

BL O/332/10

24 September 2010

PATENTS ACT 1977

APPLICANT

William Brownlie

ISSUE

Whether patent application number GB 0703167.7 complies with sections 2 and 3

HEARING OFFICER

B Micklewright

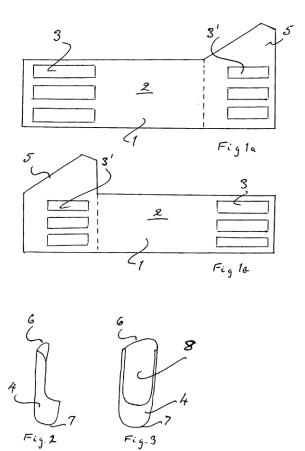
DECISION

Introduction

- 1 Patent application number GB 0703167.7 entitled "Comfort sock" was filed on 19 February 2007 in the name of William Brownlie and claimed a priority date of 17 February 2007 from an earlier UK patent application. The examiner argued that the claimed invention lacked novelty and an inventive step. The applicant disagreed and requested a hearing. The matter therefore came before me at a hearing on 28 July 2010. The applicant, Mr. Brownlie, represented himself. The examiner, Miss. Emily Jones, also attended.
- 2 It emerged before the hearing that Mr. Brownlie had some ideas in relation to how his invention was distinguished from the cited prior art. The examiner warned Mr. Brownlie that he could not add into the application subject matter which was not in the application as filed. At the hearing I re-iterated this warning and confined discussions to features of the invention which were either claimed or were described in the description.

The invention

3 The invention described in the application relates to a prosthetic mounting socket aimed in particular at people with a through-knee or above-knee amputation. The socket, illustrated in Figures 2 and 3 below, includes a cutaway slot 8 extending longitudinally of the socket. In use the socket is mounted over the stump. Figures 1a and 1b illustrate an adjustable retention means 1 comprising a length of flexible material which is wrapped around the socket and fastened using the releasable fastening means 3, 3' to provide a tight comfortable fit around the stump. A flap 5 is also included.



- 4 According to the application, the invention has the advantages that no further additional components, such as strapping or a waist belt, are required in the attachment of the prosthesis. The prosthesis also increases the comfort for the wearer when in a seated position. Moreover it is adjustable to allow for changes in the size of the limb contained in the socket, reducing the necessity to replace the socket when such changes occur.
- 5 There are 8 claims in total. The two independent claims, claims 1 and 8, read:

1. An article for use by a person who has had a through-knee or above-knee lower leg amputation and has the ability to end bear on the upper leg stump, the article comprising a socket adapted for size adjustment and fitment over the stump, having proximal and distal edge portions, wherein the proximal edge portion of the socket is of variable size, and has a notch or gap therein, and adjustable retention means for loosening or tightening the fitment of the proximal edge, said adjustable retention means including a releasable fastening, and comprising flexible material which is configured to be applied to the socket to circumvent at least the proximal edge and overlap the notch or gap to secure the article to the upper leg stump by partially closing the gap or notch.

8. A prosthesis for use by a person having a through-knee or above-knee lower leg amputation and retaining the ability to end bear on the upper leg stump, comprising, a socket adapted to fit over the stump, having proximal and distal edge portions, wherein the socket is configured for attachment of a lower leg prosthesis at the distal edge, and the proximal edge portion is partially cutaway to form a notch or gap in the posterior proximal edge whereby said portion is of variable size, and

a comfort sock adapted to fit over the top of the socket and having adjustable retention means comprising a length of flexible material having at respective ends thereof releasable fastening means and a flap, the releasable fastening being controllable by the wearer of the prosthesis to apply appropriate adjustment for loosening or tightening the fitment of the proximal edge, and comprising flexible material configured to be applied to the socket to circumvent at least the proximal edge and overlap the notch or gap to secure the article to the upper leg stump by partially closing the gap or notch.

The law

Novelty and inventive step

6 Section 1(1) of the Patents Act 1977 ("the Act") states:

1.-(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say –

- (a) the invention is new;
- (b) it involves an inventive step;
- (c) it is capable of industrial application;
- (d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below;

and references in this Act to a patentable invention shall be construed accordingly.

7 Section 3 of the Act states:

3. An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above).

- In *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd,* [1985] RPC 49, the Court of Appeal formulated a four-step approach for assessing whether an invention is obvious to a person skilled in the art. This approach was restated and elaborated upon by the Court of Appeal in *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588 where Jacob LJ reformulated the *Windsurfing* approach as follows:
 - (1)(a) Identify the notional "person skilled in the art".

- (1)(b) Identify the common general knowledge of that person.
- (2) Identify the inventive concept of the claim in question or if that cannot be readily done, construe it.
- (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or claim as construed.
- (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps that would have been obvious to the person skilled in the art or do they require any degree of invention?
- 9 In assessing whether the invention of present application involves an inventive step, I will therefore use this *Windsurfing/Pozzoli* approach.

Assessment

10 The examiner argued that claims 1-7 lack novelty and that claim 8 lacks an inventive step in the light of the following documents:

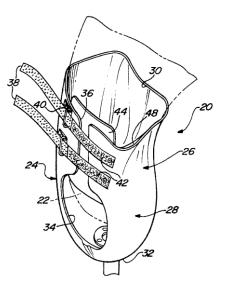
D1: US 5653766 (NASER)

D2: US 2006/009860 A1 (PRICE)

The examiner also referred to other documents, including the following document:

D3: US 5728165 (BROWN)

11 D1 discloses a prosthetic device for use immediately after above-the-knee limb reduction surgery until the patient is fitted with a more permanent device. Figure 1 is reproduced below. Sleeve 24 is at least partially received about the limb 22. The sleeve includes a longitudinal slit 36, Adjustable fastening means 38, 42 enable the sleeve to fit tightly yet comfortably around the limb. The device also includes a foam pad or flap 44 in order to enhance patient comfort.



12 D2 discloses an adjustable prosthetic socket designed for above-knee amputees. It includes cup 12 with a lateral cutaway portion 20 secured by adjustable strap 34 (see Figure 1 below) with an upper open portion. Lateral wall 14 is adjustably attached to cup 20. Tubular sleeve 16 (referred to as a brim in D2) has two open ends and is adjustably mounted in the cup 12.

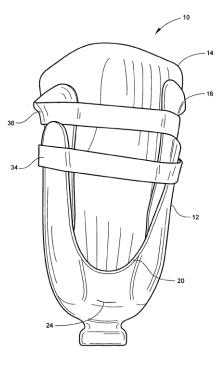


Fig. 1

Novelty

13 Documents D1 and D2 disclose prosthetic sockets with all the features of claim 1 with one possible exception. Claim 1 of the present application states:

"said adjustable retention means including a releasable fastening, and comprising flexible material which is configured to be applied to the socket

to circumvent at least the proximal edge and overlap the notch or gap to secure the article to the upper leg stump by partially closing the gap or notch."

14 If claim 1 can be construed such that the adjustable retention means circumvents the entire proximal edge 6, namely the entire circumference of that edge in a wrap-around fashion, rather than merely a section of that circumference, such that the adjustable retention means circumvents the entire socket, then this constitutes a difference between claim 1 of the present application and the cited prior art. The straps 38 in D1 and the strap 34 in D2 clearly do not completely circumvent sleeve 24 or cup 12 respectively. In my view, when reading the claims in the light of the description, it is clear that the separate adjustable retention means 1 must wrap completely around the socket illustrated in Figures 2 and 3. I therefore construe the claim in this manner and claim 1 is therefore novel over documents D1 and D2. Similarly claim 8 is also novel over D1 and D2.

Inventive step

15 I agreed at the hearing to consider not only the differences between the invention claimed in the present application but also any further differences set out in the description but which were not present in the claims in my consideration of inventive step in relation to documents D1 and D2. Further searching may be necessary if I find that any such features involve an inventive step over the devices disclosed in D1 and D2.

Step 1(a): identify the notional "person skilled in the art"

16 The examiner identified the person skilled in the art as a medical practitioner or person with a background in prosthetics or orthotics. This identification was not disputed by the applicant and I agree with it.

Step 1(b): identify the common general knowledge of that person

17 The examiner considered that the person skilled in the art would be aware of different types of lower leg amputation and also the different types of sockets available to these different amputees. He would also be aware of the benefits and problems associated with these prosthetics. I agree that this information would be part of the common general knowledge of the person skilled in the art.

Step 2: Identify the inventive concept of the claim in question or if that cannot be readily done, construe it

- 18 As I mentioned above, I will assess the inventiveness not only of the claimed invention but also the addition of a number of features of the description or the dependent claims.
- 19 At the hearing Mr. Brownlie emphasised that a key advantage of his invention is to improve comfort for the wearer when sitting down, in addition to the adjustability to allow for changes of the size of the limb contained in the socket. The location of the cutaway at the rear of the socket rather than at the front combined with the separate strap which wraps around the proximal edge of the

socket, overlapping the cutaway, are essential to this advantage. I will therefore include them in the inventive concept despite claim 1 not at present including all these features. The purpose of the flap 5 which according to the description is said to 'overlie the "handedness" rising profile of the proximal edge 6' is not made clear in either the description, the claims or the drawings. It does not appear to relate directly to the problems the invention is aiming to solve and I have therefore not included it in the inventive concept.

20 The inventive concept of the invention is therefore the provision of a gap or cutaway in the proximal edge portion of the posterior of a socket for use by a person who has a through-knee or above-knee amputation which has the ability to end bear on the upper leg stump, along with a separate adjustable retention means which circumvents the entire proximal edge of the socket and overlaps the gap to secure the upper leg stump by partially closing the gap or cutaway.

Step 3: identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or claim as construed

21 The following differences exist between the inventive concept listed above and the disclosure of documents D1 and D2:

a. The adjustable retention means comprising a separate strap which wraps entirely around the proximal edge of the socket

b. A socket with a gap or cutaway in its posterior rather than in its anterior.

Step 4: viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps that would have been obvious to the person skilled in the art or do they require any degree of invention?

The adjustable retention means comprising a separate strap which wraps entirely around the proximal edge of the socket

I note that neither D1 nor D2 disclose an adjustable retention means with comprises a separate strap which wraps entirely around the socket. There are however many different designs of straps used in the field. D1 and D2 disclose two kinds, and D3 discloses a strap which appears to wrap entirely around the socket, albeit in the different context of a device designed for use by below-knee amputees. In my view a person skilled in the art would look at various types of straps, including those that wrap entirely around a socket and those which are not integrally attached to the socket. I therefore do not consider that the adjustable retention means comprising a separate strap which wraps entirely around the proximal edge of the socket involves an inventive step in itself over D1 or D2.

The Gap in the posterior

23 Mr. Brownlie focused on the fact that in his invention the gap was in the posterior of the socket rather than the anterior as a key difference between his invention and the prior art, a difference which he considered to be inventive. This is

because in his view a key benefit of his invention is that it enables its wearer to sit down more comfortably (this benefit is discussed in page 1 lines 15-22 of the description as filed).

- According to both the examiner and to Mr. Brownlie such prosthetic devices would usually have a gap or cutaway located in the front of the device rather than in the rear (the examiner was not able to find any above-knee prosthetic devices which clearly disclosed a gap in the rear). This is, according both to the examiner and to Mr. Brownlie, who has some experience in this field, because the device needs to provide support at its rear, and the presence of a gap would reduce that support. Mr. Brownlie overcomes this problem by his design of the adjustable retention means which he says provides that support in a more comfortable and adjustable manner by using the flexible and adjustable comfort sock as opposed to the hard plastic or laminate of a standard socket. This adjustable retention means is wrapped around the socket towards the proximal edge 6 and fastened to provide a tight comfortable fit around the stump.
- 25 A suggestion was made that D3, which relates to a below-knee prosthesis, discloses a socket with a slot or gap in its rear. The prosthetic device in this document uses a modular system with several different parts. Although it seems from some of the Figures that at least one of these parts could have a notch or gap in its rear, I do not believe this is clearly disclosed and in any case the issues in terms of comfort and support for a below-knee prosthesis are very different to those for an above-knee prosthesis.
- 26 The examiner argued that a person skilled in the art would consider the possibility of placing the gap at the rear of the socket but would then reject that possibility in favour of placing the socket at the front or side, so that support could be maintained. Mr. Brownlie did not disagree with this, although he did disagree with the examiner's contention that the placement of the gap at the rear would therefore be obvious to the person skilled in the art. He argued that because of the problem of providing support for the limb a skilled person would not adapt the sockets disclosed in D1 or D2 to locate the gap in the posterior.
- 27 In deciding on this matter I have to take into account both the positive and negative aspects of the common general knowledge held by the person skilled in the art. The person skilled in the art may have considered the possibility of placing the slots of the devices of documents D1 and D2 at the rear rather than at the front, but in my view they would be prejudiced against doing so because of the problems with supporting the rear of the limb. Mr. Brownlie has solved this problem with his particular design of adjustable retention means in the form of a length of flexible material which wraps entirely around the proximal edge of the socket and is separate to the socket. Although I have found that this particular design of adjustable retention means is not in itself inventive, the idea of using it to provide support so that a cutaway portion may be placed at the posterior of the socket in my view is. The prosthetic device of D1 is designed only for postoperative use and thus, given the problems with maintaining support, I do not believe the person skilled in the art would adapt the device so as to move the slot to the rear. The limited application of the device to post-operative use would not prompt the skilled person even to consider issues such as long-term comfort. In the device of D2 cup 12 is designed to be used with a separate brim and a

separate lateral wall and is thus a more complex design. It would need significant re-design if the slot were to be moved to the rear of the cup 12 whilst maintaining support for the posterior of the limb and there is in my mind nothing which would prompt the skilled person to do this. I therefore consider that a socket with a gap or cutaway in its rear and with an adjustable retention means which wraps entirely around the proximal edge of the socket so as to overlie the gap constitutes an inventive step over the cited prior art.

28 Claim 1 is not limited to a gap or cutaway located in the posterior of the socket. In its current form it therefore lacks an inventive step. Amendment will be necessary to include this limitation into the claim. Independent claim 8 does however include this limitation and this claim is therefore inventive over the cited prior art.

Conclusion

I have found that claim 1 lacks an inventive step because it lacks the feature of locating the gap in the posterior of the socket. Claim 8 does however have this feature and therefore involves an inventive step. The compliance period for this application expired on 17 August 2010. A two-month extension is however available to the applicant under rule 108 providing the applicant files the relevant form and fee before the end of the two-month period. I therefore remit the application back to the examiner for consideration of any amendment which includes this feature into claim 1 should the applicant choose to extend the compliance period and file such an amendment. If the compliance period is not extended and no amendment is filed then the application will be refused as claim 1 in its current form lacks an inventive step.

Appeal

30 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal must be lodged within 28 days.

B MICKLEWRIGHT

Deputy Director acting for the Comptroller