Neutral Citation Number: [2025] EWHC 497 (Pat)

CLAIM No. HP-2023-000030

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Mr. Ian Karet OBE sitting as a Judge of the Chancery Division

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: 5 March 2025

Between:

SALTS HEALTHCARE LIMITED

Claimant

- and -

PELICAN HEALTHCARE LMITED

Defendant

- -
- -

Mr. Douglas Campbell KC and Mr. Tim Austen (instructed Shakespeare Martinu) for the Claimant
Mr. Richard Davis KC and Ms. Laura Adde (instructed by Murgitroyd) for the Defendant

Hearing dates: 18, 19, 20 and 22 November 2024

- -

Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

.....

Ian Karet:

Introduction

1. This is my judgment following the trial of an action concerning infringement and validity of UK Patent no. GB 2,569,212 (the "Patent") for "An ostomy appliance". The priority date is 22 September 2017.

2. The Claimant ("Salts") allege the Defendant ("Pelican") through acts related to their "ModaVi" ostomy bag infringe claims 5 and 8 of the Patent and claim 20 when that is dependent on claims 8, 18 and 19. Salts allege infringement both on the basis of a normal interpretation of these claims and through the doctrine of equivalents. Ostomy bags may be closed or drainable. The drainable bag has an outlet at the bottom through which the contents may be emptied. Salts allege that the ModaVi closed form infringes all of the claims above and that the drainable form infringes only claim 8. Salts say that these claims are independently valid.

3. Pelican denies infringement and alleges that the Patent is invalid in the light of four prior art citations:

   (i) European Patent Application EP 2 229 924 A1 ("Grum-Schwensen")

   (ii) European Patent Application EP 1 177 781 A ("Falconer")

   (iii) United States Patent Application US2014/0163497 ("Hannan")

   (iv) United States Patent Application US2011/0190718 ("Wheaton")

   At trial the argument was about claims 5, 8 and 20.

4. Salts have applied conditionally to amend the Patent. Pelican came into the trial opposing that on the grounds that the amendment does not cure the invalidity and the amendment will introduce added matter. Pelican's position moved during trial as I describe below. The UKIPO does not object to the proposed amendments.

5. Salts and Pelican compete in the market for ostomy bags. Salts' product is called "Confidence BE".

6. The Patent addresses known problems with ostomy bags of unsightly "bulging" and waste in the bag causing pulling on the top of the wafer which connects the bag to the user. This, for these purposes, is called "sagging". The parties accepted that an ostomy bag will fill during use and so increase in size and that the Patent addresses problems with unevenness in that filling.

7. At trial Salts were represented by Mr. Douglas Campbell KC and Mr. Tim Austen. Pelican were represented by Mr. Richard Davis KC and Ms. Laura Adde. The trial was heard over 4 days and ran to a tight timetable. Both sides served extensive written submissions. I am grateful to counsel for their assistance.

The witnesses

8. There were two fact witnesses for Pelican.

9. Mr Benjamin Mahood is the Design Manager of the team leading the design of the alleged infringing bag, ModaVi. He provided Pelican's product and process description given in lieu of disclosure ("PPD"). There were three versions of the PPD. Mr Campbell was highly critical of Mr Mahood's evidence, submitting that Mr Mahood had no real understanding of disclosure; that the first PPD was incomplete; and that the second and third versions used "lawyered" wording.

10. The PPD made assertions about the ModaVi bag which Salts dispute. It said that the C-shaped weld in the fabric at the top of the ModaVi bag helped to prevent the bag bulging, but Pelican's expert witness did not realise that. It also said that the shape of the bag avoided the creation of a sharp edge on folding, even though the edge did not touch the skin and the bags are made of soft material. I address these matters further below.

11. Mr Mahood also gave evidence about patent application WO2021/165703A1 ("Eakin") in the name of Eakin R&D Limited, the parent company of Pelican. Eakin was filed on 22 February 2021 claiming a priority of 20 February 2020. Salts says that this is not long after the Patent was published and that Eakin takes from the Patent. The invention disclosed in Eakin looks similar to the ModaVi bag, and Salts relied on the description in Eakin as indicating infringement of the Patent. Salts asserts that it is notable that the application for the Patent was published in June 2019 and that Pelican began its project to devise the ModaVi in the same month.

12. Mr Mahood was distinctly uncomfortable giving evidence about both the PPD and the Eakin patent application and I treat his evidence with caution.

13. The role of the PPD in this case was, however, limited. That is because the features of the ModaVi bag are apparent from an inspection, and in this case the PPD does little if anything to add to that. Salts argued that the PPD misstated the position so as to avoid infringement. Mr Campbell said that Pelican did intend to infringe and intention may be relevant to infringement because the court should accept that a defendant intending to infringe has succeeded in doing so.

14. Eakin speaks for itself. I conclude that Pelican was aware of the application for the Patent and turned their attention to making an ostomy bag which might compete with that. But that is not a conclusion as to when the work on ModaVi actually started or whether Eakin describes infringement of the Patent.

15. Mr Owen McNamara gave evidence about a marketing presentation about the ModaVi bag. I accept his evidence.

16. Salts' expert was Mr Thomas Brie. Mr Brie has a degree in engineering and is qualified in product design. He started working in the design and production of ostomy bags in 1987. Since 2012 he has worked as a consultant in medical device technology, including ostomy bag production. His first language is German. He gave evidence in English with a translator accompanying him in the witness box to whom he occasionally referred.

17. Pelican's expert was Ms Birthe Vestbo Andersen. Ms Andersen has a degree in engineering and from 1993 to 2018 worked in ostomy product development for

Coloplast, a leading company in the ostomy field. Her first language is Danish. She gave evidence in English.

18. It was common ground that the notional skilled addressee of the Patent is an engineer who develops ostomy products. Both experts had significant experience and were well qualified to give evidence on the issues.

19. Neither witness is a native English speaker. Each had certain difficulties with questions put to them during cross-examination. I concluded that in both cases this was in part due to them tiring during that process. I address this further below.

20. Mr Campbell criticised Ms Andersen as highly inventive and so over-qualified for the role of expert witness. He suggested that she had signed up to matters in her report that she did not understand. There was part of her cross-examination where she and Mr Campbell appeared at cross-purposes over the phrase "common general knowledge" in which she appeared to answer on the basis of a different meaning to that he used in putting his questions.

21. Mr Campbell also criticised Ms Andersen for using hindsight in reading the prior art and for making proposals to change the prior art based on the desired end point of the claimed invention. He said that her approach to the CGK was too broad, which he blamed on those instructing her. He submitted that these were fundamental errors that undermined her approach, in particular on inventive step.

22. I do not accept those criticisms. I found Ms Andersen a helpful witness who was trying to assist the court. She had been given the material which she considered in a particular order, so that she did not see the Patent first and tailor her answers to that. Criticisms about her review of the earlier art were misplaced.

23. Mr Davis criticised Mr Brie for his responses to the experiments. Mr Brie was not involved in designing Salts' experiments. He did not criticise those but he did criticise Pelican's experiments. In contrast, Mr Davis pointed out that Ms Andersen had criticisms of both sides' experiments. He criticised Mr Brie for failing to take a position on them. I do not think there is much in that.

24. Mr Brie also stumbled during cross-examination over the meaning of the word "buckling", which is a term that was used in his written evidence and is relevant to the behaviour of the bags in use. This was of some concern and raised the question how proficient in English Mr Brie actually is. While his English in court was good, this, coupled with the presence of a translator who was there for reference and not to translate all his evidence, cast some doubt on how much of his expert report was his own work. I accept that he was doing his best to assist the court and was otherwise clear, but I approach his written evidence with a degree of caution.

Common General Knowledge

25. The parties agreed a statement of what was common general knowledge ("CGK") at the priority date. That included the following.

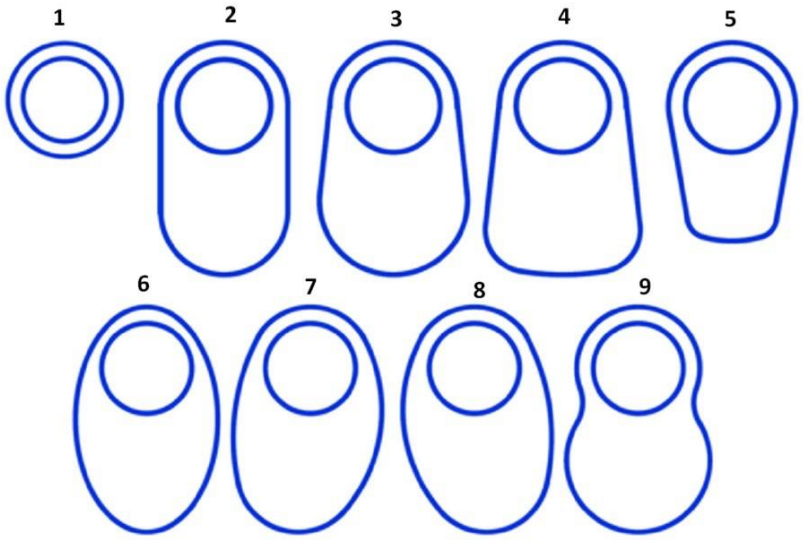
26. Ostomy appliances are made of a bag for receiving the waste and an adhesive baseplate to fix the bag to the body. The baseplate contains a central hole to accommodate the

stoma. Waste enters the bag from the stoma and collects in the bottom of the bag. The top of the bag extends above the stoma creating a ‘headspace’.

27. The bag is typically connected to the baseplate using welding or a mechanical or adhesive coupling. Ostomy bags typically comprise two or more layers, including an internal polymer film layer which contains the waste, and an external layer of fabric to improve user comfort and reduce the noise produced by the film layer.

28. Ostomy bags may be ‘closed’ i.e. typically one-use products, which are thrown away once filled and replaced by the user, or ‘drainable’, which allows emptying and re-use.

29. Ostomy bags varied in size and volume between manufacturers, depending on the bag design and user requirements. There were three types of ostomy bags (colostomy, ileostomy and urostomy), which generally correspond to the three types of ostomy surgery. They have a variety of shapes including those shown below.



Shape 9 has a “figure of eight” shape. Various commercial products were of this shape such as the Convatec Esteem and the Stomocur Select.

30. The diagram above shows eight bag shapes and at 1 a stoma cap (which is not a bag).

31. Output from colostomy and ileostomy stomas varies in consistency. Colostomy waste is generally more solid than ileostomy waste. Urostomy waste is liquid. In Europe typically a colostomate would use a closed bag and an ileostomate would use a drainable bag. A urostomate would typically use a drainable bag that also had a non-return valve to prevent urine moving back toward the stoma so as to reduce the risk of infection

32. When looking to design a new type of ostomy bag, the skilled reader would have looked to include features from other types of ostomy bag that were universal and appropriate, for example, the materials for the wafer. An ostomy bag manufacturer would not have liked to change the design or specification of a bag once it had been put onto the market.

A user would not have liked to change the product that they were using once they had become used to fitting and using that particular design of bag.

33. The parties disagreed on whether design features were transferable from one type of ostomy bag to another. Ms Andersen gave evidence that a designer might use features seen in one bag in another, and in cross-examination she provided an example of that in process. In my view there was no strict division between the types of bags and the skilled reader might look to other types of bags where it was appropriate for the task concerned. However, it is not the case that the range of CGK designs shown above means there is no room for invention in this field.

34. There were some differences internationally in how ostomy bags are used. Users of all three types are concerned that the bag does not fill too much to risk reflux, i.e. return through the stoma. In the US users may use drainable colostomy bags. Salts argued, relying on *KCI Licensing In v Smith & Nephew* [2010] FSR 31 and *Terrell*, 20th Edn. at 8-73 that the differences between the US and other markets were important because matters that were known in the US should not be taken as known in the UK. Having heard the expert witnesses discuss features of various bags, I conclude that the skilled reader would have information about the different types of bags and their uses in different places and that knowledge could be adopted anywhere in the world and in any device. The skilled reader of the Patent in the UK would have been aware of US practices and in particular that a drainable bag might be used for a colostomy. The division which Salts sought to erect did not exist in practice.

35. The bag shown at 9 in the diagram above has a figure of eight outline. The bag has a waist and that has an effect on how the bag will fill. Salts submitted that only the specific figure of eight bag shown in the diagram was CGK and that others were not. I reject that. First, the outline is given as a general example and not a specific item. Second, both experts understood that the relative proportions of a bag could be varied. Mr Brie accepted that the waist would make the bag smaller and that a larger bag with a waist could be designed. Ms Andersen said that a waist would influence the width of the bag and so the volume available to collect waste.

36. Prior to the preparation of expert reports the parties agreed that the terms ‘bulging’ and ‘sagging’ were not terms of art and agreed working definitions of these terms for the purposes of these proceedings as follows. “Bulging” means to swell outwards. This may be in any direction and is not limited to the direction perpendicular to the plane of the ostomy bag itself. “Sagging” means to bulge in a generally downward direction.

The Patent

The description

37. The Patent is entitled “An ostomy appliance”. It relates “in particular, but not exclusively” to “closed ostomy appliances”. The Patent sets out the problem to be solved starting at page 1, lines 12-19:

> “Ostomy appliances are well known. When an ostomy appliance becomes fuller it tends to start to bulge outwardly. Such outward bulging is unsightly, which may cause a user embarrassment. Also, the collection of waste in the bottom of the appliance can cause a user discomfort as it tends to "pull" at the top of a wafer

which connects the appliance to a user. This can lead to the wafer detaching, which is clearly undesirable."

38. Figure 1 shows a front view of an appliance of the invention. It is a bag 10, with a top 11 and a bottom 13, a front wall 14 (and a back wall 12, shown in Figure 2) "connected… at or near their peripheries 15". That connection may be a weld or some other form of bonding. There are two pairs of weld portions 20/22 and 28/30. The dotted line 50 indicates that the bag can have an outlet for drainage.

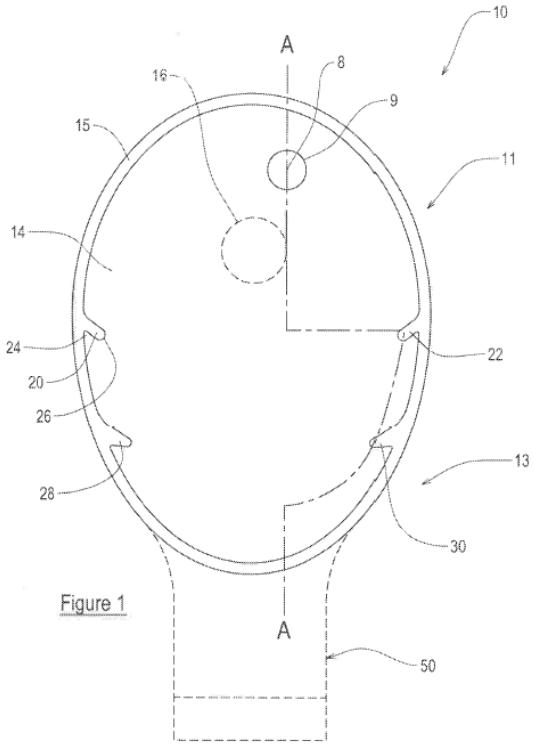


Figure 1

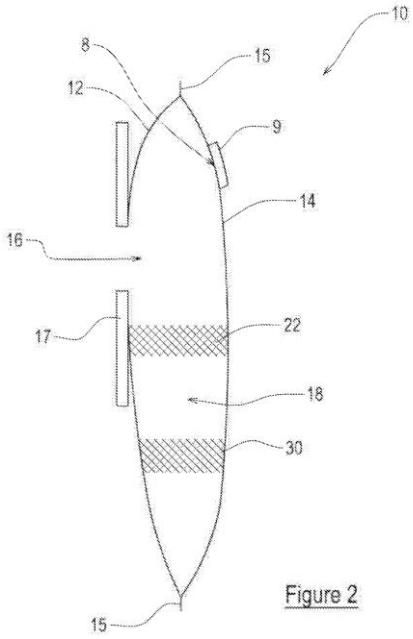


Figure 2

39. Figure 2 shows a bag side-on, with the left-hand side of the bag worn against the body.

40. The weld portions of the bag are shown in more detail in figures 3 and 4. Each of 22a and 30a is a "free end". 22b, 30b is a "top edge" and 22c and 30c are "bottom edges".

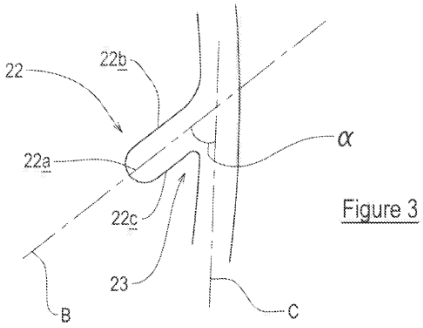


Figure 3

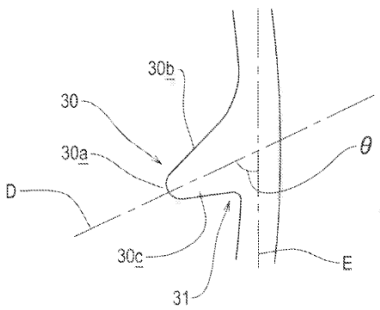


Figure 4

41. Further figures show aspects of this embodiment, giving various measurements that may be made for the relative positioning and form of the weld portions, for examples the angles α and θ shown in Figures 3 and 4.

42. At page 1, lines 29-32 the bag is described as having;

> "…a first weld portion positioned to one side of the appliance and which connects the first and second walls together, which first weld portion extends away from a periphery of the appliance and downwardly towards the bottom of the appliance…".

43. Starting at page 2, line 17 the Patent says:

> "The first and/or second weld portion may be connected to the peripheral connection of the first and second walls.
>
> The first and/or second weld portion may be an extension or continuation of the peripheral connection of the first and second walls.
>
> The first and/or second weld portion may be generally arcuate or a portion thereof may be generally arcuate.
>
> The first and/or second weld portion may be generally curvilinear.
>
> The first and/or second weld portion may be generally elongate.
>
> An end of the first and/or second weld portion remote from the periphery of the appliance may be curved or rounded."

44. At page 12, line 26 the Patent says that the appliance shown in the figure is a "closed colostomy appliance" which could be drainable with an outlet such as shown at 50 in Figure 1.

45. Starting at page 13, line 18 the Patent says:

> "Advantageously, the appliance 10 includes additional weld portions (to the peripheral weld which connects the first and second walls 12, 14 to each other). In the present embodiment, the appliance includes four such additional weld portions - two on each side of the appliance. There are weld portions 20, 28 on the left side of the appliance 10 and weld portions 22, 30 on the right side of the appliance (as viewed in figure 1). The weld portions 20 and 22 are positioned directly opposite each other, and the weld portions 28, 30 are positioned directly opposite each other. The weld portion 20 is positioned above the weld portion 28, whilst the weld portion 22 is positioned above the weld portion 30.
>
> Each weld portion 20, 22, 28, 30 extends away from the periphery 15 of the appliance 10 and downwardly towards the bottom of the appliance 10. The weld portions 20 and 22 are positioned at least partly below the stoma-receiving opening 16."

46. Page, 15 lines 4-9 says:

> "The weld portions 20, 22, 28, 30 are highly advantageous in preventing bulging of the appliance 10 during use when it contains waste. The weld portions 20, 22, 28, 30 ensure that the force acting on the appliance as a result of the waste is distributed relatively evenly along the length of the appliance. This helps to prevent the appliance 10 from "pulling" on the top of the connection member 17."

47. The Patent does not explain what forces are acting on the appliance or how the welds work to achieve the result claimed. It appears that the inclusion of the welds will narrow the bag, but it is not explained whether that is significant.

48. Page 22, lines 24-26 say that:

> "The weld portions 20, 22, 28, 30 are each elongate with upper edges which are generally arcuate. The weld portions 20, 22, 28, 30 could be curvilinear. 25 An end of the weld portions 20, 22, 28, 30 remote from the periphery 15 of the appliance is curved or rounded."

49. There is no description of how the weld portions work when the bag is filling in use or what effect they have other than the relative benefits of solving the problem described at the outset. There are no experiments, comparisons with prior art behaviour or measurements of how the bag will perform in use. Where measurements of angles or distances are indicated all the figures and ranges are permissive.

50. At trial the experts gave some explanations of how the structure of the bag might work in practice. Ms Andersen said that the higher the centre of gravity of the waste in the vertical direction, the more evenly the force on the wafer is distributed in that vertical direction. As a result, the weld portions reduce pulling on the top of the wafer, which relieves user discomfort at least to some degree.

51. Mr Brie described the structure as reducing a 'pendulum' effect by which the force is further away from the wafer attachment to the body, so the force can become amplified like a pendulum. As a human abdomen is not typically flat in the area that a stoma is created, if waste collects just at the bottom of the pouch it can hang outwardly, away from the body.

52. Salts said that if the centre of gravity is higher up, then the weight is closer to the wafer, and the moment on the top plate is reduced. That is what is meant by the relatively even distribution of force along the vertical length of the appliance. Salts' position was that for the purposes of the invention of the Patent it is important is that the force is distributed relatively evenly, not perfectly evenly. Even with these explanations, the performance of an appliance of the invention is relative.

The claims

53. The Claims alleged to be infringed are 5, 8 and 20 as dependent on 18 and 19.

54. Claim 5 is as follows:

> "5. A colostomy or ileostomy appliance for receiving waste including:
>
> first and second walls connected to each other at or near their peripheries, the first wall having a stoma-receiving opening;
>
> a waste collecting cavity defined between the first and second walls;
>
> a first weld portion positioned to one side of the appliance and which connects the first and second walls together, which first weld portion extends away from a periphery of the appliance and downwardly towards a bottom of the appliance;

a second weld portion positioned on an opposite side of the appliance to the first weld portion and which connects the first and second walls together, which second weld portion extends away from a periphery of the appliance and downwardly towards a bottom of the appliance;

a third weld portion positioned to one side of the appliance above the first weld portion and which connects the first and second walls together, which third weld portion extends away from a periphery of the appliance and downwardly towards a bottom of the appliance; and

a fourth weld portion positioned on an opposite side of the appliance to the third weld portion and which connects the first and second walls together, which fourth weld portion extends away from a periphery of the appliance and downwardly towards a bottom of the appliance."

55. Claim 8 is as follows:

"8. A colostomy appliance for receiving waste including:

first and second walls connected to each other at or near their peripheries, the first wall being provided with a stoma-receiving opening;

a flange or connection member positioned around the stoma-receiving opening;

a waste collecting cavity defined between the first and second walls;

a first weld portion positioned to one side of the appliance below the stoma receiving opening and which connects the first and second walls together, which first weld portion extends away from a periphery of the appliance and downwardly towards a bottom of the appliance; and

a second weld portion positioned on an opposite side of the appliance to the first weld portion below the stoma-receiving opening and which connects the first and second walls together, which second weld portion extends away from a periphery of the appliance and downwardly towards a bottom of the appliance."

56. Claims 18-20 are as follows:

"18. An ostomy appliance according to any preceding claim including a plurality of said first weld portions and a plurality of said second weld portions.

19. An ostomy appliance according to claim 18 including upper and lower first weld portions one positioned above the other, and upper and lower second weld portions one positioned above the other.

20. An ostomy appliance according to claim 19 wherein the upper first weld portion is a different shape from a lower first weld portion, and wherein the upper second weld portion is a different shape from a lower second weld portion."

57. Claims 6 and 9 cover appliances with weld portions which terminate in a "free end". Claim 12 covers appliances of any earlier claim in which a weld portion is connected to the periphery of the appliance.

Construction

58. Each of the claims alleged to be infringed requires a "weld portion" which "extends away from a periphery of the appliance… downwardly towards a bottom of the appliance".

59. The "weld portion" is a weld that connects the front of the bag to the back. The requirement that the weld "extends away from a periphery of the appliance" means that it is either part of or additional to the peripheral connection between the front and back of the bag. It may form part of the peripheral connection as shown in Figure 1 of the Patent or be separate.

60. The phrase "extends downwardly towards a bottom of the appliance" means that the weld points down towards the bottom of the bag. The weld portions shown in the figures of the Patent all point downwards in that way.

61. Salts submit that all the Patent requires is that the welds must slope downwards in a direction that is between the horizontal and the vertical. For example, it does not matter if the periphery of the bag itself simply changes direction to achieve that effect if the result is that the waste is still directed downwards. I disagree. The description requires the weld portion - which is different from the periphery - to have a downward direction, examples of which are shown in the figures. There is also an aspect of the invention in which the welds are not required to extend downwards but are placed substantially midway down the cavity.

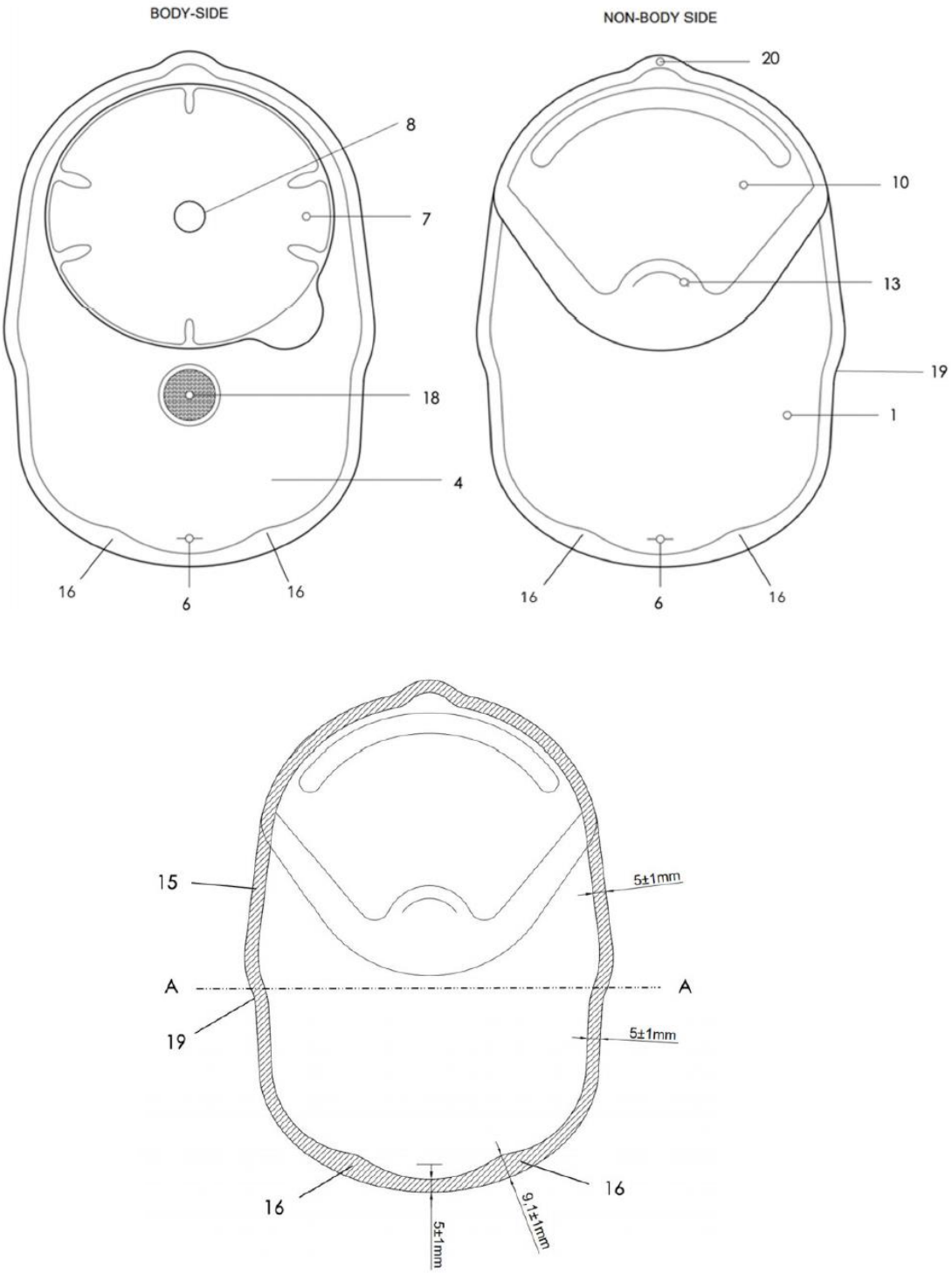
62. The phrase "below the stoma receiving opening" in claim 8 is for these purposes self-explanatory.

Infringement

63. Salts allege that the ModaVi bag infringes the Patent and a range of evidence shows this. That includes the PPD, publications by Pelican and experiments. The particular elements that make the bag infringing are the 'waist' and 'lobes' described below. I was also invited to inspect samples of the Pelican and Salts' products. The videos produced as part of the experiments showed how bags may perform in use (although not all the aspect of the experiments were agreed).

PPD

64. The PPD contains the following numbered images of the ModaVi bag, showing the peripheral weld (15), the waist (19) and the lobes (16).



65. The PPD addresses the lobes as follows:

> "2.5.3 The lobe sections (16) of the peripheral weld (15) each have a convex waveform shape extending inwardly and upwardly away from the lower edge of the pouch to respective apices. The thickness of the peripheral weld (15) increases to 9mm at the apex of each lobe section (16). The thickness of the peripheral weld (15) returns to the nominal width of 5mm in the region between the lobe sections (16).

2.5.4 The lobe sections (16) are known to control the folding or "kinking" of the lower edge of the pouch as it fills. The edge seam of the lower part of the pouch can kink irregularly as the pouch fills. As the seam kinks it can protrude rearwardly into contact with the user's skin. This contact can cause discomfort due to the stiffness of the seam and its relatively sharp edge. The curved shape of the lobe sections (16) is configured such that under loading the lobes kink and pull the lower edge forwardly (i.e. away from the patient's body) to avoid contact with the skin. This is the only known effect of the lobe sections.

2.5.5 The Defendant has no information as to whether or not the lobe sections (16) understood to affect 'bulging', 'sagging' or how the force acting on the appliance as a result of the waste is distributed along the longitudinal axis of the appliance."

66. The PPD addresses the waist as follows:

"2.7.1 The Pelican ModaVi® pouch is foldable to allow the user to reduce the overall length of the pouch for discretion.

2.7.2 A fold line A-A is defined at the waist (19) of the pouch (1), and a Velcro® tab (18) is located, immediately below the fold line, beneath the baseplate (7). The pouch is folded upwardly and forwardly about the fold line A-A …

2.7.3 The outward taper of the pouch (1) above the waist (19) increases the width of the upper part of the bag above the fold line A-A. The width of the lower part of the pouch (1) is reduced such that the section of the pouch (1) below the fold line A-A is narrower than the section of the pouch (1) immediately above the fold line. Consequently, when the lower section of the pouch (1) is folded upwardly about the fold line A-A the peripheral edge of the lower section sits inwardly of the peripheral edge of the upper section of the pouch (1). Locating the peripheral edge of the lower section of the pouch (1) inboard of the peripheral edge of the upper section prevents the hard or sharp edge of the lower section from contacting the user's skin when the pouch (1) is folded, thereby improving comfort and preventing irritation.

2.7.4 The waist (19) facilitates the comfortable folding of the pouch (1), as shown in Figure 7. This is the only known effect of the waist. The Defendant has no information as to whether or not the waist affects 'bulging', 'sagging' or how the force acting on the appliance as a result of the waste is distributed along the length of the appliance."

67. The PPD also says that the C-shaped weld, which appears as a feature of the cover on the non-body side, between 20 and 10 in the upper right-hand image at paragraph 51 above helps the pouch hold its shape.

68. As shown in Figure 6, the bag peripheral weld increases to around 9mm deep at two portions near the bottom of the bag. Figure 6 also illustrates that the bag may be folded at line A-A. When folded in use the bottom points up and this portion sits 'inside' the perimeter of the upper half. Pelican say that this avoids a sharp edge that would be formed if the peripheral weld continued down to create an oval as seen, e.g. in Figure 1 of the Patent. The folded bag is shown in Figure 7

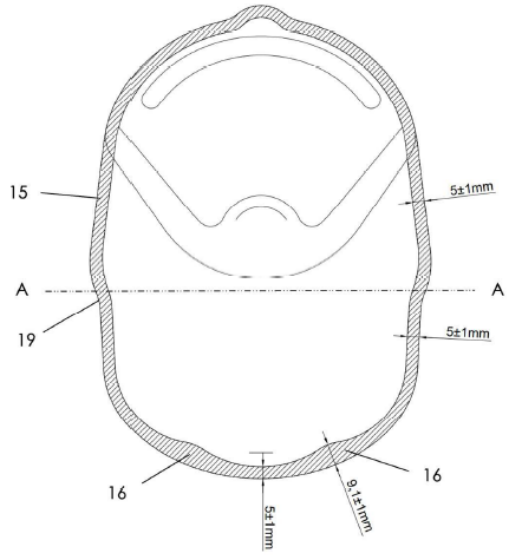


Figure 6 – Pelican ModaVi® Peripheral Weld

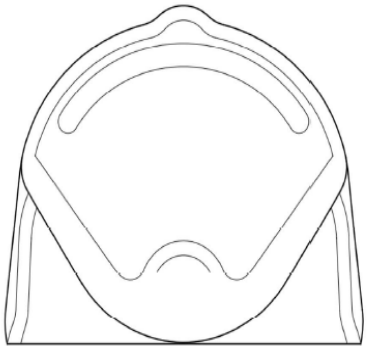


Figure 7 – Pelican ModaVi® Closed Pouch in folded configuration

Expert evidence

69. Mr Brie said this in his first report:

> "…the essence of the invention described in the Patent is to use areas of the peripheral weld to create an effect on the distribution of the contents of the bag, being to make it fill more evenly and to reduce bulging, sagging and pulling on the wafer, by ensuring that the force acting on the appliance as a result of the waste is distributed relatively evenly along the length of the appliance….
>
> The inventive concept does not require a thickening of the weld area, for example. The collecting volume of a pouch will be the same if the *internal* bag weld profile (i.e. the inner periphery of the collecting chamber) or deviations are the same. Therefore I think that it is not a part of the inventive concept whether the weld portions "extend away" from the periphery in the same way as Pelican say that their waist weld portions do not do so. As long as the weld portions create the inward change to the inner weld profile and creates the same effect on bulging, sagging and/or distribution of forces, then it does not matter whether there is actually a thickening of the weld in that area."

70. Ms Andersen said in her first report that the output is forced up the bag rather than out away from the body, in that the waste is distributed more evenly along the length of the appliance, reducing irregular bulging and achieving a flatter/more uniform profile. Further:

> "…The way the Patent works is by limiting of the volume of the bag by adding weld portions that limit the amount by which the front wall of the bag can be separated from the back wall of the bag.
>
> It is this limitation of volume that distributes waste (not force) more evenly along the length of the bag, and this reduces the visibility of the bag through clothing by reducing bulging (or preventing irregular bulging) and reducing sagging."

71. Ms Andersen accepted that solid output cannot fill right to the edges of the bag, so that the more solid the waste the higher it will sit. The collected waste will have a higher the centre of gravity and sit more centrally. A higher centre of gravity will give a more even force on the wafer and reduce pulling. It also helps to reduce "irregular" bulging.

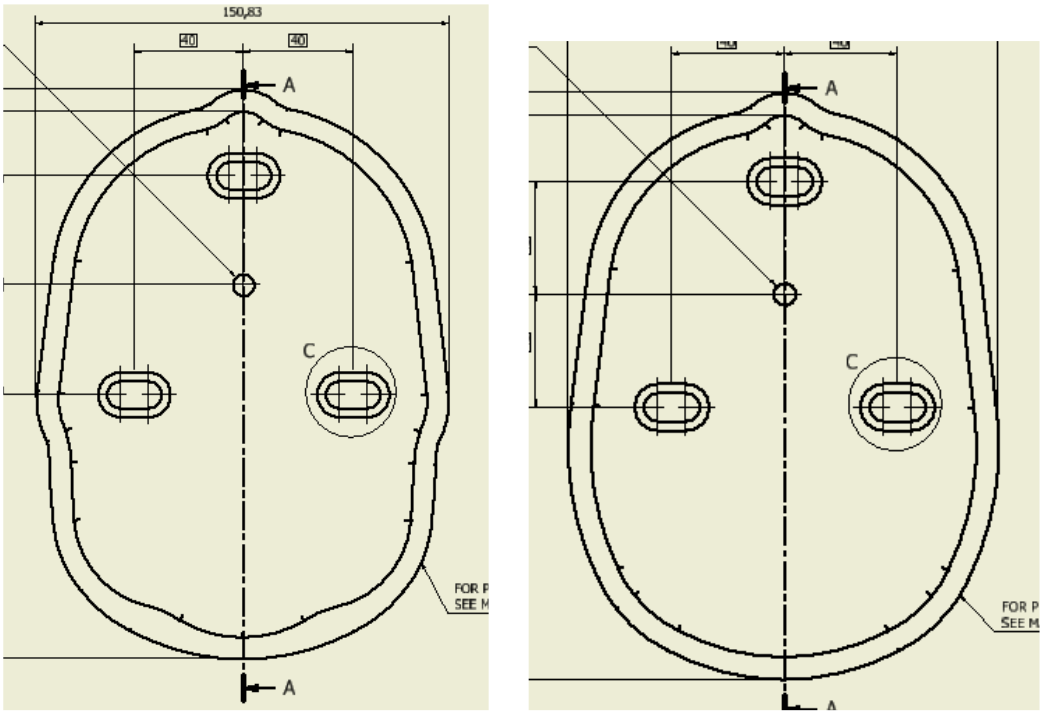
Experiments on infringement

72. Both sides carried out significant numbers of experiments. It was agreed that while there are no standard protocols for testing ostomy bags, it is conventional to fill bags with water or synthetic fill to see how they perform. The Patent contains no measurements or experimental examples against which an alleged infringement can be assessed.

73. The parties also carried out different numbers of repeats of the experiments. Nothing turns on that.

74. Both sides took photographs and Pelican produced videos of bags filling. They took different approaches to measuring the performance of the bags tested.

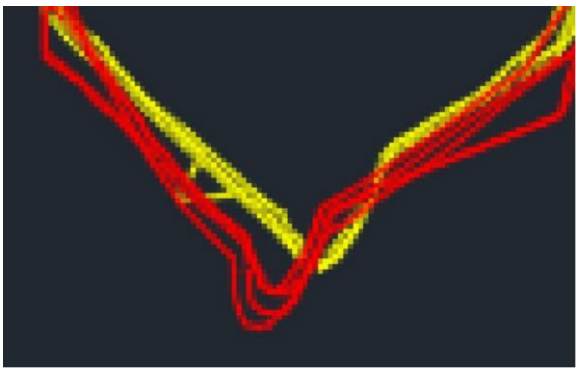
75. Salts carried out experiments on two types of bags. Both had the same basic outline as the ModaVi bag and were made of the same materials, omitting components which Salts alleged were immaterial. Salts thus omitted the C shaped weld, which Pelican say helps the pouch hold its shape. The first bag (left below) had the lobes and waist of the ModaVi bag. The second bag (right below) did not have the waist or lobes, and that was used as a control.



76. It can be seen that the right-hand bag above has a larger perimeter than the first, because the waist has been taken out. It has a greater volume than the first. When two bags are filled with an equal volume of water the fill line in the second bag would be lower than in the control.

77. In Experiment 4 Salts filled the bags with 350ml water and imaged the perimeter to show that the alleged infringement would sit lower against the body (on the left) than that with welds, as it is said the images below show.

78. When the overlay image on the right above is enlarged it can be seen that the very bottom of the bag with welds sits further forwards and that the bottom of the peripheral weld points away from the body, whereas the periphery of the bag with no welds points toward the body. Salts said that this shows that the weight and force is more evenly distributed in a longitudinal direction in the alleged infringement.



79. Ms Andersen criticised the preparation of the outlines as potentially inaccurate. In my judgment, it does show the different position of the bottom of the bag, but due to the different nature of the bags it does not clearly show whether this is significant.

80. In another set of experiments Salts filled the two types of bags with plaster to create casts. Salts says that the control shows a regular shape with a reduction in bulging and sagging. The experts agreed that preparation of such casts is not an industry standard practice. In the examples shown in Salts' notice of experiments the ModaVi bag did appear to give a more regular cast at the upper part of the bag, as shown below, but it is not clear that this is significant given the unusual material used.

81. Pelican carried out experiments on a wide range of products including the Salts Confidence Be (which they allege is representative of the Patent); a similar model without the welds of the Patent; the ModaVi and versions of that bag without lobes ("Mod A"), waist ("Mod B") and without both ("Mod C"). The bags are shown filled in the images below taken from Pelican's Notice of Experiments.

Pelican ModaVi
2.1-2

Salts Confidence
Be 2.2-1

(vi) Pelican ModaVi
2.1-2

(vii) Pelican ModaVi
Prototype 2.20-1

(viii) Pelican ModaVi Mod.
A

(ix) Pelican ModaVi Mod. B
2.11-1

(x) Pelican ModaVi Mod. C
2.12-1

Pelican ModaVi 2.1-2

(vii) Pelican ModaVi Prototype 2.20-1

(viii) Pelican ModaVi Mod. A 2.10-1

(ix) Pelican ModaVi Mod. B 2.11-1

(x) Pelican ModaVi Mod. C 2.12-1

82. Pelican also carried out experiments on other commercial bags made by Convatec and Hollister (competitors in this field), alleged to represent the prior art.

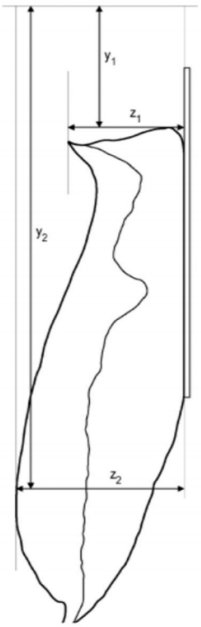
83. Pelican filled its bags to 75% volume and made various measurements shown in the diagram below of the how various parts of the bag moved when filled. Ms Andersen had not seen this before but found it useful in making comparisons in a field in which workers tend to rely on visual assessment of how a bag fills. Salts did not use this method and were critical of it.

y1 is the vertical displacement downwards of the upper edge of the ostomy bag compared to its starting position prior to filling.

z1 is the distance of protrusion of the upper edge of the ostomy bag measured perpendicular to the base plate affixed to the test rig.

y2 is the vertical distance of the z2 point below the starting position of the upper edge of the ostomy bag.

z2 is the maximum distance of protrusion of the ostomy bag measured perpendicular to the base plate affixed to the rig.



84. The experts were largely in agreement about what the experiments shows about the effect of the peripheral welds, waist and lobes on the various bags.

85. Ms Andersen said that the weld portions of the Patent: (i) reduce the available volume of the bag and in use create folds that further reduce volume; (ii) reduce irregular building and sagging by limiting the distance between the front and back films; and (iii) force the waste up (towards the wafer) rather than out (away from the body). She also said that the weld portions reduce shearing between the front and back films, which reduces sagging. The reduction was due to that rather than the channelling of the waste. The centre of gravity of the bag was closer to the body which reduced pulling on the wafer.

86. Ms Andersen said that the C-weld reduced sagging and Mr Brie agreed that the top of the bag stuck out further without such a structure.

87. Ms Andersen did not see a difference between the plaster moulds resulting from the two bag shapes. She thought the sagging was around the same in both and that the bulging was similar, possibly greater in the bag with lobes. That would reflect the waste there being pushed upwards.

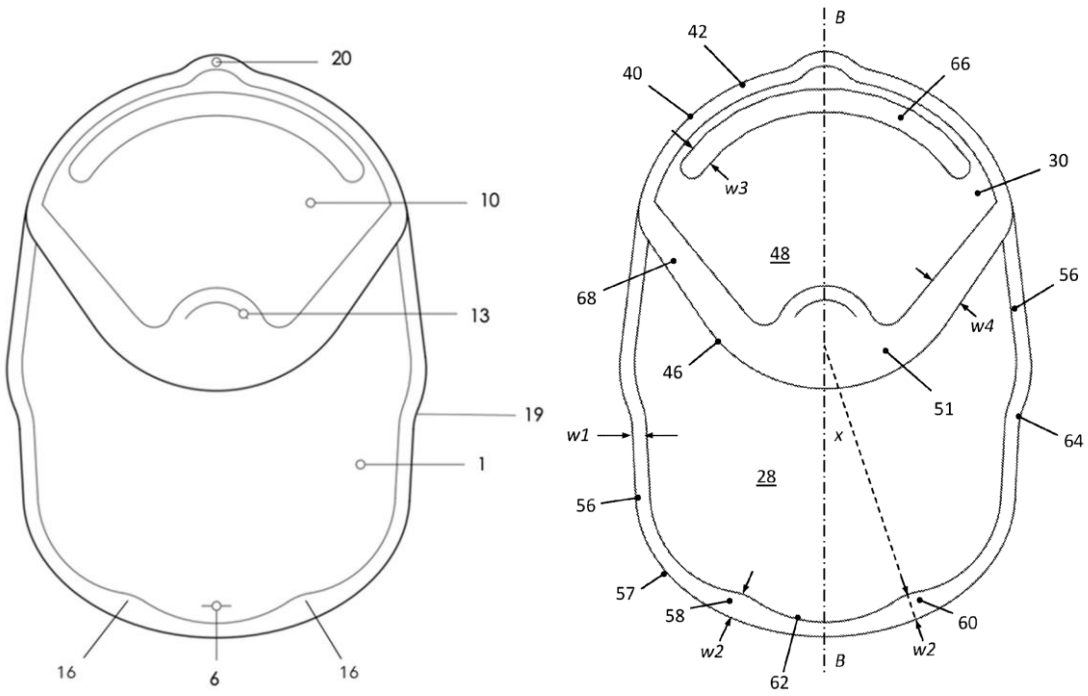
88. Mr Brie agreed that the weld portions caused pinching folds as the bag filled, and that the folds halfway up the ModaVi bag are caused by the attachments to the base plate. He also agreed that the kinks at the 5- and 7 o'clock positions on the ModaVi bag are caused by the lobes.

89. In my view, while the experiments were helpful to demonstrate the behaviour of the bags in practice, none of them was decisive on the issue of infringement. They confirmed what Ms Andersen said about the presence of weld portions leading to a reduction in volume and waste being placed more centrally. It is hard to draw conclusions as to the significance of any of these measurements and observations in the context of the Patent because it gives no guidance as to what is significant in achieving the invention disclosed.

Other documents

90. Salts say that there are two publications that show how the ModaVi bag works. These are Eakin and a launch presentation used at Pelican.

91. Eakin contains similar diagrams to those in the PPD:



92. Eakin describes the peripheral bond as follows:

> "[0058] The peripheral bonding region 56 extending around the periphery of the pouch 1 is formed having a first width w1. The width w1 is selected to ensure a robust bond and seal between the layers forming the pouch 1. The bonding region 56 includes first and second strengthening zones 58 located at the lower end of the pouch 1 along the curved lower edge 57. The strengthening regions 58 comprise lobes formed by undulations in the bonding region 56 whereby the width of the bonding region is locally increased to a width w2, greater than width w1. As such, the pouch 1 is locally stiffened and reinforced in the region of the strengthening zones 58. The strengthening zones 58 are symmetrically spaced on opposing sides of the longitudinal centreline B-B of the pouch. The strengthening zones 58 are arranged along the curved lower edge at an angle x to the centreline B-B, which is preferably between 10 and 40 degrees and more preferably between 15 and 30 degrees. The strengthening zones 58 only increase in width in the inward direction, that is to say inwardly towards the collection volume of the collecting bag. As such, the outer peripheral edge of the bonding region 56 maintains the curved form of the pouch 1 at the strengthening zones 58. At the inner edge of the bonding region 56, the strengthening zones 58 symmetrically curve gradually inwards from the width w1 to a curved peak defining the maximum width and then curve back outwards to the width w1. The strengthening zones therefore have an undulating, wave-like form and face substantially upwardly away from the lower end of the bag towards the upper end. A concavely curved 'valley' or 'bowl' region 62 is formed between the two convex strengthening zones 58."

93. The "strengthening zones" and waist are described:

> "[0059] In use, as the collecting bag 2 fills, the strengthening zones 58 provide increased stiffness to the lower edge 57, helping it to maintain its form and resist buckling. As the collecting bag 2 continues to fill, the contents are channelled to the centre by the concave valley region 62 formed by the strengthening zones 58. As such, the centre of mass of the load is maintained along the centreline B-B,

> which prevents uneven distribution of the load across the mounting plate 8. As the collecting bag 2 fills further, the inwardly curved form of the strengthening zones 58 causes the seam defined by the bonding region 56 to kink forwardly, away from the wearer, thereby preventing uncomfortable contact with the stiff seam. The lower end of the pouch 1 is also narrower than the upper end of the pouch 1, with a narrowed waist section 64 being defined at the transition between upper end lower ends. The waist section 64 pinches inwards as the collecting bag 2 fills, further assisting in channelling the contents to the centre of the collecting bag 2."

94. Salts say that this shows that the waist and lobes direct the content towards the centre of the bag so as to prevent uneven distribution of the load across the mounting plate. What this does not say in terms is that bulging and sagging are reduced.

95. Pelican say that Eakin is irrelevant and the that the primary source of evidence about the ModaVi bag is the PPD. Eakin is not a description of the ModaVi bag but of the invention claimed in that application.

96. I accept that Eakin is relevant and makes claims for the effect of the lobes and waist. On their own, however, these claims do not show infringement.

97. The second document on which Salts relies is a launch presentation used at Pelican. There was a dispute earlier in the proceedings whether this was confidential. I proceed on the basis that if it was confidential at the time it was delivered then the parts to which I refer below are no longer confidential.

98. The presentation states that users wanted a pouch that filled evenly and did not bulge or sag. The new bag has a patent protected smart lobe which provides "even more structure to the pouch" so that the bag does not bulge. There is a simplified image that shows the shape of the bag with the waist, lobes and C-weld identified.

99. As with Eakin, this presentation is not decisive as to how the ModaVi bag works in practice.

100. Salts also relied on an article entitled "Not a bag for life... a bag for living", published in the British Journal of Nursing on 24 March 2022. This was said to contain disclosures similar to the launch presentation. It was not discussed at trial and I proceed on the basis that it does not disclose anything further of relevance here.

The law

101. The law on infringement on a normal interpretation of the claims is described in *Terrell*, 20th Edn. at 9.14-9.37. The claims are considered purposively and not literally.

102. The principles of infringement by equivalents are set out in the decision of the Supreme Court in *Actavis v Lilly* [2017] UKSC 48:

> "(i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?
>
> (ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

(iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was 'yes' and that the answer to the third question was 'no'."

103. In *Icescape Ltd v Ice-World International BV* [2019] FSR 5. Lord Kitchin explained that:

> "The first *Improver* question, whether the variant has a material effect on the way the invention works, was addressed by Lord Neuberger [in *Actavis*] at [60]. He thought this was generally satisfactory but the court must focus on "the problem underlying the invention", "the inventive core", or the "inventive concept". In effect the question is whether the variant achieves the same result in substantially the same way as the invention."

The inventive concept of the Patent

104. Salts submits that the inventive concept of the Patent is this:

> "The inventive concept of the claims of the Patent as granted is the use of weld portions forming part of the peripheral weld in an ostomy appliance (of the type specified in each of the claims asserted), such as an ostomy pouch, in preventing bulging and/or sagging of the appliance during use when it contains waste and/or ensuring that the force acting on the appliance as a result of the waste is distributed relatively evenly along the length of the appliance."

105. Pelican says this:

> "More specifically, the inventive concept includes (at least) the following, both individually and in combination: (i) that the weld portions extend away from the periphery…; (ii) that the weld portions extend downwardly…(iii) that the weld portion extensions achieving achieve anti-bulge functionality…; (iv) insofar as it is any different from anti-bulge functionality, that the weld portion extensions achieve anti-sag functionality; and (v) insofar as it is any different from anti-bulge functionality, that the weld portion extensions ensure that the force acting on the appliance as a result of the waste is distributed relatively evenly along the length of the appliance.…"

I have removed from this quotation Pelican's assertions that the ModaVi bag does not have these features.

106. The invention of the Patent relates in particular to "closed ostomy appliances" (page 1, line 9). The problem which the Patent addresses is outward bulging of an ostomy device and a tendency to pull at the top of the wafer (page 1, lines 11-17). The Patent addresses these problems through a series of appliances. The description discloses ten devices, each of which has a "weld portion" which "extends away" from the periphery.

107. In the first, third, fourth and seventh appliances the weld portions extend "downwardly" towards the bottom of the bag. In the second appliance the first and second weld portions are "positioned substantially midway between a top and a bottom of the waste

collecting cavity". In the fifth, eighth and ninth appliances the weld terminates in a "free end". In the sixth appliance the top and bottom edge of the welds are "generally parallel". The tenth appliance may take features from the others.

108. Each of the 32 claims is to an appliance, and ten of them are independent. Some claims are for a colostomy appliances and others for colostomy or ileostomy appliances, and some are for "drainable ostomy" appliances.

109. As I have said, the performance of all these appliances is relative to some unspecified version of a bag. This makes the concept hard to distil.

110. In my view the inventive concept is an ostomy appliance that has weld portions additional to the periphery of the appliance which are placed so as to minimise bulging outwards or downwards or pulling at the wafer as the bag fills in use. The welds are additional to the periphery. The inventive concept is not simply a bag of a different shape.

111. The Patent does not disclose any principle or method to address the problems it identifies. Instead, the Patent discloses a series of particular appliances that employ welds additional to the periphery.

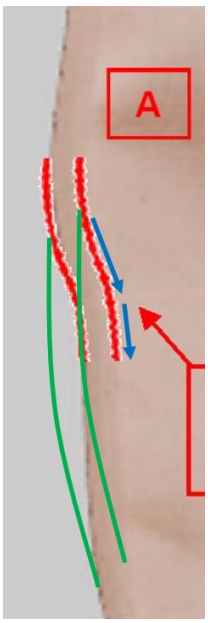
Discussion

112. Each of claim 5, 8 and 20 includes a weld portion that "extends away from the periphery of the appliance and downwardly towards the bottom of the appliance". The dispute on infringement turns on this phrase. Salts argue the point both on a normal, purposive construction and on the basis of equivalents.

113. The parties made separate submissions about the waist and lobes of the ModaVi bag. The claims cover an "appliance" and it is necessary to consider the alleged infringement as a whole.

Normal infringement

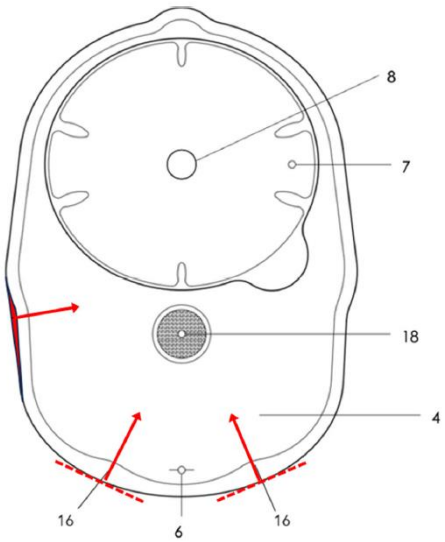
114. Salts argue that the ModaVi bag has weld portions as claimed. Salts say that the change in the direction of the peripheral weld (at 19 in the figure in paragraph 51 above) is in effect a weld portion. The diagram below taken from Mr Brie's expert report illustrates this. The change in direction of the weld is shown in red; the direction it would have taken but for that change is in green; and the blue arrows indicate that there is an inwards slope what points downwardly towards the bottom of the bag:



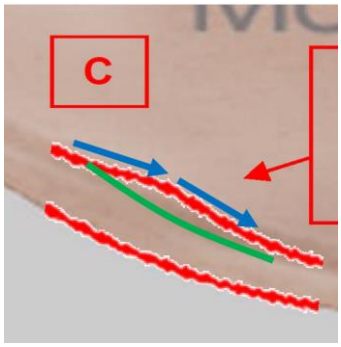
115. Salts argue that it is sufficient that the periphery extends inwardly and downwardly (as shown in blue) compared to the line which shows (in green) where the peripheral weld would otherwise have continued but for the Pelican design.

116. I do not accept this. Each of claims 5 and 8 requires a weld portion that extends away from the periphery of the appliance. That is the actual periphery of the bag and not a hypothetical one. The purpose of the welds is to create a space within the periphery of the bag that channels the waste and also makes the bag narrower than it would be without the welds. The Patent does not claim a specific aspect ratio for a bag or a particularly narrow bag.

117. Further, I am not persuaded that if the waist is a weld portion that it extends downwards toward the bottom of the bag. Pelican's argument as to why not is as shown by the red arrow in this diagram in Ms Andersen's report.



118. Salts further argue that the lobes extend inward of the periphery of the ModaVi bag and so extend away from a periphery of the appliance. I agree. The direction of the slope of the lobes is illustrated by the annotated diagram provided in Mr Brie's expert report.



119. Salts say that the lobes extend downwardly towards the bottom of the appliance as required by the claim. That direction is shown by the blue arrows on the diagram above. I do not accept that. In the context of the Patent "downwardly" indicates that it is the weld portion that extends downwardly and not slope or the flow over it, as illustrated in the Figures showing welds. See also the diagram above from Ms Andersen's report. The reading for which Salts contends would require me to ignore the word "downwardly" in the claims or to give it a different meaning which the context does not bear. Further, the lobes are at the bottom of the bag, as the various photographs from the experiments show.

120. The ModaVi bag does not have the weld portions of claims 5, 8 or 20 of the Patent and there is no infringement on a normal, purposive construction.

Infringement by equivalents

121. Salts also allege infringement by equivalents. The first *Actavis* question is whether the lobes and waist portions of the ModaVi bag achieve substantially the same result in the substantially the same way as the inventive concept of the Patent. It is the bag that is alleged to infringe and that contains both a waist and lobes. I will consider the waist and lobes both separately and together.

122. I have found that the inventive concept is an ostomy appliance that has weld portions additional to the periphery of the appliance which are placed so as to minimise bulging outwards or downwards or pulling at the wafer as the bag fills in use. The welds are additional to the periphery.

123. The answer in respect of the waist of the ModaVi bag is 'no' because it does not appear that the waist achieves the result by limiting within the periphery the space available to fill with waste. The experimental results shown above do not in my view show that the waist minimises bulging outwards or downwards or pulling at the wafer as the bag fills in use. Removing the waist does not appear to affect the deformation of the bag - see the pictures in paragraph 81 above. Ms Andersen said that the measurements taken of these various bags also supported that, but it is not clear to me that these are significant. The visual assessment, which I accept is the usual way the skilled worker approaches matters in this field, appears to give a good answer.

124. The weld portions of the Patent create horizontal folds across the front of the bag and cause the peripheral weld on the sides of the bag to pinch inwards.

125. The question with respect to the lobes of the ModaVi bag is not easy to determine from the experiments. The lobes do appear to have some impact on the way the bag expands and holds its shape, although the effect on bulging appears small – there does appear to be some more regularity in Pelican's experimental Mod B bag with lobes as compared with the bags without, and it appears clear that the lobes do have the effect of making the peripheral weld point away from the body. That is in line with the description in Eakin.

126. The inventive concept is an ostomy appliance that has weld portions additional to the periphery of the appliance which are placed so as to minimise bulging outwards or downwards or pulling at the wafer as the bag fills in use. The lobes extend inward of the periphery of the ModaVi bag and away from a periphery of the appliance. While they do not extend downwards, the experiments and Eakin show that they do affect the shape of the bag so as to minimise bulging outwards or downwards or pulling at the wafer as the bag fills in use. The answer is for the lobes is 'yes'.

127. As the alleged infringement is a bag with both waist and lobes, for the further questions the answer to the first question for the bag as a whole is 'yes'.

128. The second question asks whether it would be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention. In this case, the answer is 'yes'. The invention limits the portion of the bag that can be filled and that can be achieved in a number of ways.

129. The third question asks whether such a reader of the patent would have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention? In this case the answer is 'yes' for the bag as a whole and for the waist and the lobes considered separately. The invention can be achieved in a number of ways, for example, as Salts put it in closing, by making a narrower bag. In this case the patentee has chosen a particular way in which to achieve the intended effect and has limited the claims to the specific structures claimed. The Patent describes a set of appliances that have particular features. It would, for example, have been straightforward for the patentee to formulate a claim by result or to a 'narrower' bag or to omit the word 'downwardly', but none of the asserted claims does that. The claims are limited to appliances with the particular structures claimed and strict compliance is intended.

130. The ModaVi bag does not infringe claims 5, 8 or 20 of the Patent.

Validity – Novelty and Inventive Step

131. Pelican relied on four publications to attack validity. There was no dispute as to the applicable law on novelty or inventive step. The parties agreed that the test for obviousness is set out in *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588. Pelican also invited me in some cases simply to say that the Patent was obvious in the light of the prior disclosure; I have used the *Pozzoli* test.

132. Salts submitted that Pelican's approach relied on too many citations and that this was a case where that indicated they could not find one that worked. They relied on *Terrell*, 20th Edn. 10-17 to 10-18. This is not such a case. A number of the citations were relied on for inventive step and/or as part of a squeeze on infringement. Had Salts prevailed

on infringement it can be seen why Pelican would have found squeeze arguments attractive.

Grum-Schwensen

133. Grum-Schwensen discloses a drainable ostomy pouch with a particular fastener for the drainage outlet which folds up to provide closure. Figure 1 shows a general view of the bag and Figure 2 a cross section of the outlet.

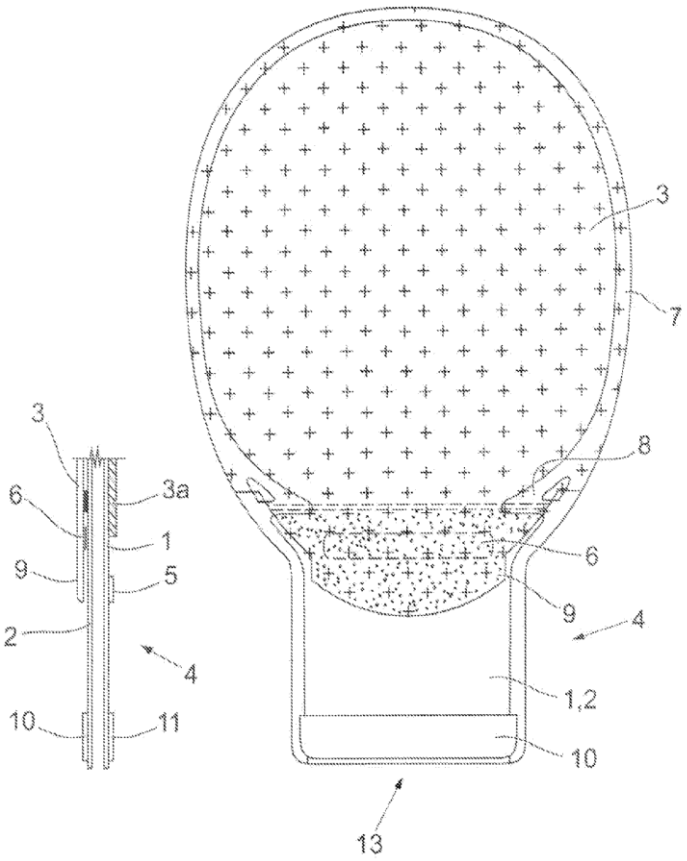


Fig. 2 Fig. 1

134. Figure 9 shows a plan of the drainable pouch from the body side, and figure 10 shows a closed bag with a similar off-centre starter hole 17.

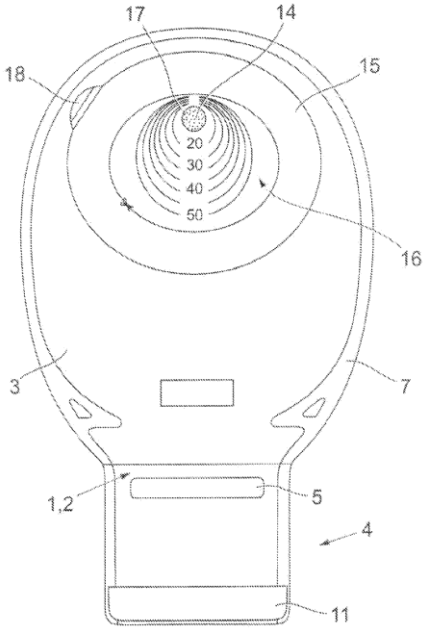


Fig. 9

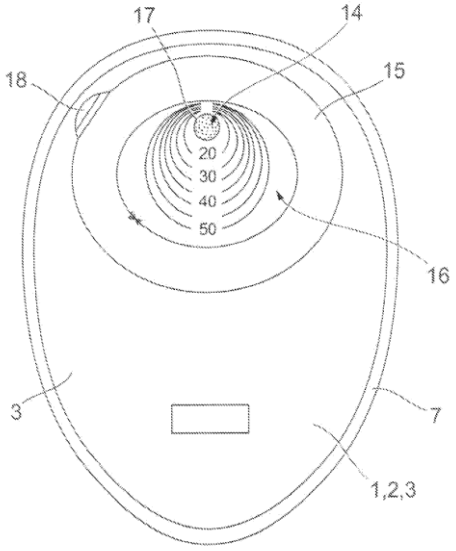


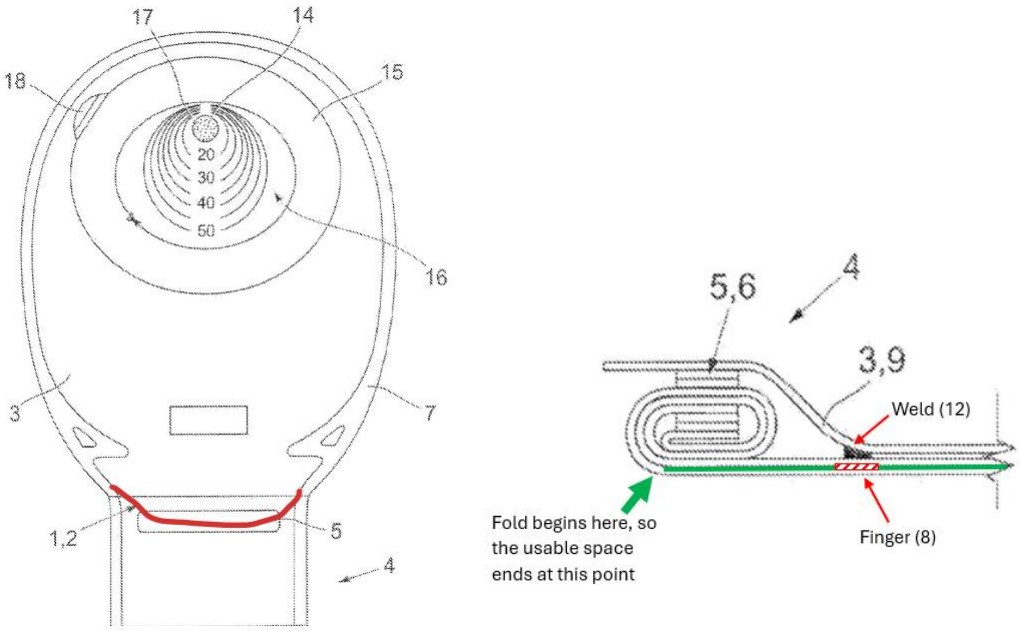
Fig. 10

135. The design includes "inwardly protruding welding portions 8 [which] define the passage between the cavity of the pouch and the outlet section of the pouch" [0023]. These are numbered in Fig. 1 and seen more clearly in Fig. 9.

136. Pelican argue that the design of the drainable bag anticipates claim 8 of the Patent which is for a colostomy bag. Salts say that (i) the disclosure is only of an ileostomy bag for liquid waste and (ii) there are no weld portions that extend away from the periphery and downwardly towards the bottom of the appliance. Salts say that the portions [8] are "merely a continuation of the periphery" and form the bottom of the bag when it is closed. Further, they do not perform the same function as the as the weld portions of the Patent.

137. As to the first argument, Grum-Schwensen uses only the term "ostomy" (and not "colostomy" or "ileostomy") and it does not describe the type of waste for which the bag may be used. Ms Andersen said that the skilled worker would understand that colostomy bags could be closed or drainable and that this bag could be used by colostomates. Mr Brie described the bag as "most suitable" for ileostomates. I accept Ms Andersen's view.

138. The experts disagreed over where the bottom of the bag would be when the drain was folded up. Ms Andersen said that when the drain was folded waste would still enter the top of the fold and move down to the point at which the two sides of the bag were held directly together. Mr Brie said that the closure would form at the level of the weld portions. Having heard the experts, I prefer Ms Andersen's explanation, which she illustrated in her reports as shown below on the left (second report) and further in the diagram on the right (first report) in which the finger is shown in red. The waste would collect below the weld portions when the bag was closed. That forms the bottom of the bag for these purposes.



139. I do not accept Salts' second argument that the weld portions are a continuation of the periphery. It ignores the description in paragraph [0023] and is contrary to the position that Salts take on infringement. The projections are clearly additional to the periphery of the bag and extend away from the periphery and downwardly toward the bottom of the bag, as shown in the diagram above. The Patent does not describe the function of the welds or seek to put any limitation on how they work.

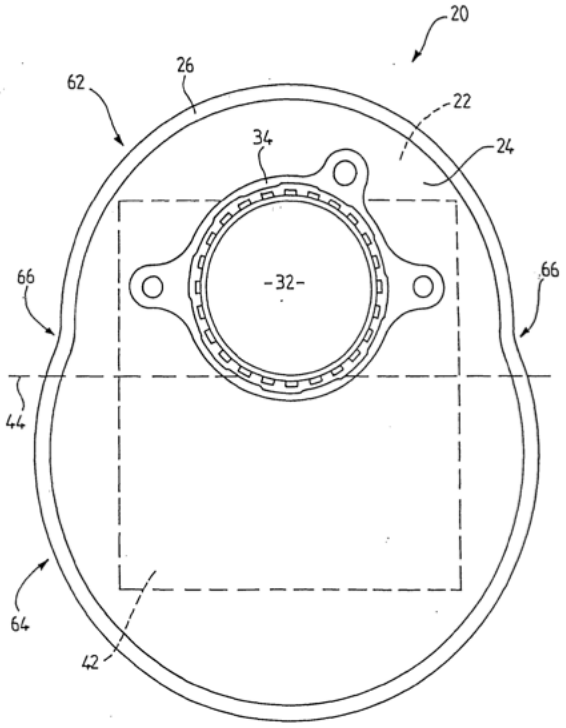
140. It follows that Grum-Schwensen anticipates claim 8 of the Patent. It does not anticipate claims 5 or 20 because there is only disclosure of a single set of weld portions, and not two, as required by those claims.

141. Pelican argue that claims 5 and 20 of the Patent are obvious over Grum-Schwensen. In my view they are not. Applying the ***Pozzoli*** test it would not be obvious to add a second pair of weld portions to the structure. There is only one set of welds in Grum-Schwensen and they assist with channelling the waste downwards toward the drain. They are not placed so as to minimise bulging outwards or downwards or pulling at the wafer as the bag fills in use as required by the inventive concept of the Patent. It would not be obvious to add a second of welds set higher up the bag without any knowledge of the alleged invention as claimed.

Falconer

142. At trial Pelican did not pursue its pleaded novelty attack and argued only inventive step. Pelican also said that the case on Falconer was primarily a squeeze against Salts' argument that the waist in the ModaVi bag are additional weld portions that extend away and downwardly. Figure of eight bags are also agreed to be part of the CGK.

143. Falconer discloses "a pouch for collecting matter excreted by the body, in particular excreted liquid". The bag as shown in Figure 2, below, is closed and is not able to release gas. That indicates that it is intended to collect liquid, because solid waste will have gas associated with it.



144. The pouch contains an absorbent pad, shown above by the dotted line, directed to absorbing urine. For the purposes of this claim, the important feature of the design is the figure of eight design. Pelican note that the abstract of Falconer says that the design has "a waist (66) which helps to control bulging of the pouch, and help (sic) keep the pouch flat for an optimum wicking effect [by the pad]".

145. Falconer says that the embodiment described is intended as "a disposable, short duration urostomy pouch" which is "a little smaller than usual" [0058]. However, "the same principles may be used to improve the characteristics of larger pouches for any suitable use" [0059].

146. Falconer notes at [0025] that in the prior art it is known to control bulging by use of spot welds (which connect the front film to the back) to create a "quilted arrangement", but these are known to create high stresses in the pouch and they sometimes fail.

147. Falconer is directed to the collection of liquid waste and while that might include some use in ileostomy in my view that does not extend to colostomy.

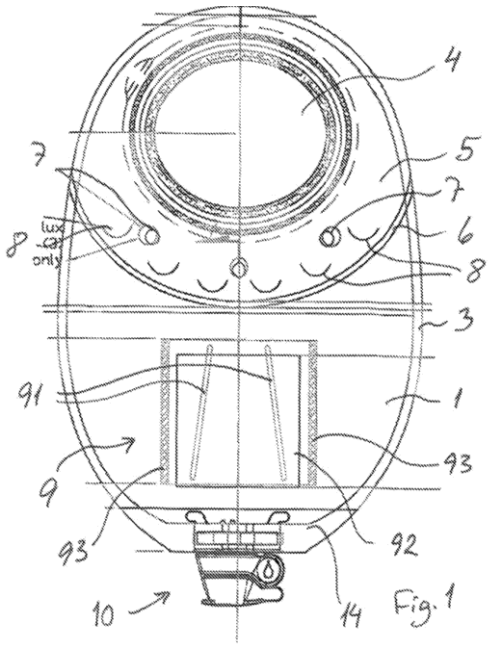
148. The waist of this bag is not a weld portion that extends away from the periphery of the appliance and it does not extend downwardly. It is the periphery of the bag itself that changes direction. The waist is placed relatively close to the stoma and does not appear to restrict the filling of a bag in the way that the weld portions of the Patent do.

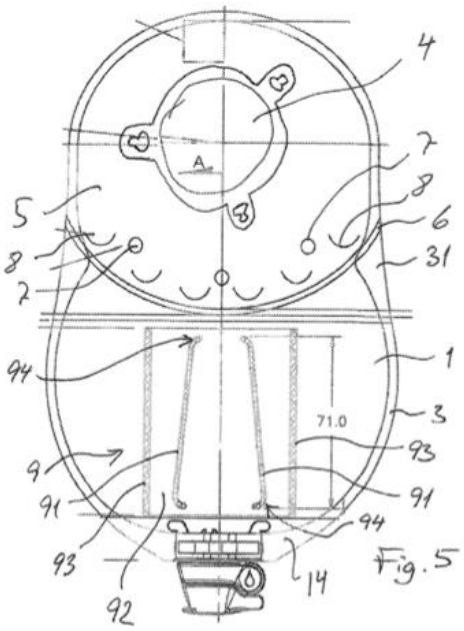
149. Applying the ***Pozzoli*** test the claims are not obvious in the light of Falconer. Assuming for these purposes the bag was useful in ileostomy, it would not be obvious to add one or two sets of weld portions to the bag without any knowledge of the alleged invention as claimed. The inventive concept requires weld portions additional to the periphery of the appliance which are placed so as to minimise bulging outwards or downwards or pulling at the wafer as the bag fills in use. It would not be obvious to make weld portions instead of the waist. There is little in Falconer in this regard that extends beyond the CGK of figure of 8 bags.

Hannan

150. Hannan is entitled "Pouch for collecting liquid excretions". Pelican rely on Hannan for inventive step only, there is no novelty attack.

151. The disclosure includes a non-return valve between the top and bottom sections of the bag. These are used to prevent liquid waste from flowing back into the stoma. A number of embodiments are disclosed including Figures 1 and 5 shown below.





152. The design in Figure 1 includes an anti-reflux film [5] and spot welds at [7] to join the wall of the bag to the film. The film covers the opening [4]. A lower seal [6] divides the bag into two chambers.

153. Figure 5 is said to have a "relative flat configuration" in use. This embodiment has what Pelican describe as "lobes" at [31] in Figure 5. Hannan says at [0028]:

> "However, since this [the different anti-reflux valve] may involve the risk that the pouch bulges when being filled with liquid whereby the pouch may become more visible on the user, the peripheral seal 3 may be provided with inwardly protruding widened heat seal portions 31 to ensure a relative flat configuration of the pouch when being filled during use."

154. Salts says that the disclosure is limited to urostomy bags. Pelican says that the bags can be used in very effluent ileostomy cases. In my view the design is intended to deal with liquid output. To the extent that it covers ileostomy cases it would only be those with particularly liquid output.

155. It appears that the lobes at [31] are intended to provide some effect to reduce bulging. They are additional to the periphery of the bag and extend downwardly. Ms Andersen explained in her first expert report that the purpose of the lobes is to limit the volume

higher up the bag. The baffle takes up room and limits the potential volume of the bottom of the bag, which means that there is a risk that the top of the bag will be over-filled.

156. In cross-examination Mr Brie accepted that the Figure 5 bag has a figure of eight shape.

157. In my view applying ***Pozzoli*** the Patent is not obvious in the light of Hannan. The lobes in Hannan are intended to address a problem of overfilling with liquid at the top of the bag. The weld portions of the Patent are directed to issues towards the bottom of the bag and how it fills there. There are significant differences between Hannan and the inventive concept of the Patent. First, claims 5, 8 and 20 are directed to "colostomy or ileostomy" and "colostomy" appliances. These deal with more solid waste than Hannan. Second, the inventive concept of the Patent is to minimise bulging outwards or downwards or pulling at the wafer as the bag fills in use. That is different to dealing with overfilling with liquid at the top of the bag.

158. It would not in my view be obvious to the skilled reader to apply the teaching of Hannan to colostomy or ileostomy appliances.

Wheaton

159. Pelican rely on Wheaton only for inventive step.

160. Wheaton discloses an ostomy pouch suitable for the collection of liquid or semi-liquid waste. The patent identifies a problem with prior art bags is that they can expand outward to create an obvious bulge. The invention is a bag made with spot welds, shown as [22] on the diagram below. These join the front to the back of the bag and limit its capacity to expand. The bag also includes a fold at the periphery that can expand outwardly, so that the volume of the bag increases.

161. A plan of the bag is shown in Figure 1:

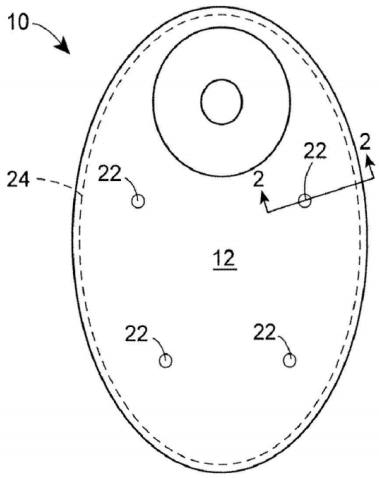


FIG. 1

162. The operation of the periphery can be seen from the sections in Figures 2 and 3, shown below. The spot welds [22] can be seen holding the two sides of the bag together.

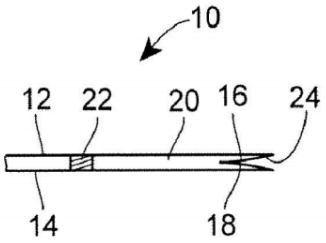


FIG. 2

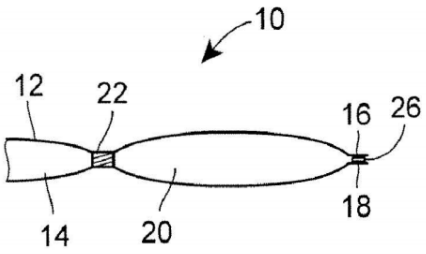


FIG. 3

163. It is clear that the spot welds are not connected to the periphery of the bag and do not extend in any particular direction.

164. Salts argue that Wheaton is not a colostomy bag and is designed only for liquid and semi-solid waste. However, the experts appear to agree that the bag could be used for colostomy; Mr Brie accepted that the waste in both colostomy and ileostomy bags will be semi-solid.

165. The experts also agreed that the spot welds were known to cause high stresses on the bag which could cause film failure and the bag to leak. That is a significant problem. Ms Andersen suggested using oval or oblong welds would help with that.

166. While the claims of the Patent do not require the weld portions to be connected to the periphery, they must "extend away from a periphery". Mr Brie accepted that the welds could be connected to the periphery, but he maintained that this would create problems with the operation of the fold in the periphery. Ms Andersen said that this would only be a local effect, and the that welds would limit bulging.

167. Applying the ***Pozzoli*** test, claims 5, 8 and 20 of the Patent are not obvious in the light of Wheaton. The inventive concept of Patent requires weld portions additional to the periphery of the appliance which are placed so as to minimise bulging outwards or downwards or pulling at the wafer as the bag fills in use. The spot welds in Wheaton do not do this. In my view they are part of a structure that enables the action of the peripheral fold to move outward and increase the available volume. While it may have been possible to elongate the spots into oblongs or ovals, in my view the structure of Wheaton makes a point of the peripheral fold. Extending the welds to the periphery would interfere with that and would be a disincentive to do so and it would not be obvious to address bulging and pulling on the wafer in that manner.

Validity - Added Matter

168. Pelican attack claim 5 of the Patent on the grounds of added matter. They say that in the application for the Patent, the only support for claim 5 is claim 28 as filed (together with an identically worded consistory clause at page 7, line 4). Claim 28 as filed relates to "an ostomy appliance" and claim 5 of the Patent is limited to a "colostomy or ileostomy" appliance.

169. Pelican rely on *Palmaz's Patents* [1999] RPC 47 at page 71, lines 1 – 8 to say that claim 5 is for an impermissible intermediate generalisation. Claim 28 in the application set out a particular collection of features in the context of their being generally applicable to all ostomy bags. Salts now claims only the sub-class of ileostomy and colostomy bags which are said to be different from each other.

170. Salts relies on the principles set out in *European Central Bank v. Document Security Systems* [2008] EWCA Civ 192, approving the summary of Kitchin J (as he then was) at first instance. The test for added matter was explained by Aldous J (as he then was) in *Bonzel v Intervention Ltd* [1991] R.P.C. 553 at [574] and approved in *ECB*:

> "The decision as to whether there was an extension of disclosure must be made on a comparison of the two documents read through the eyes of a skilled addressee. The task of the Court is threefold:
>
> a) To ascertain through the eyes of the skilled addressee what is disclosed, both explicitly and implicitly in the application.
>
> b) To do the same in respect of the patent as granted.
>
> c) To compare the two disclosures and decide whether any subject matter relevant to the invention has been added whether by deletion or addition.
>
> The comparison is strict in the sense that subject matter will be added unless such matter is clearly and unambiguously disclosed in the application either explicitly or implicitly."

171. The application says that the field of invention is ostomy appliances and "*in particular, but not exclusively, the invention relates to closed ostomy appliances*" (page 1 lines 9-10). The application sets out various aspects of the disclosed ostomy appliances having particular features. Where such aspects are described by reference to an "*ostomy appliance*", there is no suggestion that any such features, or combinations of features, should be used with any particular categories of ostomy appliances. Some of the aspects of the invention are limited e.g. to a "*colostomy appliance*".

172. Claim 5 corresponds to the fifth aspect of the invention on page 7, lines 4-24 of the application and is for an "*ostomy appliance*".

173. So far as the Patent is concerned, the disclosure is similar and uses the term "ostomy appliance".

174. Salts says that the skilled person would understand that an ostomy appliance could generally be a urostomy, ileostomy or colostomy appliance. That is in line with the expert evidence.

175. In my view there is no added matter here. The options disclosed in the application are present in the Patent and the form of claim 5 is not objectionable.

Amendment

176. I have found that claim 8 lacks novelty in the light of Grum-Schwensen. Salts have made a conditional application to amend claims 5 and 8 Patent in the event that they are invalid to limit them to a "closed colostomy appliance". Pelican originally opposed an amendment to cure invalidity over Grum-Schwensen, but at trial dropped its opposition in respect of that citation.

177. Salts say that the basis for a closed colostomy appliance is found in the Patent at page 1, lines 9-10 and page 12, lines 26-38. The proposed amendments do not add matter because claim 8 is already limited to a colostomy appliance and the proposed amendment is a limitation of that.

178. The UK IPO has given a positive opinion as to the allowability of the amendments. There is no other objection to amendment. Claim 8 of the Patent may be amended in the manner sought.

179. The amendment has no impact on the assessment of infringement set out above. That turns on the effect of the construction of other parts of claim 8.

Conclusions

180. My conclusions are as follows:

i) The ModaVi bag does not infringe claims 5, 8 or 20 of the Patent either as granted or in the proposed amended form.

ii) Claim 8 lacks novelty in the light of Grum-Schwensen.

iii) The inventive step attacks on Claims 5 and 20 fail.

iv) Salt's application to amend claim 8 to a "closed colostomy appliance" succeeds.

v) Pelican's added matter attack on claim 5 fails.