its length, and concavely curved in the direction of the height of the projection.

4. An element according to claim 2 or claim 3 having two projections (22; 122; 230) rising from the plate portion, the cable paths extending around the opposing peripheral edge portions of the two projections.

5. An element according to claim 4 wherein the two projections (22) are closely spaced so that, in use, two cerclage cable portions extending around respective cable paths will be in frictional contact with each other.

6. An element according to claim 1 wherein the body (450) has the form of a pulley, with a

circumferential edge portion (424) which is concave in the thickness direction of the body.

7. An element (220-234) according to claim 1 wherein the body has a through-opening (234) through which cerclage cable is passed in use.

8. An element according to claim 7 wherein the through-opening is laterally elongate with lateral sides (224) delimited by portions of the body which are concave in the height direction of the through-opening so as to define cable paths.

9. An element according to any preceding claim having means (126; 426) for attaching the body to bone.

10. An element according to claim 9 wherein the means comprises a screw, and the body has an opening for the screw.

11. A kit of parts for use in a bone fixation technique, comprising cerclage cable (504) and one or more cable engagement elements according to any preceding claim.

12. Use of an element according to any of claims 1 to 10 in the production of a kit of parts for use in a bone fixation technique.

13. In a method of bone fixation wherein a first bone component (400; 506; 610) and a second component (402; 507,508; 600) are secured together by binding them together with one or more cerclage cables 404; 504; 606,608), including the steps of tensioning the cable or cables and applying one or more crimp sleeves 406; 408;

510; 612,618) to hold them in tension, the improvement consisting of providing at least one cable engagement (408; 510; 612,614) element consisting of surgically acceptable material(s) and comprising a body having a portion defining a cable path, and locating said element so that a said cable describes a loop which extends around the cable path of the element.

14. A method according to claim 13 wherein the element provides two opposed body portions defining cable paths, and respective cable portions are located so as to extend around said cable paths.

15. A method according to claim 13 or 14 including a step of securing the element to the first bone component.

16. A method according to any of claims 13-15 wherein the or each element is according to any of claims 1 to 10.

Fig.1
(PRIOR ART)

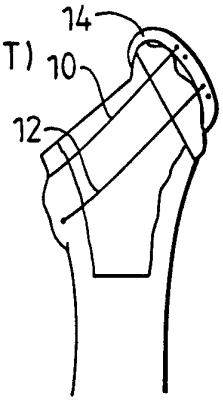

Fig. 2 (PRIOR ART)

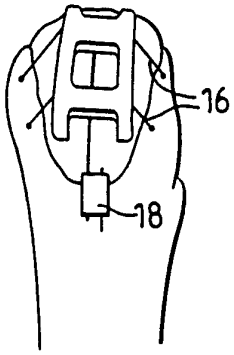

Fig. 3

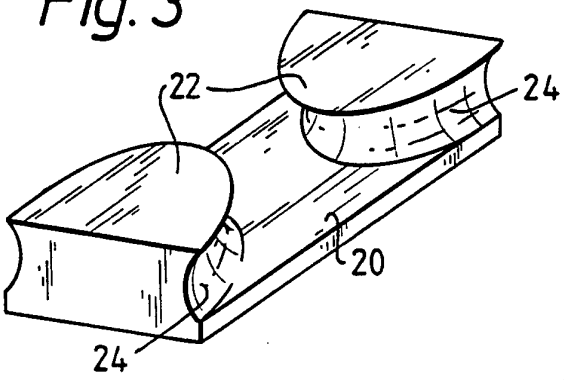

Fig.4

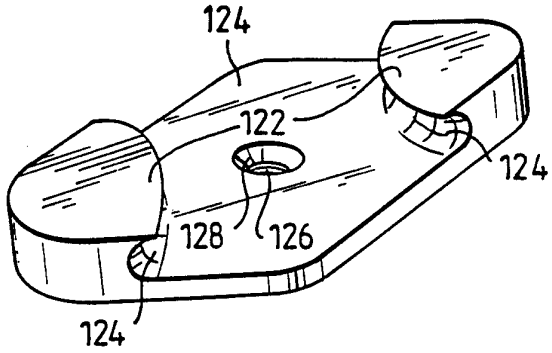

Fig.5

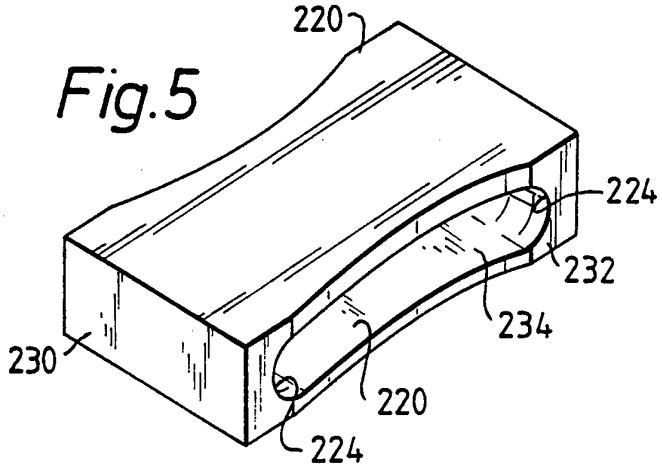

Fig.6

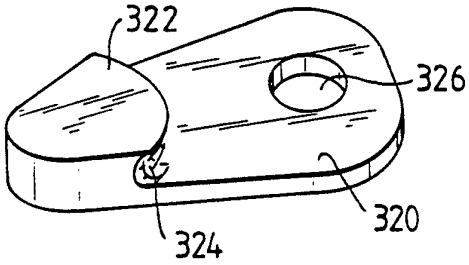

Fig.7

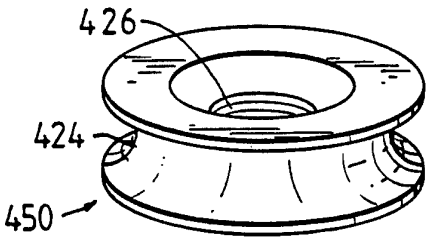

Fig.8

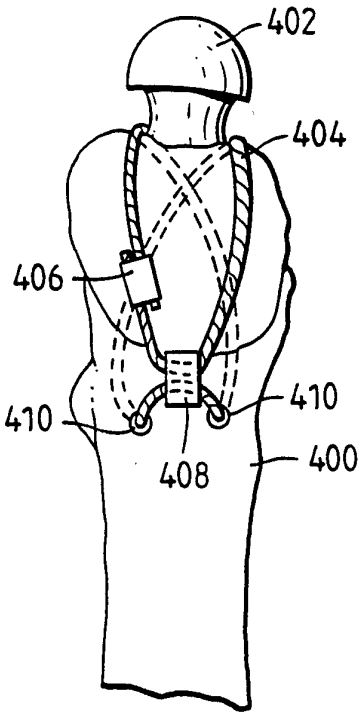

Fig.9

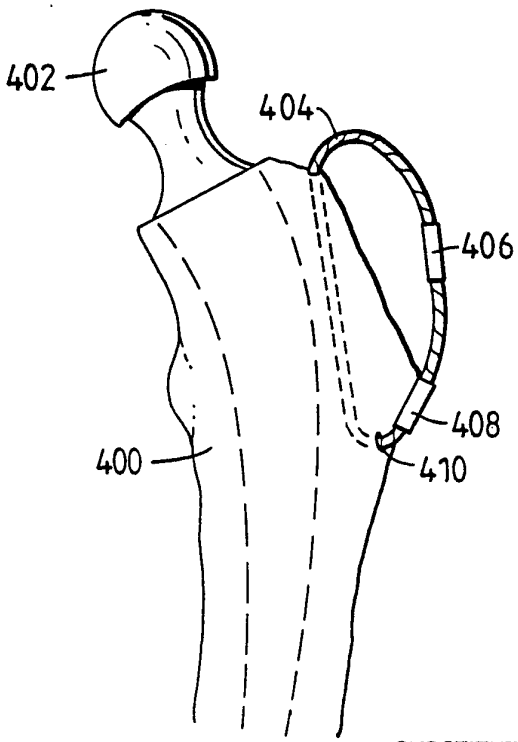

Fig. 10

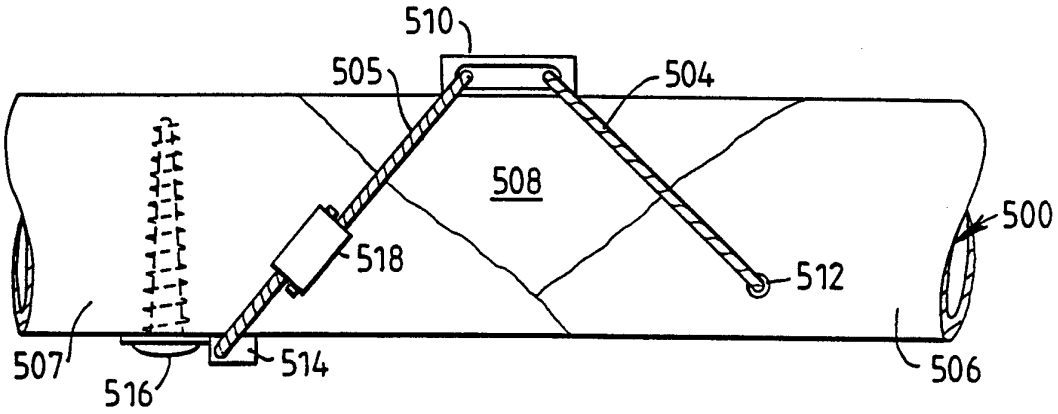
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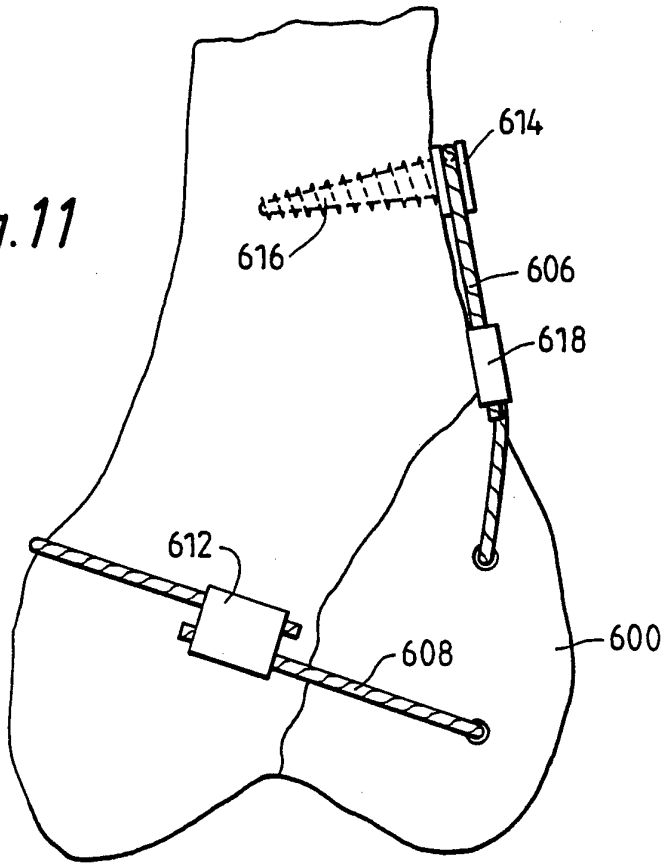
Fig. 11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International application No.
PCT/GB 94/01592

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/58

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61F

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 413 549 (MINNESOTA MINING AND MANUFACTURING COMPANY) 20 February 1991 see column 6, line 36 - column 8, line 54; figures 3-8 ---	1,2,4, 9-12
X	EP,A,0 279 129 (CEROL BANDEIRA ET AL.) 24 August 1988 see column 2, line 50 - column 3, line 9; figures 1-5 ---	1,3,6, 9-12
X	WO,A,93 03681 (HOWMEDICA INC.) 4 March 1993 see page 5, line 18 - page 6, line 12; figures 2-9 --- -/--	1,2,7, 11,12

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
15 November 1994	21. 11. 94

Name and mailing address of the ISA	Authorized officer
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Form PCT/ISA/210 (second sheet) (July 1992)

International application No.
PCT/GB 94/01592

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE,C,38 03 435 (ETHICON GMBH & CO KG) 21 September 1989	1,11,12
A	see column 2, line 68 - column 3, line 49; figures 2,3	2,3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB94/01592

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

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

1. [X] Claims Nos.: 13-16
because they relate to subject matter not required to be searched by this Authority, namely:
SEE RULE 39.1(IV):METHOD FOR TREATMENT OF THE HUMAN OR ANIMAL BODY BY SURGERY

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] 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.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/GB 94/01592

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0413549	20-02-91	US-A-	5002574	26-03-91
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		JP-T-	6505907	07-07-94
		PT-A-	100811	31-05-94
DE-C-3803435	21-09-89	NONE		