

**PATENTS ACT 1977**

APPLICANT Welland Medical Ltd

ISSUE Whether patent application  
N<sup>o</sup> GB 2432120 should be refused  
for lack of inventive step

HEARING OFFICER Stephen Probert

Dr Michael R Hutchins (of M R Hutchins & Co.) for the applicant

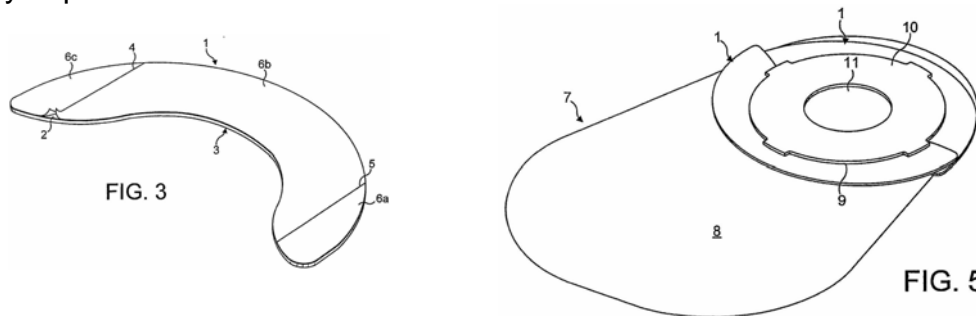
Hearing date: 2<sup>nd</sup> June 2011

---

**TRANSCRIPT OF ORAL DECISION**

- 1 The invention claimed in this application concerns a sealing support for an ostomy bag. Stripped to its bare essentials, and in crude layman's terms, it is a piece of sticky tape for holding and sealing a collection bag against part of the human body. The application was filed on 9<sup>th</sup> November 2005.
- 2 In the latest official letter, dated 5<sup>th</sup> May 2011, the examiner maintains his previous objection that the claimed invention is obvious in the light of an earlier published document ("Clinimed"), when combined with the common general knowledge.
- 3 Claim 1 is the only independent claim. At the beginning of the hearing it was as follows:—
  1. A support for an ostomy bag, the support being shaped to fit around and extend a portion of a hydrocolloid adhesive flange of the ostomy bag, characterised in that the support comprises a backing layer, a layer of silicone adhesive, and a releasable cover layer on the silicone adhesive.
- 4 During a short adjournment, Dr Hutchins prepared two further amended versions which more clearly define the inventive concept that the applicant wished to rely upon. For the purposes of this decision, only the first of these amended versions is relevant. It reads:—
  1. A **sealing** support for an ostomy bag, the support being shaped to fit around and extend a portion of a hydrocolloid adhesive flange of the ostomy bag **so as to seal against an edge of the flange and prevent or inhibit the ingress of water;** wherein the sealing support comprises a backing layer, a layer of silicone adhesive, and a releasable cover layer on the silicone adhesive.

- 5 The earlier published document is GB2397230A (“Clinimed”), published on 21<sup>st</sup> July 2004. It is a very similar disclosure; the drawings are identical. The invention described in Clinimed is a shaped adhesive strip (1) called a “support”, that can be used to reinforce the adhesive flange (10) of an ostomy bag (7). Typically, an ostomy bag would already have an adhesive flange for attaching to the body, but for a variety of reasons experience has shown that additional means of securing the ostomy bag in place is often desirable.
- 6 Figure 3 shows one such support before it is attached to an ostomy bag. Figure 5 shows the same support attached to the left side of the flange of an ostomy bag. In practice, several of these supports might be used to hold an ostomy bag securely in place.



- 7 Clinimed explains that the adhesive used on the flange of an ostomy bag is normally a hydrocolloid. Hydrocolloid adhesive is particularly “skin friendly”. The invention in Clinimed uses the same hydrocolloid adhesive on the support as would typically be used on the flange of an ostomy bag.
- 8 But hydrocolloid adhesives, while being “skin friendly”, are not as resistant to eg. water ingress (when bathing, showering or swimming) as one would like. Prolonged exposure to water saturates the water absorbency of the hydrocolloid, causing the seal to fail. According to the present application, an alternative product used by some ostomy bag wearers is a similar curved (or annular) support covered with an acrylic adhesive. However, acrylic adhesives are not as skin friendly as the original hydrocolloid material, and tend to increase skin trauma.
- 9 What the inventors of the present application have realised, is that a silicone adhesive can be used on the support, instead of an acrylic or hydrocolloid adhesive. This improves the sealing function of the support, by preventing water from getting to the flange of the ostomy bag.
- 10 My initial reaction on reading the application was that it must have been obvious to consider and/or test other well known adhesives for the support. Like many other DIY enthusiasts, I have used silicone and acrylic adhesives (as well as several other types of adhesive) for many years. I know from personal experience that if one type of adhesive doesn’t work, I need to try an alternative.
- 11 Nevertheless, the examiner and the applicant, during the course of several rounds of correspondence, used the structured *Windsurfing*<sup>1</sup> / *Pozzoli*<sup>2</sup> approach

<sup>1</sup> Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd, [1985] RPC 59

<sup>2</sup> Pozzoli SPA v BDMO SA [2007] EWCA Civ 588

to determine obviousness, and therefore I will also follow this well established test now.

## The Law

- 12 Section 1(1)(b) says that a patent may be granted only for an invention if, among other things, it involves an inventive step. Section 3 then defines what is meant by “inventive step” as follows:

### 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 by virtue only of section 2(2) above (and disregarding section 2(3) above).

- 13 The *Windsurfing/Pozzoli* approach involves the following steps:—

- 1(a) Identify the notional “person skilled in the art”
- 1(b) Identify the relevant common general knowledge of that person;
- 2 Identify the inventive concept of the claim in question or if that cannot readily be 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 the claim as construed;
- 4 Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

## Applying the Windsurfing/Pozzoli steps

### *Step 1(a) The notional “person skilled in the art”*

- 14 There was no difficulty here. The applicant agrees that the notional person skilled in the art in this instance is a person skilled in ostomy bags and wound drainage or wound manager bags. He or she is a person with the skill to make routine workshop developments but not to exercise inventive ingenuity or think laterally.

### *Step 1(b) The common general knowledge*

- 15 The examiner reports that the common general knowledge includes the use of silicone adhesives to attach things, including ostomy bags, to parts of the human body. Six of the seven documents cited against this application all disclose the use of silicone adhesives for these purposes<sup>3</sup>. However, as Dr Hutchins convincingly demonstrated, several of them are actually hydrocolloid adhesives that may contain some silicone. Dr Hutchins said that such adhesives would not fall within the scope of “silicone adhesive”, at least for the purpose of construing the claims of this application.
- 16 The applicant contended, quite rightly, that individual patent specifications and their contents do not normally form part of the relevant common general knowledge. But this is not a matter of relying on an individual patent specification

---

<sup>3</sup> EP81907A1, US4327727, EP955347A2, US6846508, GB2094809A & US6746765B1

to establish common general knowledge. As suggested above, even without the help of published documents, I would have thought it was common general knowledge that there are many different types of adhesives, some of which are more suitable in certain applications than others. So I don't think this wasn't a case of the examiner seizing upon an individual patent specification and regarding it as common general knowledge. I think it is more likely that he cited six documents that each confirmed what he already thought was common general knowledge.

- 17 The applicant also supplied a witness statement from one of the inventors, Dr Rory James Maxwell Smith (Director of Research and Development at the Welland Medical Ltd). Dr Smith has worked in the field of ostomy care devices since 1992, and is clearly an expert in this field. He says that he is "*not aware of any instances of silicone adhesives being used in adhesive flanges on commercially available ostomy bags or ostomy bags in clinical trials for the purpose of attaching ostomy bags to a patient's body*".
- 18 However, the issue is not whether it has been done before, but whether it would be an obvious thing to consider. The fact that there are no similar products on the market using silicone adhesive does not mean that silicone adhesive is excluded from the common general knowledge. I therefore conclude, partly on the basis of the six prior art documents, but mostly from my personal knowledge, that at the filing date of this application it would have been common general knowledge that adhesives come in many different forms, including silicone, and that many of these could be suitable for adhering things to the human body. It would also be common general knowledge that some adhesives are more water proof than others.

*Steps 2 Identify the inventive concept*

- 19 The inventive concept as claimed in the application when the hearing began was a shaped support for an ostomy bag, wherein the support attaches by means of a layer of silicone adhesive. During an adjournment, Dr Hutchins prepared some further amendments to the claims which make it clear that the inventive concept is primarily the sealing characteristic of the silicone adhesive layer on the support, whereby it protects the edge of the hydrocolloid flange from water ingress.

*Step 3 Identify the difference(s)*

- 20 The difference between Clinimed (the state of the art) and the inventive concept is the replacement of the hydrocolloid or acrylic adhesive on the support with a silicone adhesive to seal the edge of the flange against ingress of water. Clinimed talks about the hydrocolloid or acrylic support improving the seal of the flange, but this is in connection with preventing [body] fluids from leaving the bag, rather than preventing water (eg. during a shower) from getting to the edge of the hydrocolloid flange adhesive.

*Step 4 Is the difference obvious to the person skilled in the art?*

- 21 Yes. Whichever way I look at it, it seems obvious to me to consider using a silicone adhesive as an alternative to hydrocolloid or acrylic in this situation. I believe that a support such as the Clinimed product, whether using hydrocolloid

or acrylic adhesive, would still seal the edge of the flange — as now claimed. Silicone may do the job better, but that is because it is a water proof adhesive. I don't think it would have required any inventive step to take a Clinimed product and use a silicone adhesive instead of the hydrocolloid. I therefore conclude that the difference between the inventive concept and the state of the art (Clinimed) is a step that would be obvious to the skilled person.

22 This is a relatively short application. I have read it through several times, and I cannot envisage any amendment that would overcome the obviousness objection.

23 Consequently the application is refused under section 18(3) because the invention described and claimed in it does not involve an inventive step as required by section 1(1)(b), and as defined in section 3.

### **Appeal**

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

**S PROBERT**

Deputy Director acting for the Comptroller