

29th November 2007

PATENTS ACT 1977

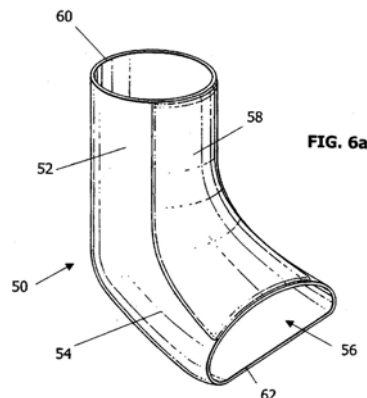
APPLICANT Robert John Watts

ISSUE Whether the invention in patent application N^o GB 2400562A is obvious

HEARING OFFICER Stephen Probert

DECISION

- 1 This decision concerns a patent application for an ankle-foot orthosis. Orthoses are mechanical devices which impose forces upon a patient's limb for eg. supportive, functional, corrective or protective purposes. An ankle-foot orthosis is typically used to provide protection to the ankle and foot of a patient as well as to provide support against excessive plantarflexion or "foot-drop" as it is more colloquially known. Figure 6a, taken from the patent application and reproduced below, conveniently illustrates the invention.



- 2 The main body of the orthosis is a sock-like structure made of an elastic material (a compression stocking). On the dorsal aspect of the sock-like structure, is a rib (indicated by the numeral **58** above) which is formed of a silicone elastomer and is permanently attached to the compression stocking.
- 3 Mr Robert John Watts applied for the patent on 29th April 2003, claiming priority from an application that was filed a couple of weeks earlier on 14th April 2003. His application was published on 20th October 2004.
- 4 During substantive examination, the examiner reported that the invention appeared to lack an inventive step. As far as claim 1 (the only independent 'apparatus' claim) is concerned, the examiner relied upon the disclosure of an

earlier patent belonging to Mr Watts — GB 2,330,309 A, published on 21st April 1999.

- 5 The applicant did not agree with the examiner's report, and requested a hearing. That hearing took place earlier this morning, during which the applicant was represented by his patent attorney, Mr Mark Milhench of First Thought IP.

Claims

- 6 There are two independent claims in the application as it now stands. Claim 16 is a method claim covering a method of manufacturing the ankle-foot orthosis defined in claim 1. Both claims 1 and 16 have been amended since the application was published, and they now read as follows:

1. An ankle-foot orthosis comprising: a compression stocking formed of contiguous first and second tubular members, said second tubular member being set at an angle to the first tubular member to define, as least in use, a generally L-shaped cavity configured to accept and fit closely about the foot and ankle of a patient; and a rib which is permanently bonded or otherwise permanently affixed to a region of the structure which overlies the dorsum of the patient's foot in use, said rib being formed of a silicone elastomer to have a resilience appropriate for resisting the particular degree of plantarflexion experienced by the patient.

16. A method of manufacturing an orthosis, the method comprising the steps of: providing a compression stocking formed of contiguous first and second tubular members set at an angle to one another to define, as least in use, a generally L-shaped cavity configured to accept and fit closely about the foot and ankle of a patient; mounting the structure on a foot-shaped anvil; preparing a silicone elastomer having a resilience which is appropriate for resisting the particular degree of plantarflexion experienced by the patient; applying the silicone elastomer to the compression stocking to form a rib that will in use overlie the dorsum of the patient's foot; allowing the silicone elastomer to cure; and removing the compression stocking from the anvil.

The Law

- 7 The law regarding inventive step is found in sections 1 and 3 of the Patents Act. The relevant parts read as follows:

Patentable Inventions

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)
- (b) it involves an inventive step;
- (c)

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

- 8 The following part of section 3 is also relevant, since it defines what is meant above by 'inventive step'.

Inventive Step

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

- 9 The examiner followed the test for inventive step found in *Windsurfing*¹ — with the elaborations made by the Court of Appeal in *Pozzoli*². Mr Milhench agreed that this was the correct test in law, although he did not think it was particularly helpful in this case because it still leads to the essential (fourth) question - “was it obvious?”

Step 1a — The person skilled in the art in this case

- 10 The examiner considered the skilled person to be a technician in the field of orthopaedic devices, either concerned with the manufacture or use of such appliances. Mr Milhench accepted this, but added that in the applicant’s experience the people who manufacture these orthoses are usually not specialists in orthopaedics, and are just following instructions. In his opinion, with which I agree, the skilled person is more likely to be an orthopaedic technician responsible for designing, measuring and/or fitting such devices.

Step 1(b) — The common general knowledge

- 11 Both the examiner and Mr Milhench agreed that the skilled person would be aware of existing orthoses, the materials suitable for making them, and the prior art cited by the examiner. In addition, the examiner highlighted US 6,430,970 (Gardon-Mollard et al) which is an example of a compression stocking that he considered would also be familiar to the skilled person.

Step 2 — The inventive concept of the patent

- 12 In the most recent examination report, the examiner summarised the inventive concept as “an ankle-foot orthosis having an L-shape, formed of a compression stocking with a permanently fixed rib formed of a silicone elastomer that overlies the dorsum of the foot when the orthosis is in use.” Mr Milhench thought that this was an accurate summary. Having read the description as a whole, and considered the claims carefully, I would say that it is a very good assessment of the inventive concept in the patent application. I am happy to adopt it.

Step 3 — Difference(s) over the prior art

- 13 The description of GB 2,330,309 clearly discloses an ankle-foot orthosis comprising “a resiliently flexible sock-like structure”. It also teaches that the orthosis may have a reinforcing rib overlying the dorsal aspect of the foot and that the rib may be formed of a silicone elastomer. It suggests that the rib could in one embodiment be made of the same material as the body of the orthosis, and formed integrally with it. (Alternatively, the rib may be formed separately and subsequently inserted within the sock-like structure.)
- 14 However, as the examiner accepted in his report, GB 2,330,309 does not specifically indicate the use of a compression stocking. Rather it suggests that the orthosis could be made of rubber, silicone, plastics or any other material apparent to persons skilled in the art. It further says that the resilience of the

¹ *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd*, [1985] RPC 59

² *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588

sock-like structure and the reinforcing means (the rib) are chosen, and may be varied, in dependence upon the degree to which the patient suffers from plantarflexion. From this I infer that the body of the orthosis (and not principally the rib) is expected to contribute to its functional character. This inference is bolstered by the very next line in the description which says:

“Indeed, the reinforcing means 36 can be dispensed with if sufficient resistance to plantarflexion is provided by the sock-like structure 34.”

- 15 Lastly, I note that the sock-like structure described in GB 2,330,309 is provided with a slit down the back to enable it to be fitted around the patient’s ankle. The slit is then held closed using eg. Velcro[®] or a zip.
- 16 Therefore it seems to me that GB 2,330,309 teaches the use of a resiliently flexible (eg. silicone elastomer) sock-like structure that is able to function as an orthosis on its own, and which may or may not be stiffened further by the addition of a reinforcing rib. In contrast, the invention in the present application relies entirely on the reinforcing rib to perform the function of the orthosis, with the main body of the orthosis (the compression stocking) being responsible for holding the reinforcing rib tightly to the dorsal aspect of the patient’s foot so that it is able to perform its function.

Step 4 — Was it obvious over the difference(s)?

- 17 The examiner, who is more familiar with this technical field than I am, reported that the skilled person, familiar with the common general knowledge, would think of a compression stocking when presented with the “resiliently flexible sock-like structure” described in GB 2,330,309. That being so, he did not think that the skilled person would need to exercise any inventiveness to arrive at the combination of features required by the present invention. That does not appear to me to be an unreasonable view to take, but it is not the conclusion that I came to when trying to put myself in the shoes of the skilled person reading GB 2,330,309.
- 18 Mr Milhench argued that there is nothing in GB 2,330,309 that would motivate the skilled person to ignore the particular teaching that the entire sock-like structure should be made of silicone, and decide instead to provide only a silicone rib running along the dorsal aspect of a compression stocking. It seemed to me that Mr Milhench might be attributing less weight than the examiner to the influence of the common general knowledge on the skilled person in framing his argument, but even making allowances for the fact that the skilled person would be fully aware of compression stockings I still consider that the difference between the structure described in the prior art and the one claimed in this application would not be an obvious change to make.

US 4,559,934 - Philipp

- 19 The examiner also relied upon a further prior art document (US 4,559,934) to object that some of the later, dependent claims lacked an inventive step. During the substantive examination of this application, and at the hearing, Mr Milhench concentrated his arguments on proving that claim 1 is both novel and inventive. He relies upon the fact that if claim 1 is novel and inventive, then the subsequent claims, being dependent on claim 1 for their novelty and

inventive step, must also be new and inventive.

- 20 Clearly this must be correct, and since I have found that claim 1 does not lack an inventive step (nor the independent method claim 16), there is no need for me to consider the attack against the dependent claims based upon US 4,559,934.
- 21 Although US 4,559,934 has not been cited against claim 1 (or 16), and therefore I did not take it into account when reaching my decision above, I have read it and considered whether perhaps it should have been cited against claim 1. It is clearly a relevant document since it describes an ankle-foot orthosis which is constructed using an elastic support stocking. It also teaches the use of a 'rib' overlying the dorsum of the patient's foot in a similar position (and for a similar purpose) as the present invention.
- 22 In US 4,559,934 the rib is made of metal or plastic (eg. Ortholen), and is not permanently attached to the orthosis. Instead the two ends of the rib are inserted into two sewn-in pockets on the orthosis. In my view, the specification would lead the reader away from the idea of permanently attaching the 'rib' to the body of the orthosis since it says (column 3 lines 1-9):
- "Putting on the sock is facilitated when the plate is removed since in practice it is simpler first to put on the sock without the plate and thereafter insert the plate in the pockets. The sock is more troublesome to put on when the plate is inserted first."
- 23 From this I conclude that the examiner was right not to cite this document against claim 1. Furthermore, although it discloses the use of an elastic support stocking in combination with a rib to provide an ankle-foot orthosis, there is no suggestion that this would have been common general knowledge in April 2003 when the application was filed. Moreover, the description of the current application distinguishes between support stockings and compression stockings, and states that a support stocking would not provide sufficient elastic force to keep the rib in close contact with the patient's lower leg while walking. For these reasons I don't think that US 4,559,934 would lead the skilled person in the direction of the invention claimed in this application.

Conclusion

- 24 I have found that the invention described and claimed in this application does involve an inventive step. This was the only objection remaining against this application when the period for putting it in order expired on 14 October 2007. Therefore I remit the application back to the examiner so that it may be sent to grant.

S J PROBERT

Deputy Director acting for the Comptroller