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Claim No: HP-2019-000012

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

Rolls Building
Fetter Lane
London
EC4A 1NL

Date 18th January 2021

Before:

MR NICHOLAS CADDICK Q.C.
(sitting as a Deputy High Court Judge)

- -

B E T W E E N:

COLOPLAST A/S

Claimant

– and –

SALTS HEALTHCARE LIMITED

Defendant

- -

ANDREW LYKIARDOPOULOS Q.C. and **MAXWELL KEAY** (instructed by **Powell Gilbert LLP**)
for the Claimant
DOUGLAS CAMPBELL Q.C. and **TIM AUSTEN** (instructed by **Shakespeare Martineau LLP** for the Defendant

- -

Hearing dates: 28th, 29th, 30th September, 1st, 6th and 7th October 2020

- -

Judgment Approved by the court for handing down

Nicholas Caddick Q.C. (sitting as a Deputy High Court Judge):

1. In this action the Claimant, Coloplast A/S ("Coloplast") claims that its patent EP (UK) 2 854 723 ("the Patent") has been infringed by the Defendant, Salts Healthcare Limited ("Salts"). Salts denies infringement and counterclaims for revocation of the Patent on the bases of a lack of novelty, obviousness (lack of inventive step), insufficiency, *AgrEvo* obviousness and added matter.

Background

2. The Patent was filed on 17 May 2013 and has a priority date of 25 May 2012. It is entitled "Comfort layer for a collecting bag" but, as its claims make clear, it is limited to ostomy bags. An ostomy (or stoma) is an opening in a human body created surgically to allow the discharge of body waste (faeces or urine). An ostomy bag connects to the stoma to receive such waste. It includes a pouch made of a layer of impermeable material (the barrier film) with a flange which allows the bag to be connected to the stoma. The Patent concerns a further layer which can be added to such a bag and which is known as a comfort layer. As its name suggests, a comfort layer is intended to make wearing an ostomy bag more comfortable. I will say more about such bags later when dealing with the common general knowledge in this case.

3. In around November 2017 Salts launched its "Confidence BE" range of ostomy bags. In Coloplast's original Particulars of Infringement dated 5 April 2019, it was asserted that those bags fell within "at least claims 1, 2, 6, 7, 8, 11 and 13 of the Patent". In its amended Particulars of Infringement dated 13 March 2020, Coloplast added claims 3 and 4 to this list. However, at trial, it relied solely on claim 6 as dependent on various combinations of antecedent claims, namely:

    a. Claim 6 as dependent on claims 1, 2 and 3 ("Claim 6A");
    b. Claim 6 as dependent on claims 1, 2 and 4 ("Claim 6B");

c. Claim 6 as dependent on claims 1, 2, 3 and 4 ("Claim 6C").

4. It is common ground that these are the only claims on which Coloplast relies for the purposes of the validity of the Patent (as well as of infringement). Accordingly, if none of Claims 6A, 6B or 6C is valid, the Patent falls to be revoked. However, to the extent that any of those claims is valid, Coloplast will seek to amend the Patent to reflect that claim or claims.

5. In respect of its claim that the Patent was invalid due to a lack of novelty, Salts' counterclaim relied on the following pieces of prior art:

a. US Patent Application No. 2005/0273064, published 8 December 2005 and referred to as "**Dircks**";

b. GB Patent GB No. 2 064 333B, published 23 January 1985 and referred to as "**Watkins**";

c. PCT Application No. WO 2008/112337 A1, published 18 September 2008 and referred to as "**Willis**";

d. Salts' own ND13 ostomy bag (the "**ND13**") which had been made available to the public in the United Kingdom before the priority date of the Patent; and

e. The Novalife 915-10 ostomy bag made by Dansac Limited (the "**Dansac Novalife**") which had, again, been made available to the public in the United Kingdom before the priority date of the Patent.

6. In support of its claim that the Patent was invalid because it was obvious, Salts relied on those same pieces of prior art but also on the common general knowledge.

7. I should mention that, in other proceedings concerning the Patent, the Opposition Division of the European Patent Office ("the EPO") has rejected an added matter argument raised by Salts but has nevertheless decided that the Patent was invalid for lack of novelty over Dircks. That decision is under appeal to the EPO's Boards of Appeal and, as it was based on a different claim set and on different evidence, it is common ground that I must consider those issues afresh.

The witnesses

8. There were six witness of fact for Salts whose evidence was unchallenged and can, therefore, be accepted. It is, however, necessary to comment on the expert witnesses (two for each side) each of whom was cross examined.

Ms Becke

9. Coloplast relied on the expert evidence of Gail Susan Becke. Ms Becke has a degree in chemical engineering from the Massachusetts Institute of Technology and has worked in a number of jobs from which she has gained considerable knowledge of and experience in relation to materials (predominantly plastics) and the bonding of materials, including dissimilar materials. Ms Becke admitted to having no particular expertise in relation to ostomy bags and has never designed or been asked to design one. She said that, in the period between 1988 and 1994, when she was a lead researcher for the Dow Chemical Company ("Dow") in relation to polystyrene films, her team had shared a laboratory with the team at Dow which made barrier film for ostomy bags and she had, as a result, "gained some experience with ostomy products" and become "familiar with [their] structure". However, she was far more familiar with diapers, feminine hygiene and adult incontinence products (many of which she has designed) and often her evidence as regards the qualities (such as comfort) of a particular material was based on her familiarity with those products. As a result, in giving evidence with regard to ostomy bags and the ostomy bag market, she relied on information provided to her by Coloplast's solicitors or derived from her own researches in 2019 and 2020 after being instructed as an expert in this case rather than on any personal involvement in the ostomy bag market as at the priority date of 25 May 2012. This inevitably affected the extent to which she was able to assist me with regard to issues such as the attributes of the skilled person, or what constituted common general knowledge, or what was or was not obvious in relation to ostomy bags.

10. In closing, Mr Campbell Q.C. (Counsel for Salts) was critical of Ms Becke personally and of her evidence. He referred to aspects of her evidence where he said she had erred or had displayed a lack of knowledge or had simply relied on information provided to her by Coloplast's solicitors. Where necessary, I will deal with these at the relevant points in this judgment. Mr Campbell also suggested that Ms Becke had been selected by Coloplast because she was "a professional witness"

and because, as she knew so little about ostomy bags and the ostomy market, she "could not give the game away" for Coloplast. To the extent that this was a criticism of Ms Becke, then I do not accept it. In this regard, it is important to bear in mind what Jacob LJ said in *Rockwater Ltd v Technip France SA* [2004] EWCA Civ 381 at [12] and [15] about the role of an expert, namely:

> "12. I must explain why I think the attempt to approximate real people to the notional man is not helpful. It is to do with the function of expert witnesses in patent actions. Their primary function is to educate the court in the technology – they come as teachers, as makers of the mantle for the court to don. For that purpose it does not matter whether they do or do not approximate to the skilled man. What matters is how good they are at explaining things.
>
> …
>
> 15. Because the expert's conclusion (e.g. obvious or not), as such, although admissible, is of little value it does not really matter what the actual attributes of the real expert witness are. What matters are the reasons for his or her opinion. And those reasons do not depend on how closely the expert approximates to the skilled man."

11. Ms Becke is not (and does not claim to be) representative of the skilled person or to have had personal experience of the ostomy bag market as at May 2012. However, she does have considerable experience with regard to the use of materials in other types of disposable product for collecting human waste or discharges where (as with ostomy bags) avoiding leakage and ensuring user comfort and dignity are of central importance. In my judgment, this means that she was able to provide me with expert assistance with regard to certain matters that are central to this case, namely the nature and characteristics (particularly bonding characteristics) of those same materials when used in ostomy bags. Indeed, in cross examination, Mr van der Leden (Salts' expert) stated that Ms Becke knew more than he did about how polymers are made and how they react to each other.

12. Mr Campbell nevertheless sought to undermine Ms Becke's credibility as an expert. He submitted that she had given evidence "that she did not honestly believe to be true" when she said that, using her own hands, she could determine that the weld zone of Coloplast's SenSura Mio gen 2 product had a

peel strength of more than 5N/12.5mm (and would therefore fall within claim 2 of the Patent). I have no hesitation in rejecting this criticism. The product involved was not in issue in the action and it had not been previously tested. Accordingly, when Ms Becke was asked during cross examination whether it would meet the peel strength requirement in claim 2 of the Patent (a strength of "above 5N/12.5mm width"), she used her hands as a means of testing that peel strength. I accept Ms Becke's evidence with regard to that test, namely that:

> "I have used it frequently. In the factory setting, I can use it many, many times per day when I am testing materials".

And, later, that:

> "This is something that many people do on a daily basis, and have found to be reliable".

13. It seems to me that this is precisely what people working with and testing materials and their bonding characteristics are likely to do. Ms Becke was not suggesting that her hand test could provide a precise measurement of peel strength. She was simply saying that, given her experience, she could tell by using her hands that the weld zone of the bag in question had a peel strength of more than 5N/12.5mm width (which is, after all, all that claim 2 of the Patent requires). It is notable that Mr van der Leden (who has years of experience of designing and manufacturing ostomy bags) did not suggest that Ms Becke's evidence in this regard could not be true.

14. I find that Ms Becke was a careful and clearly knowledgeable expert witness and I found her evidence and explanations on matters within her area of expertise to be helpful. However, as the passage from *Rockwater* quoted above shows, that does not mean that I have to accept her (or, for that matter, Mr van der Leden's) conclusions as to what would or would not have been obvious to the skilled person at the priority date.

Mr van der Leden

15. Salts relied on expert evidence from Mr Aat van der Leden. In contrast with Ms Becke, Mr van der Leden has huge personal experience of the ostomy bag market and of the products in that market based on his having worked in that sector for some 43 years, including at the priority date of May 2012. He has also edited a quarterly ostomy journal and has experience of designing ostomy bags. It is clear from his evidence that he has acquired a substantial practical knowledge of the sorts of

materials used in making ostomy bags and of their characteristics.

16. Subject to one exchange relating to diapers early in his cross examination (which in my judgment was probably due to a misunderstanding), Mr Lykiardopoulos Q.C. (counsel for Coloplast) accepts that Mr van der Leden tried his best to assist the court. However, Mr Lykiardopoulos did suggest that Mr van der Leden did not always distinguish between his own experience and views and those of the skilled person. I will deal with this, where relevant, in this judgment.

17. For my part, I found Mr van der Leden's evidence to be helpful and informative. Moreover, contrary to concerns expressed by Mr Campbell, I did not think that Mr van der Leden's evidence was significantly affected by tiredness (whether brought on by his age (72 years), shortage of sleep, COVID restrictions and/or the stress of giving evidence). There may have been occasions when Mr van der Leden misunderstood a question (English not being his first language) but, overall, it seemed to me that he remained enthusiastic and alert and was well aware of the import of his answers – including when they were favourable to Coloplast.

Professor Drummond-Brydson

18. Professor Drummond-Brydson was the expert called by Coloplast to give evidence with regard to the scanning electron microscopy ("SEM") images and the optical microscopy images in the parties' Notices of Experiments. He is impressively qualified and has very considerable experience with regard to microscopy. Mr Campbell's main criticism of his evidence was that certain matters had been omitted from his reports and that he did not venture outside the scope of his instructions. Where relevant, I will address these points later. On matters where Professor Drummond-Brydson did give evidence, I find that he was a very good and careful expert witness on whose evidence I am happy to rely.

Professor Barron

19. Professor Barron was Salts' expert witness instructed to consider the Patent and Coloplast's Notice of Experiments and to conduct the experiments set out in Salts' Notice of Experiments. He too is impressively qualified in relation to processing and interpreting optical and SEM images.

20. I have some concerns about some aspects of Professor Barron's evidence. For example, he defended his team's use of scissors in cutting samples for imaging. However, he had not personally overseen how the scissors had been used and he was unable to confirm that the cutting had been carried out in a way that minimised damage to the samples. It seems to me to be very obvious from the images that the samples produced by his team had been significantly more damaged in the cutting process than those produced by Coloplast, yet Professor Barron seemed reluctant to accept this.

21. Further, Salts' images (or at least the copies in the trial bundles) tended to be very dark or very bright and, as a result, less easy to interpret than Coloplast's. Indeed, Professor Barron said that he had spoken to Salts' lawyers offering to produce better images but had been told to "go with [the existing] images". There was a dispute between the experts as to the cause of the problems with Salts' images (and in particular whether it was due to "charging" of the images caused by inadequate preparation and presentation of the sample and/or by the choice of voltage for the scanning instrument). I do not need to resolve that dispute. Ultimately, the issue is whether the images are sufficiently clear to allow them to be interpreted and, in this regard, notwithstanding the concerns outlined above, I have no reason to doubt Professor Barron's expert opinion and I accept his evidence as to what the images show.

22. I should note that, as Mr Campbell submitted in closing, the SEM images were of less significance at trial given the narrowing of the claims being pursued.

The Skilled Person

23. The Patent is directed at a notional person (or team of persons) with a practical interest in its subject matter, namely bags for collecting human waste. In my judgment, this person would be a product developer or designer of such bags and would have the sort of knowledge required of such a person. He or she would be aware of the sort of issues faced by and the needs and concerns of users of such bags. However, he or she would also be aware of the manufacturing processes used to make such bags and would be reasonably knowledgeable about the sort of materials that were available and their characteristics, in terms of both manufacture and end-user experience. It seems to me that this knowledge would be founded on experience in the ostomy bag sector and need not be based on any particular academic qualifications.

24. There is a dispute between the parties as to the extent to which the skilled person may (like Ms Becke) have worked with or be familiar with feminine care and adult incontinence products and diapers. As the example of a Mr Harrington recruited by Hollister Inc (a major manufacturer of ostomy bags) showed, there were clearly some people involved in developing ostomy bags who had had experience of making other hygiene products and, as I have already found, knowledge derived from such experience may well be useful in the ostomy field. I note, for example, that Mr van der Leden asserted that the skilled person would know about wound dressings, products which are, if anything, less relevant than the products with which Ms Becke was more familiar. Nevertheless, I do not think that the skilled person in the present case would be expected to have more than a general knowledge or awareness of products outside the ostomy bag sector. Ultimately, though, I cannot see that much really turns on this and it seems to me that this dispute was more about the value I should attribute to Ms Becke's evidence than about the attributes of the skilled person.

The common general knowledge

25. The common general knowledge is the information which at the priority date of 25 May 2012 would have been widely known to those engaged in the art and regarded by such persons as a good basis for further action. It includes not only information within the memory of the skilled person but also information that the skilled person knows exists and would, if needed, look up as a matter of course. I set out below my findings as to what was common general knowledge in this case.

Types of ostomy bag

26. There were (and are) three types of ostomy bags: colostomy bags (which collect faeces from a stoma in the large intestine), ileostomy bags (which collect faeces from a stoma in the small intestine), and urostomy bags (which collect urine from a stoma in the urinary system).

27. Ostomy bags could be "one-piece" or "two-piece". One piece is where the whole of the pouch, including the flange that connected the pouch to the stoma, would be removed and discarded when the pouch was to be replaced. Two piece is where the flange remained attached to the user's body when the pouch was removed to be replaced.

28. Ostomy bags could be closed or drainable. Typically, a colostomy bag would be a closed bag to be discarded and replaced by the user as and when required (typically, depending on the user's needs, once or twice daily). However, some colostomy bags (used where the user's output was more liquid) were drainable as, typically, were ileostomy and urostomy bags. Drainable bags have a tap or a foldable opening at the bottom of the bag which allows the contents to be discharged and the bag to be re-used which, again depending on the user's needs, was typically between four and six times a day.

The barrier film

29. Central to an ostomy bag was a collecting pouch to collect and contain waste emitted from the stoma and any associated odours. Such pouches were made from two layers of an impermeable material known as a barrier film which layers were joined at their edges to form the pouch. On the body facing layer was a hole which fitted over and connected to the stoma via the flange.

30. Typically, the barrier film was made up of 3 or, preferably, 5 layers including an inner layer of polyvinylidene chloride (PVDC), which performed the main containment function, with further layers of ethylene vinyl acetate (EVA) and/or a polyethylene (PE)/EVA mix acting as an additional sealant to the PVDC layer and as a hot melt adhesive during the welding process by which the pouch was formed. Such barrier film was well known and widely available and, typically, ostomy bag manufacturers would buy it from companies such as Dow and Sealed Air Corporation.

The comfort layer

31. By the priority date, ostomy bags normally had an additional layer attached to one or both sides of the collecting pouch. This additional layer was known as a comfort layer. The need for a comfort layer arises because, when a bag is in use, the barrier film making up the collecting pouch tends to become damp with condensation and perspiration and, therefore, uncomfortable for a user. It may also emit rustling or crinkling noises which users find embarrassing.

32. To counter these problems, it had become common from at least the 1970s for users to insert the pouch within a removable and re-useable cover (similar to a hot water bottle cover). Such covers were widely available, almost as clothing accessories, from a range of suppliers. By 2012, such removable covers were still in use but less extensively because by then it had become common for ostomy bags to have their own integrated comfort layers (i.e. a comfort layer bonded to the barrier film to form an integral part of the bag). The idea of an integrated comfort layer had been a key element of the Watkins patent (the application for which had been published as long ago as 17 June 1981). The concept, therefore, of adding a comfort layer to an ostomy bag (whether removable or integrated) was common general knowledge as at May 2012.

Use of woven and non-woven materials for comfort layers

33. It is common ground that it was well known in May 2012 that the removable and reusable (i.e. non-integrated) covers for ostomy bags could be, and often were, made from woven fabrics (including, for example, cotton). It is also common ground that integrated comfort layers made out of non-woven fabric were well known.

34. There is, however, a dispute as to whether the use of woven fabrics for integrated comfort layers was common general knowledge. In this regard, the 1980s' Watkins patent had indicated that the fabric layer for an ostomy bag could be made of a woven fibre material. So too had Dircks (published in December 2005) (at [0016]) and Willis (published September 2008).[1] However, in describing the existing state of the art in 2004, Dircks (at [0005]-[0009]) had referred only to the use of a "non-woven or other fibrous layer". Willis was similar with regard to the position in 2008, referring (at [0005]) to a "non-woven or other fibrous or fabric-like layer". Notwithstanding Mr Campbell's suggestion to the contrary, I do not accept that these statements suggest that there had been any actual use of woven integrated comfort layers.[2] In this regard, Mr van der Leden's evidence (directed at the position in 2012) was that:

[1] Willis refers (at [0011] and [0023] to the fabric layer being, preferably, comprised of a natural or synthetic material including, inter alia, cotton or silk. From which it appears that it too envisaged the use of a woven fabric.
[2] Why did they not use the word "woven" in this context, particularly as Dircks had used that word elsewhere and, in the case of Willis, why refer in this context to "a fabric-like layer" rather than the word "fabric" that it had used elsewhere?

> "I can assure you at 2012 and earlier I was quite aware what was in the market in ostomy and what was not in the market in ostomy. That was my specialty, and please see that I run a company which had 50% of the market. We were selling all kind of materials. I was visiting all kinds of medical exhibitions. We met each other, all the big companies, we saw each other twice a year in big ostomy congresses, but you are right, the Coloplast pouch was the first pouch with a woven comfort layer, as far as I know. I have never seen one before."

35. Unsurprisingly in view of this evidence from its own expert, Salts was unable to identify an ostomy bag on the market in 2012 with a woven integrated comfort layer. However, in the course of cross-examination, Mr Campbell asked Ms Becke about a statement in a 1986 book called Stoma Care Nursing by Catherine Elcoat that "One or two appliances feature a woven backing to prevent sweating". I can see that this statement may be referring to the existence of ostomy bags with woven integrated comfort layers, although it is hardly conclusive. However, neither expert appeared to be aware of the book and there was no evidence as to the book's circulation or provenance and, as Mr van der Leden (Salts' own expert) rightly said in his initial report, the fact that something is mentioned in a textbook or journal does not make it common general knowledge. In my judgment and particularly in view of the clear evidence of Mr van der Leden quoted above, the statement in the 1986 Elcoat book comes nowhere near to proving that the existence of ostomy bags with woven integrated comfort layers was common general knowledge at the May 2012 priority date.

36. Mr Campbell sought to rely on the fact that Mr Becke, when asked if she had any reason to doubt that what Ms Elcoat had written was part of the common general knowledge, answered "I have no reason to doubt that, but I am…" – before she was cut off by the next question. The difficulty for Mr Campbell is that Ms Becke had stated only a few lines before that "I agree that the word 'backing' implies integrated, but I am unaware of any other product that was available in 1986 with this procedure". It seems to me that her interrupted answer was intended to be qualified and (contrary to Mr Campbell's submission) I do not accept that she changed her position due to an intervention by Mr Lykiardopoulos (although she did move on to point out that the word "backing" was ambiguous). In any event, it is unclear on what basis Mr Campbell can rely on Ms

Becke's unfinished answer given Mr van der Leden's evidence and given that it is Salts' case that Mr van der Leden's knowledge of the ostomy market as at 2012 was far greater than Ms Becke's.

37. I therefore reject the suggestion that the actual use of woven materials for integrated comfort layers was a matter of common general knowledge. However, a somewhat different question is whether the *possibility* of using a woven material for that purpose was common general knowledge.

38. As mentioned above, it was certainly well known that a woven material could be (and often was) used for non-integrated comfort layers. Further, as also mentioned above, Watkins (published in 1981), Dircks (published in 2005) and Willis (published in 2008) had each expressly provided for the possibility of using a woven fabric for an integrated comfort layer. Even if those particular publications were not common general knowledge as at May 2012, the fact that they provided for the use of a woven integrated comfort layer shows that that was a possibility in the minds of those designers of ostomy bags and, I assume, of their employers (being, in the case of Dircks, Hollister, a major ostomy bag manufacturer). If that possibility was in their minds at those dates, notwithstanding the lack of actual bags embodying that idea, then in my judgment it is probable that it would also have been in the mind of the skilled person (being someone also involved in the design of ostomy bags) as at May 2012.

39. It is true that Mr van der Leden's evidence was that he could see no reason why the skilled person in 2012 would have tried to use a woven material for an integrated comfort layer. However, he went on to explain that there were practical rather than technical reasons for this, reasons which I accept would have been known to the skilled person. First, a woven material was typically "much more expensive" than a non-woven. Second, when using wovens, "you need much more plastic, which is not so very good for the environment". Third, non-wovens are adaptable and can, as Ms Becke said, "be highly engineered and functionalised" to meet specific needs and uses (e.g. single or multiple use). There was no suggestion that a woven was not used for integrated comfort layers for any technical reason. It was known that it was capable of such use.

40. On this basis, I find that it was common general knowledge that the use of a woven material for an integrated comfort layer was

possible but that it had not been pursued because of its cost and environmental disadvantages (see further below) and because it was not apparent that there would be any countervailing advantages to its use. I will return later to the question whether, despite this and despite the prior art disclosures (including Watkins, Dircks and Willis), the Patent nevertheless involved an inventive step by, for example, teaching that there was a previously unrecognised advantage in using a woven fabric, an advantage that meant it was worth taking forward and implementing an idea which had hitherto been no more than a theoretical possibility in the mind of the skilled person.

41. Both experts (Ms Becke and Mr van der Laden) accepted that the use of needle pin fabric for integrated comfort layers was part of the common general knowledge. However, so far as I am aware, nothing much turns on this although it does tend to show that the skilled person was not necessarily wedded to the use of non-woven fabrics.

Characteristics of woven and non-woven fabrics

42. In my judgment, the skilled person would have known the following about woven and non-woven fabrics and about the differences between them.

43. A non-woven material is made of randomly arranged fibres matted together (by chemical, mechanical or thermal means) to form a web and then a fabric. Such a fabric does not have the inherent strength that friction within an organised geometrical structure gives to a woven fabric. Having said that, non-woven fabrics can be highly engineered and functionalised and tailored to meet specific needs and uses and their strength can be increased by chemical, thermal or mechanical bonding of the fibres. As a result, such fabrics were widely used and popular in many fields, including the ostomy field as at May 2012.

44. As mentioned above, non-woven fabrics had advantages over woven fabrics in terms of cost and of their impact on the environment. Mr van der Leden stated that wovens were typically much more expensive than non-wovens and Ms Becke accepted that they were at least twice the price. In closing, Mr Lykiardopoulos pointed out that this needs to be kept in perspective given that a bag would sell, typically, for £2-£4 and that the cost of the non-woven element was only some 2 pence

per bag (i.e. around 0.5% - 1% of the sale price). In the absence of any evidence as to the manufacturers' profit margins, it is difficult to know how serious an issue this would have been in the mind of the skilled person. Nevertheless, in view of Mr van der Leden's evidence and the very large volume of ostomy bag sales, I am satisfied that the additional cost of a woven fabric would have been of some significance to the skilled person.

45. As regards environmental issues, Mr van der Leden's evidence was that, when using wovens, "you need much more plastic, which is not so very good for the environment" and he pointed out that the polyester woven fabric used by Coloplast for its new product weighed 71g/m^2 whereas the polypropylene non-woven it used for its other products weighed 30g/m^2 and may even be reduced to 25g/m^2 (albeit that other manufacturers typically used a non-woven fabric weighing 40g/m^2 or, in the "exceptional" case of Dansac, 60g/m^2). Ms Becke was less convinced by this. She commented that it depended on the weight of the woven used and that designers would, in any event, look to compensate by making other adjustments. She also considered that any environmental concerns would have been focused more on the PVDC in the barrier film than on the material used in the comfort layer. Nevertheless, as Mr van der Leden's figures (and, indeed, the figures mentioned in the Patent) show, the weight of wovens when used for this purpose does appear to have been greater than the weight of non-wovens. Accordingly, I accept Mr van der Leden's evidence that designers in 2012 would have believed that, typically, use of a woven fabric was likely to involve using more plastic than use of a non-woven and that this was undesirable for environmental reasons.

46. Of course, as all manufacturers at the time were using non-wovens for their comfort layers, an additional factor would be the cost and effort involved in changing over to using a woven. The skilled person would have known that to move to a woven would require some degree of experimentation (using the well-known welding parameters discussed below) to ensure a satisfactory weld with the new material and may also require investment in new machines.

Materials used for comfort layers

47. In relation to the material used for integrated comfort layers, it appears to be common ground (or at least I could detect no significant disagreement in the parties' closing submissions)

that, as at 2012, it was generally known that polyethylene or polyester could be and were being used; the former being used by most manufacturers (including Salts and Hollister) and the latter by a few (including Coloplast and Dansac). Mr van der Leden's evidence was that manufacturers were usually aware of what materials other manufacturers were using – either from observation or by a simple test or because suppliers of materials were happy to discuss what they were supplying to other manufacturers.

48. There is, however, a dispute as to whether it was common general knowledge that polypropylene was being used for a comfort layer. Coloplast's case (which, in cross examination, Mr van der Leden was inclined to accept) was that in 2010 it had decided to switch from polyester to polypropylene for some of its products. Moreover, Dircks (at [0016]) and Willis (at [0011] and [0023]), both expressly refer to polypropylene as a preferred material for the fabric comfort layer. Despite this, Mr van der Leden's evidence was that as at May 2012 he was unaware of such use and he explained that Coloplast's products using polypropylene may not have been widely available on the market at that date as its old stock made of polyester was still being sold off. Given Mr van der Leden's knowledge of the ostomy market, I do not think that I can find that the *actual* use of polypropylene was common general knowledge. Having said that, given Coloplast's adoption of it in 2010 and the fact the designers of Dircks and Willis had referred to it as one of their preferred materials, it seems to me that the *possibility* of its use must have been something that designers (and therefore the skilled person) would have known about in May 2012. Ultimately, however, I cannot see that anything really turns on this point. As Mr van der Leden said, "it is not so important for me, I must say".

49. All such materials (and samples of them) were widely and easily available to a skilled person not least from the textile suppliers who exhibited and marketed their products at medical trade fairs such as Medica in Dusseldorf and Med-Tech. However, most manufacturers tended to buy materials "off the shelf" and tended to be reluctant to change if it would mean changes to their existing production methods (which would typically involve what Ms Becke referred to as "experimentation") and to their production machinery in which they may have invested significant sums.

Manufacturing and welding methods

50. The way in which ostomy bags were made and how the chosen materials respond to the manufacturing process is of some importance in this case.

51. In my judgment, the skilled person would have had the knowledge needed to manufacture an ostomy bag with an integrated comfort layer. He or she would have known that, typically, a bag was made of two layers of barrier film (which would form the collecting pouch) and an external comfort layer. As Mr van der Leden said in his first report, "Typically, these barrier film and comfort layers were attached together, and the pouch was formed, by welding all layers simultaneously around the periphery of the pouch". This would, most often, be by heat or radio frequency ("RF") welding although ultrasound could also be used. The use of peripheral welding was almost universal. Whilst Dircks and Willis had envisaged a different approach (one whereby the comfort layer was attached across the entire, or substantially the entire, surface of the barrier film as opposed to just the periphery), that method appears never to have been popular not least because it was uncomfortable for users as the surface of the comfort layer suffered from the problem of retained moisture. Mr van der Leden described bags that had been made in this way as "lousy".

52. As at 2012, the weld area around the perimeter of a typical ostomy bag was typically film-like or glossy in appearance and somewhat rigid in feel. This was perceived to be something that users liked because it gave them reassurance that the weld was secure and, therefore, that the bag would not fail. However, the skilled person would have been well aware that the nature and appearance of the weld was dependent on the welding conditions being used and on how those conditions operated in relation to the particular materials being welded. For example, the skilled person would have known that if a pouch was welded at too low a temperature, the appearance of the material in the weld area would be less affected (and would be less film-like or glossy) but the weld might be weak and the layers at risk of separating. If, on the other hand, a higher temperature was used, it was more likely to alter the appearance of the material in the weld area (so as to become more film-like or glossy) and, if the heat was too great, to damage the barrier film. At either extreme, there was a risk that the bag would be unfit for purpose. However, between these two extremes, it was common ground that the skilled person could adjust the welding conditions or parameters and could vary the materials

used depending on what he or she was trying to achieve, whilst still creating an ostomy bag with a secure weld.

53. It is also common ground that if the chosen material was polyethylene or polypropylene then, as those materials have a relatively low melting point, the weld zone created in the welding conditions typically used in making ostomy bags would result in a weld with a glossy, film-like appearance and a somewhat rigid feel. This was because under those conditions, more of the fibres making up the comfort layer would melt and mix with material from the outer layers of the barrier film (which contained EVA) so that, on cooling, the resulting mixture did not have a fibrous appearance.

54. In contrast, if polyester was used for a comfort layer, because it melts at a much higher temperature than polyethylene or polypropylene, then at the temperatures typically used in making an ostomy bag, its fibres would not melt and the bonding was achieved by the fact that melted material from outer layer of the barrier film would flow into the gaps between the fibres of the polyester comfort layer. As a result, the surface of the polyester comfort layer would retain much of its structure and appearance and, therefore, be less glossy or rigid.

55. The fact that this was how the different materials reacted under the conditions that typically applied in manufacturing ostomy bags in May 2012 does not mean that such results were inevitable. Rather, as I have already indicated, it was common general knowledge that the end result would depend on the material chosen (e.g. polyethylene, polypropylene or polyester as mentioned above), on the thickness or weight of such material and on how the skilled person decided to adjust the three key welding parameters of time, temperature and pressure. For example, Mr van der Leden was clear that in the case of polypropylene, “a hard welding zone was not necessarily formed, but it depended on the specific welding conditions … used, and which could be adjusted by the skilled person.” Equally, Ms Becke was adamant that where polyester was used, if the purpose was to reassure users that a weld was secure, then it was perfectly possible (presumably by adjusting the welding parameters) to achieve a hard, glossy welding zone.

Other issues of common general knowledge

56. Various other issues arose regarding what was common general knowledge (for example the nature of user's concerns as regards ostomy bags). However, it is convenient to consider those issues as they arise in the context of the Patent or of the relevant prior art.

The Patent

57. As I have noted, the Patent is entitled "Comfort Layer for a Collecting Bag" and has a priority date of 25 May 2012. At paragraph [0001] is a "Description" which states that:

> "The invention relates to collecting bags for human body wastes. In particular, the invention relates to a textile comfort layer of a collecting bag providing the collection bag with an increased resistance against tearing and pulling forces".

58. Paragraph [0003] sets out the background and the difficulties that the invention is said to overcome. It starts by noting that, in the field of ostomy care, a comfort layer for a bag comprises a non-woven material typically made of polyethylene, polypropylene or polyester. It then asserts that, typically, such non-woven comfort layer was heat welded to the barrier film in a process that caused its fibre structure to melt and that "experience shows" that this resulted in a "relatively hard or non-flexible welding zone". To the extent that this suggested that such a result was inevitable then, for the reasons set out above, it was incorrect as the experts agreed that the appearance of the weld zone would depend on the welding conditions and the materials used. Indeed, as Mr Campbell pointed out, the Dansac Novalife is an example of a polyester non-woven comfort layer which did not have a relatively hard and non-flexible weld zone. Having said this, I do not think that anything really turns on this inaccuracy, particularly given that, whatever was theoretically possible, the Dansac Novalife bag was the only bag in evidence whose weld zone did not conform to the description in paragraph [0003]. Further, it appears from the statement of Vigdis Hannestad that the Dansac Novalife bag had a comfort layer which had been changed in November 2011, in which case, as Mr van der Leden accepted, "it might well be the case that the skilled person was not aware of it in 2012". Mr Campbell suggested that Coloplast's own pre-priority date bags with polyester non-woven comfort layers may have resembled the Dansac Novalife bag. However, in the absence

of any evidence in relation to the construction or appearance of such bags, this was mere speculation.

59. According to paragraph [0003], the attachment between the non-woven comfort layers and the barrier film was relatively strong in terms of the strength required to peel the layers apart ("peel strength") but, in some cases, the material would break instead of being peeled apart if submitted to such a test. The problem (paragraph [0003] explained) was that the strength of the fibres had been compromised or greatly reduced by being melted and this left the welding area "more exposed to failure caused by external forces working on the collecting bag, such as tearing or pulling forces". In the worst case, it was said, "such a failure may result in the collecting bag being torn up and open and consequently leaking its contents." I will return later to the issue of strength. However, as Mr Campbell points out, no evidence was adduced of actual failures occurring or that the skilled person at the time would have thought that such failures were a particular problem with existing bags.

60. Finally, paragraph [0003] noted that the welding process left the zone or area of the welding quite visible due to the mixing of materials in that area, "thus compromising the visual appearance of the bag". Mr Campbell criticises this on the basis that visual appearance is not an issue given that the bag is worn under clothes. Again, I cannot see that much turns on this but, for what it is worth, I reject this criticism. I have no doubt that the aesthetic appearance of the bag was of real importance to many users. Indeed, Mr van der Leden gave evidence of this and went on to comment that "ladies who want to be a little bit fashionable" would want the comfort layer to match other items of clothing. As Ms Becke said, aesthetic appearance is important to user dignity.

61. The proposed solution to the disadvantages identified in paragraph [0003] is summarised in the "Summary of the Invention" at paragraph [0005]. It is that a bag with a "textile comfort layer" would have a peel strength "at least on par" with that of a non-woven comfort layer, but would also have a significantly higher resistance to external forces, improved visual and tactile characteristics in the weld zone and an "increased resistance to common wear issues such as snagging and pilling".

62. Paragraphs [0006] to [0058] contain a "Detailed Description of the Invention". Paragraph [0006] makes clear that what is

envisaged is the attachment of a textile comfort layer to a barrier film such that, in the area(s) of attachment, some but not all of the fibre filaments of the comfort layer are embedded in the barrier film material. Paragraph [0008] notes that a textile has an interlaced structure which anchors its fibre filaments which explains why textiles typically have greater strength than non-wovens whose fibres are "by definition, randomly arranged".

63. According to paragraph [0009], the attachment is made by a welding process. As the textile has a higher melting point than the barrier film materials, the former would not melt but would retain its interlaced structure into which would flow melted material from the barrier film. As a result, the two layers would be attached with a peel strength that was "on par" with that of bags featuring non-woven integrated comfort layers (and above 5N/12.5mm width, see paragraph [0010]) but the textile would have retained its structure and strength.

64. The patent then expands on the claimed benefits of the invention. Paragraph [0011] refers to an increased resistance against tearing and pulling forces. Paragraphs [0012] to [0015] refer to the fact that the weld zone would be less visible and softer (due to the presence of fibre filaments of the comfort layer that have not been embedded in the barrier film material). Paragraphs [0017] and [0018] refer to an increased wear strength giving improved resistance to snagging and pilling (small balls of fibre forming on the surface due to wear).

65. At paragraph [0018] the improvement is said to be of particular interest in connection with drainable bags because it results in a bag that is more resistant to the increased forces of friction and tension on such bags because they are often squeezed and pressed in order to empty them and because they tend to be reattached and worn for a longer time.

66. Paragraphs [0019] to [0052] expand on the method of making a bag according to the invention and on the materials to be used. Much of this is common general knowledge. In particular, the point is made at paragraph [0035] that the visual and tactile characteristics of the textile comfort layer in the weld zone may be controlled and, at paragraphs [0035], [0055] and [0056], that the level of embedding of fibre filaments may also be controlled to allow the creation of a "physical anchorage" but "without destroying the structure of the textile material". No further details are provided and, in my judgment, they would

not be needed given that the means of exercising such control would be a matter of common general knowledge, known to the skilled person.

67. Paragraphs [0059] to [0068] refer to various drawings and to the SEM (scanning electron microscope) image at Figure 4. This image shows a woven comfort layer attached to a barrier film according to the invention. In my judgment, whilst the quality of this image is not particularly good (probably due to its being a copy of a copy), the skilled person looking at this and reading paragraph [0066] would conclude that it shows the nature of the attachment and demonstrates that some fibre filaments of the threads of a woven textile comfort layer had been embedded in melted material from the barrier film, that others had been partly embedded and that others had not been embedded.

68. At paragraphs [0069]-[0074], the Patent describes an experiment with regard to the peel strength of the invention. This experiment was criticised by Salts because it lacked a proper control (a point accepted by Ms Becke), because it had not been a "like for like" comparison (the woven material tested had a weight of 71g/m^2, whereas the non-woven material probably had a weight of 30g/m^2), because the respective welding conditions had not been specified and because the tests show that the woven had produced "clearly lower" results.

69. Mr Lykiardopoulos makes the point that there is no need for a patent to include any experiments. But, in any event, I think that Salts' criticisms miss the point. The experiment was not claimed to be a "like for like" comparison based on weight or welding conditions. It was simply trying to show that a bag made to the invention could have a peel strength on par with a bag made in the known way (with "a traditional non-woven comfort layer"); in other words, that the disclosure of the Patent was plausible. Further, under this test, the woven gave a peel strength of 7.898 N/12.5mm width as opposed to a peel strength of 8.189 N/12.5mm width when a non-woven was used. There was no evidence that that difference was significant or was outside what could fairly be described as "on par".

70. Salts made much the same criticism of the second experiment, described at paragraphs [0075] to [0079] of the Patent under the heading "Notch sensitivity – external forces resistance". Once again, in my judgment this criticism misses the point. The

experiment was not a like for like comparison of materials or welding conditions but was simply intended to show that a bag made according to the invention could provide more resistance to tearing forces than a bag made in the known way, albeit one with a lighter non-woven comfort layer.

71. Turning to the claims of the Patent (and omitting cross references to drawings), claim 1 was for:

> "A collecting bag for human waste comprising a barrier film covered by a comfort layer, wherein the comfort layer is a textile material having a number of threads each comprising a plurality of fibre filaments, and the said textile material is attached to the said barrier film in one or more zones of attachment **characterized in that** some but not all of the fibre filaments of the textile material in said zone(s) are embedded in the barrier film material."

72. Claim 1, therefore, provides for the comfort layer to be of a "textile material". Read in the light of the description it is probable that this meant either a woven or a knitted material (as opposed to a non-woven). However, I do not need to resolve this given that Coloplast now only relies on claim 1 as a dependency of claim 6. Reading claim 6 into claim 1 means that the reference can be taken to be a reference to a woven textile material.

73. Subject to the textile (woven) requirement, claim 1 is, as Mr Campbell points out, extremely wide in scope. Indeed, it would seem that the only situations falling outside its scope would be the extremes where the attachment was either of only one fibre filament of the comfort layer or of 100% of those fibre filaments. The skilled person would know that the former situation could not realistically be called an "attachment" and would also know that it was unlikely that the latter situation would be achieved when making an ostomy bag, particularly in the case of a polyester comfort layer. Thus (aside from the reference to the use of a textile (woven) material), the vast majority of (and probably all) ostomy bags with integrated comfort layers at the priority date would have fallen within this claim. Mr Lykiardopoulos accepts the width of this claim and points out that it was the role of claims 2 to 4 to limit the scope of the monopoly claimed, which is why Coloplast now relies the combinations of claims referred to as claims 6A, 6B and 6C.

74. Claim 2 was for:

> "A collecting bag according to claim 1, wherein the peel strength between said comfort layer and said barrier film is above 5N/12.5mm width in said zone(s)."

75. As Mr Lykiardopoulos pointed out, this operates to limit the scope of claim 1. It informs the skilled person that the attachment of the comfort layer to the barrier film must be such as to achieve a peel strength above 5N/12.5mm width. The skilled person would know that to achieve this, the attachment would have to involve more than a few fibres and, using his or her common general knowledge, would be able to determine the appropriate combination of welding conditions and materials that would give rise to sufficient embedding to give the necessary peel strength.

76. Mr Campbell argued that the figure in claim 2 of 5N/12.5mm width was arbitrary and pointed to the fact that, at paragraph [0010], the description had listed three values for peel strength – "above 5 N/12.5mm width, such as above 6 N/12.5mm width, such as above 7 N/12.5mm width in the zone(s) of attachment". I do not see that this makes claim 2 arbitrary. Claim 2 requires that the attachment made in accordance with claim 1 should be such as to give a peel strength of more than 5 N/12.5mm width and there was no evidence to suggest that this was not a valid technical requirement for an ostomy bag. It is not, for example, like a requirement that the bag be coloured green or blue.

77. Claims 3 and 4 can be taken together. They are for:

Claim 3

> "A collecting bag according to claim 1 or 2, wherein those fibre filaments that are not embedded in the barrier film material provide a surface of the comfort layer having the same tactile characteristics as the surface of the comfort layer outside the zone(s) of attachment".

Claim 4

> "A collecting bag according to any one of claims 1 - 3, wherein those fibre filaments that are not embedded in the barrier film material provide a surface of the comfort layer having the same visual characteristics as the surface of the comfort layer outside the zone(s) of attachment".

78. Like claim 2, these claims limit the scope of claim 1. They inform the skilled person that the attachment should be such that the fibre filaments that are left unembedded after the attachment give the surface of the comfort layer in the weld zone the same tactile and visual characteristics as the surface of the rest of the comfort layer. In other words, the skilled person is being told to use his or her common general knowledge of materials and welding conditions to achieve that result rather than the sort of relatively hard, non-flexible, visible weld zone referred to in the description of the Patent that were typical at the time.

79. Mr Campbell criticised this saying it is a statement of the obvious to say that the tactile/visual characteristics *of the unembedded* fibres of the comfort layer in the weld zone would be the same as those of the surface of the rest of the comfort layer. In my judgment, that is not how the skilled person would read claims 3 and 4. Under claims 3 and 4, the surface of the comfort layer outside the weld zone is not being compared with the unembedded fibres in the weld zone. Rather it is being compared with the surface of the comfort layer in the weld zone. The skilled person is being told to ensure that there are sufficient unembedded fibres such that the overall surface of the comfort layer in the weld zone will have the same tactile/visual characteristics as in the rest of the comfort layer. If there was any doubt as to this, then the fact that claims 3 and 4 are a statement of the obvious when construed in the way suggested by Mr Campbell is a reason why the skilled person would conclude that that was not its intended meaning.

80. In effect, in claims 2 to 4, the skilled person is being told to use his or her common general knowledge to balance between two competing needs; the need for peel strength and the need to maintain the same tactile/visual characteristics of the surface of the comfort layer in and out of the weld zone. The former requires him or her to avoid embedding too few fibre filaments of the comfort layer. The latter requires him or her to avoid embedding too many.

81. Finally, lying at the heart of Coloplast's claim as it is now formulated, is claim 6 which is for:

> "A collecting bag according to any one of claims 1 – 4, wherein said textile material is a woven material".

Obviousness

82. Turning to the bases on which Salts challenges the validity of the Patent, I will deal first with the issue of obviousness. Here, Salts' pleaded case was that the Patent is invalid because its claims did not involve any inventive step (i.e. they were obvious) having regard to (1) the six pieces of cited prior art (including the five pieces referred to above) and (2) the common general knowledge. I now only need consider this argument by reference to the claims described as claims 6A, 6B and 6C.

The test: inventive step/obviousness

83. Under s.1(1)(b) of the Patents Act 1977, a patent may only be granted in respect of an invention that "involves an inventive step". In closing, Mr Lykiardopoulos questioned the emphasis that Salts placed on those words and pointed to the fact that s.3 of the Patents Act provides that:

> "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 that forms part of the state of the art by virtue only of section 2(2) (and disregarding section 2(3))."

84. Despite this, it seems to me that Salts were right to emphasise that a court must bear in mind that the issue is, ultimately, whether the claims involved an inventive step. The reason for this was explained by Jacob LJ in *Actavis UK Limited v Novartis AG* [2010] EWCA Civ 82 at [36]-[37]:

> "36. Another aspect of obviousness which is not readily answered by the PSA[3] is illustrated by the 5¼ inch plate paradox. This runs like this. Suppose the patent claim is for a plate of diameter 5¼ inches. And suppose no-one can find a plate of that particular diameter in the prior art. Then (a) it is novel and (b) it is non-obvious for there is no particular reason to choose that diameter. The conclusion, that the plate is patentable, is so absurd that it cannot be so.
>
> "37. What then is the answer to the paradox? It is this: the 5¼ inch limitation is purely arbitrary and non-technical. It solves no problem and advances the art not at all. It is not inventive. And although "inventive step"

[3] The PSA was the problem and solution approach used in the EPO when dealing with the issue of obviousness, see *Actavis* at [25].

> is defined as being one which is not obvious, one must always remember the purpose of that definition – to define what is inventive. That which is not inventive by any criteria is not made so by the definition. Trivial limitations, such as specifying the plate diameter, or painting a known machine blue for no technical reason are treated as obvious because they are not inventive."

The Pozzoli questions

85. In determining whether the claims would have been obvious to the skilled person having regard to the state of the art at the priority date, it is helpful to follow the so-called *Windsurfing/Pozzoli* approach.[4] This involves asking the following questions:

> (1) (a) Identify the notional "person skilled in the art"
> (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?

86. As noted by Lord Hodge in *Actavis Group PTC EHF v ICOS Corporation* [2019] UKSC 15 at [60], questions (1) to (3) are a means of disciplining the court's approach to the statutory question, which is question (4).

Pozzoli question (1)

87. I have already dealt with *Pozzoli* question (1)(a) and (b), the identity of the skilled person and what constituted the common general knowledge of that person.

Pozzoli question (2): the inventive concept

[4] See *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588 at [23].

88. As to *Pozzoli* question (2), the claimed technical contribution or inventive concept relied on by Coloplast was set out in Mr Lykiardopoulos' closing submissions, namely:

> "The patent for the first time teaches that a woven fabric can be used and welded in such a way to form an integrated comfort layer with improved properties".

89. It was not entirely clear whether this formulation of the inventive concept was accepted by Mr Campbell. In closing he pointed out that Ms Becke, when asked to identify the technical contribution of the claims relied on by Coloplast, had said nothing about the use of a woven fabric but had referred instead to achieving a product that balanced two competing needs (the need to have a sufficient peel strength and the need to have a comfort layer whose tactile/visual characteristics were the same in and out of the weld zone). However, looking at Ms Becke's evidence as a whole, her characterisation of the inventive concept was the same as that of Mr Lykiardopoulos. Indeed, it seems clear to me that in the passage relied on by Mr Campbell, the idea of using of a woven fabric was implicit in her answer given that she was responding to a question about the inventive concept involved in claims 6A, 6B and 6C, which all require the use of a woven fabric.

Pozzoli questions (3) and (4) – the approach

90. The third and fourth *Pozzoli* questions require me to compare that inventive concept with (i) each of the five specific pieces of prior art relied on and (ii) the common general knowledge as at the priority date and to ask (without reference to the alleged invention and without using hindsight) whether any differences identified involved steps that would have been obvious to the skilled person.

91. In determining whether the relevant steps were obvious, the court proceeds on the basis that "the skilled person, while having the compendious knowledge of the state of the art which section 2(2) requires, has no inventive capacity." (see *Actavis Group v ICOS* at [59]).

92. The approach to be adopted by the court has been explained as follows:

> "The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters

> as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."

See *Generics (UK) Ltd v H Lundbeck* [2007] EWHC 1040 (Pat) per Kitchin J at [74] and *Conor v Angiotech* [2008] UKHL 49 per Lord Hoffman at [42]. See also *Actavis Group v ICOS* at [63] where Lord Hodge also pointed out that the list of factors set out by Kitchin J was illustrative and not exhaustive.

93. In order to establish obviousness, it is enough to show that the idea said to be an invention would have occurred to the skilled person. It is not necessary to show that the skilled person would actually have implemented that idea. In *Actavis (UK) v Novartis AG*, Jacob LJ referred to this (at [42]) as "the could/would point" and, having referred to a passage in the EPO's Guidelines for Substantive Examination, he concluded at [46]-[47] that:

> "46. I do not read this as involving a requirement that the notional skilled person would actually physically implement the idea. What the passage is saying, sensibly enough, is that it [is] not enough the skilled man could have arrived at the invention from the prior art, it must be shown that he would have done. Whether he would actually press ahead and implement the idea depends on a host of other, commercial considerations.
>
> "47. That that must be so seems to me to be self-evident. A requirement that an idea can only be held obvious upon proof that it would actually be implemented would make many self-evident ideas non-obvious. For many obvious ideas may not be worth implementing commercially."

94. The same point was made by Birss J in *Hospira v Genentech* [2014] EWHC 3857 (Pat) at [229]:

> "… the word "would" is not always straightforward. Sometimes asking simply if a skilled person "would" do something risks placing too much weight on what are really minor or irrelevant factors like cost, instead of focusing on the technical issues. Moreover, the well-known 9½ inch plate[5] is not something a skilled person would make. It is more accurate to say that it is not patentable because the skilled person could make it without any inventive step."

[5] Birss J presumably intended to refer to the 5¼ inch plate referred to by Jacob LJ in *Actavis v Novartis* – see above.

95. Further assistance as to the correct approach to the issue of obviousness was provided by the Court of Appeal in *Asahi Medical Co Limited v Macopharma (UK) Limited* [2002] EWCA Civ 466. There Aldous LJ made the following points: first, at [21]:

> "I… must first make it clear that a decision on obviousness does not require a conclusion as to whether or not the skilled person would be slightly, moderately or particularly interested in any document. The court has to adopt the mantle of the skilled person. That mantle will include the prejudices, preferences and attitudes that such persons had at the priority date. Thereafter the court has to decide whether the step or steps from the prior art to the invention were obvious."

At [23]:

> "[Counsel] submitted that an invention would not be obvious unless there was some motivation to implement the disclosure in the prior art and to take the steps required to arrive at the invention. In certain cases that can be right. Such cases are usually those where the invention lies in the idea of taking a step. However, motivation may not be a requirement. The fact that nobody would dream of making a plate one inch bigger than the standard size does not mean that there would be invention in making one."

Then, at [25], Aldous LJ referred to the submissions of counsel to the effect that "it was not obvious because the skilled person would not in practice have thought of implementing it". He rejected those submissions on the basis that:

> "If the step from the prior art lacked invention, then it mattered not whether anybody would have thought of implementing it. The public are entitled to make obvious modifications. Whether they would want to do so will depend upon a variety of factors which could include such things as cost and the attitudes of users."

Finally, at [26], Aldous LJ set out counsel's submissions, namely that the correct question was "what the skilled person 'would' have done having read the prior art. No doubt he 'could' have made modifications, but there was no perceived useful purpose in either implementing the prior art or making modifications to it." At [27], Aldous LJ rejected those submissions and counsel's attempt to put cases into either a "would" category or a "could" category. He said:

> "… provided the structured approach in *Windsurfing*[6] is adopted there is no need for the Court first to decide whether the invention falls into one of those categories and then to decide which one. The isolation of the inventive concept in the first step and the ascertainment of the difference between that and the prior art in the third step, naturally lead the court to answer the correct question: namely, whether the invention was obvious. Evidence as to what could or could not or what would or would not be done can be relevant, but the correct question is that laid down in the statute."

96. In answering the statutory question, it is important to bear in mind what inventive means. An idea may be technical and may achieve a technical result. However, to be inventive, it must be adding something to the existing stock of knowledge. This addition might be the idea of using an existing technique to do something which no-one had previously thought of doing. Or it might involve finding a way to do something which people had wanted to do but had not been able to think how. Or it might be finding a way of solving a problem standing in the way of achieving a goal (see Lord Hoffmann in *Biogen Inc. v Medeva Plc* [1997] RPC 1 at 34).

97. The fact that an idea had not previously been implemented, or that there had been an unexplained delay in adopting an idea, can help show that that idea was inventive. This is the argument that: "if obvious, why was it not done before?" on which Coloplast relies in this case. However, some care is needed in this regard. In particular, as Laddie J pointed out in *Brugger v Medic-Aid Ltd* [1996] R.P.C. 635 at p.654,

> "The court has to be alert to the difference between commercial attractiveness and technical obviousness. They are not always the same. Failure to modify a piece of prior art, even if that delay extends over a long period, may be due to commercial factors rather than perceived technical obstacles."

Laddie J went on to note that there may be numerous explanations as to why a particular step had not been taken, such as, for example, a "commercial constraint" caused by a reluctance to change existing tooling, or "complacency in

[6] Now *Pozzoli*

relation to existing products or processes", or the "adequacy of existing products". He concluded (on p.655) that:

> "It is only when the answer to the question 'why was this not developed earlier' is 'a likely and reasonable explanation is that people looking for a way around an existing problem did not see this as the answer' that the age of the prior art should play a part in meeting an obviousness attack. If it is likely that in the real world no one was looking for an answer the fact that none was found says nothing about whether the answer proposed by the patent under attack was obvious."

Finally, in response to an argument that because of the success of existing products it had not been obvious to make any modifications to the existing prior art, Laddie J stated that:

> "That, it appears to me, is a non sequitur. The fact, if it be one, that existing commercial products are highly successful and satisfactory does not indicate that there are no obvious modifications to make to them. It merely demonstrates that there may be little incentive to those already making those products to change the design—a quite different matter."

Pozzoli questions (3) and (4): the present case

98. Turning then to the present case, I am satisfied that the concept relied on by Coloplast in its claims (i.e. the use of a woven to make a comfort layer with improved properties) was not inventive as at May 2012 when viewed in the light of the common general knowledge at that time. In reaching this conclusion, it seems to me that the following points are relevant.

99. First, as I have found, it was common general knowledge that a woven fabric could be used to make an integrated comfort layer. This is not a case where the idea was to use a material in an unanticipated or unexpected way. Rather, the idea was to use a material (a woven) that was well known to the skilled person and to use it in a way that was known to be possible, a way that had, in fact, been expressly anticipated by persons involved in the design of ostomy bags (as evidenced by the Watkins, Dircks and Willis prior art). This suggests that the idea was not inventive.

100. Second, the skilled person would not have seen the use of a woven material for an integrated comfort layer as being

unlikely or difficult to achieve in technical terms. There was no suggestion that the techniques used to weld a non-woven material would not have worked in respect of a woven material with, if necessary, some adjustments and experimentation in order to ascertain the appropriate combination of material (e.g. polyester, polyethylene or polypropylene) and welding methods (heat, RF or ultrasound) and welding parameters (temperature, time and pressure). Those techniques were common general knowledge. Indeed, the Patent does not set them out and must therefore proceed on the assumption that the skilled person would be well aware of them and would be able to use them in respect of a woven material to achieve a product meeting claims 1 to 4. Using those techniques, it was routine to achieve partial embedding (i.e. less than 100%) of the fibres of the comfort layer in the barrier film (claim 1) and a peel strength of more than 5N/12.5mm width (claim 2). Further, as I have found, the skilled person would have known that the weld zone did not have to be glossy and rigid and that it was possible to achieve a comfort layer surface with the same tactile and visual characteristics in and out of the weld zone (claims 3 and 4) by adjusting the choice of materials and welding conditions (for example, by using a woven polyester welded at a temperature below its melting point or by RF welding). Again, this suggests that the use of a woven in the way described in the Patent was not inventive.

101. Third, the reasons why woven materials had not been used previously were not technical but were commercial. They were the greater cost of woven materials over non-woven, the costs associated with changing machinery and systems set up to deal with non-wovens so as to deal with wovens and (probably, to a lesser extent) environmental concerns because the use of wovens typically involve a larger quantity of plastic. For the reasons set out by Laddie J in *Brugger*, the fact that, for commercial reasons, people had not previously used wovens for integrated comfort layers does not suggest that such use would be inventive. It simply shows that such use was commercially unattractive (see also Jacob LJ's "could/would point" referred to in paragraph 93 above).

102. Mr Lykiardopoulos submitted that these commercial reasons would still apply now and yet woven products sold by Coloplast and Salts now account for 24% of the UK market. On that basis, he submitted, the question had to asked "what has changed?" The answer, he said, was two-fold. First, that no-one had previously thought of using a woven in this way and that "using

very well-known materials in a way not thought of before is the stuff of invention". Second, that the Patent had disclosed that there were advantages associated with the use of a woven material, advantages that had previously not been appreciated.

103. I reject these arguments. In my judgment, on the basis of Mr van der Leden's evidence, it appears that companies such as Coloplast and Salts are now prepared to use a woven fabric because, with appropriate marketing in more affluent markets such as the UK, they have decided that the commercial disadvantages of using a woven could be overcome. As regards Mr Lykiardopoulos' reference to the 24% figure, even assuming that was not an attempt to raise an unpleaded "commercial success" argument, I do not see how it helps Coloplast. Again, on the basis of Mr van der Leden's evidence, the current success of the parties' woven products could well be due to commercial factors such as marketing and to the efforts of sponsored stoma nurses. It does not mean that the idea underlying the Patent must have been inventive.

104. As to the argument that previously no-one had thought of using a woven in this way, I have already found that the possibility of using wovens in this way was common general knowledge. Indeed, people skilled in the art had expressly thought of exactly such use, as evidenced in Watkins (application published in 1981), Dircks (published December 2005) and Willis (published September 2008). Against this, Mr Lykiardopoulos pointed out that Mr van der Leden, when asked about attaching a woven material to an ostomy bag, had said: "No, I have never done it, and also have never thought of doing it". In my judgment, Mr van der Leden was not suggesting that he (or the skilled person) was unaware of the possibility of using a woven. Rather, he was saying that it did not occur to him actually to use it given the cost and environmental concerns (of which he was very aware) and given that non-woven materials were in his view performing perfectly adequately. He was certainly not saying that the idea of switching to a woven would have been seen as inventive. Indeed, he made it very clear that in his view the skilled person in 2012 would not have regarded that idea as inventive.

105. Turning to the argument that the Patent was inventive because it disclosed previously unappreciated advantages associated with the use of a woven. The first such advantage relied on by Mr Lykiardopoulos related to the strength of the bond between the comfort layer and the barrier film and was that "The Patent

teaches that a skilled person can do away with the hard, glossy weld, but still maintain the strength". I do not accept that this was inventive. In my judgment, the skilled person would have been well aware that, whether using a woven or a non-woven material, it was possible to achieve a weld with a sufficient peel strength and without the need for a hard and glossy weld zone. It was a relatively simple matter and depended on the nature of the particular material and the welding parameters used. The reason why the weld zones of ostomy bags before May 2012 had typically been hard and glossy (and had typically involved a greater degree of embedding of fibres of the comfort layer) was not because the skilled person thought that they had to be hard and glossy in order to achieve sufficient peel strength. Rather, it was because, as Mr van der Leden said, "patients, in general, like to have a glossy weld because the pouch looks safe to them. They can see that it is welded".

106. The second technical advantage said to have been disclosed by the Patent was that by using a woven material it was possible to achieve a weld zone whose surface retained the same tactile and visual characteristics as the surface of the rest of the comfort layer and, in particular, a surface that was softer. In this regard, I accept Ms Becke's evidence that such objectives could be seen as desirable. Indeed, Salts' own advertisements from 2010 and 2011 referred to its ND13 ostomy bags as having "soft edges for increased comfort" and a "new softer weld along edge of pouch". Similarly, Coloplast's advertisement for its SenSura Mio product made with a woven integrated comfort layer included what Ms Becke referred to as a "beautiful" photograph of the surface of the comfort layer demonstrating more clearly than words the attractive visual effect where the surface of the weld zone matches that of the rest of the comfort layer. Having said this, I do not accept that the idea of using a woven material to achieve these objectives was inventive or that the Patent taught the skilled person anything in this regard. In my judgment, the skilled person would have been well aware that, whether using a woven or a non-woven material, it was perfectly possible to change the tactile or visual characteristics of the weld zone depending on his or her choice of material (polyester, polypropylene or polyethylene) and of welding parameters. For example, Mr van der Leden's evidence (which I accept) was that avoiding having too sharp or rigid a weld "was easy to manage, by changing the temperature, dwell time and pressure".

107. Further, in my judgment, the fact that no-one had previously used a woven to achieve these objectives does not mean such use was not obvious. Rather, such non-use was far more likely to be referable to the fact that there was not thought to be any problem associated with the tactile or visual characteristics of existing bags with non-woven comfort layers. In this regard, Ms Becke admitted that, despite her researches, she had been unable to find any evidence of any complaints based on a lack of softness. Mr van der Leden's evidence was that "I have never seen anyone who was interested in the appearance of the weld" and that "there has never been so much attention about the weld zone as I saw in the past week here".

108. The third technical advantage said to be disclosed by the Patent was that the use of a woven fabric for an integrated comfort layer gave the bag a greater resistance to external forces, such as tearing, snagging and pilling forces (pilling being where due to wear small balls of fibre form on the surface of a material). It was unclear whether Salts accepted that a woven integrated comfort layer did offer greater resistance to external forces given that, in closing, Mr Campbell pointed to Professor Barron's evidence that:

> "I make a composite on a polymer, a non-woven could be stronger than the woven, not because I have got more interactions, but because the fibres are actually more embedded".

It is possible that Professor Barron was here simply talking about the peel strength of the composite, but if he was talking about the ability of the composite material to resist tearing, then I do not accept this evidence. The experts agreed that wovens have a greater inherent ability to resist tearing than non-wovens. If this is so, I cannot see how that position would be reversed simply as a result of their being bonded to a barrier film. Further, if that was Professor Barron's view, then it was not supported by the other experts. Mr van der Leden (Salts' other expert) stated that "I fully agree that this woven comfort layer is stronger, is more resistant to anything…" and Ms Becke was also clear that non-wovens were less strong than wovens. It would also be contrary to the evidence of Ms Becke and Mr van der Leden to the effect that an ostomy bag with a woven integrated comfort layer would stay in better condition than one with a non-woven integrated comfort layer. Finally, it would be difficult to reconcile with Salts' advertisements for its Confidence BE product which, as Mr Lykiardopoulos pointed

out, mentioned that "The new and improved textile fabric has been designed to look great, no matter how long it's worn".

109. Whilst I accept that a woven material for an integrated comfort layer did offer greater resistance to tearing, I do not accept that this shows that the idea to use a woven to achieve this greater resistance was inventive. This was not a case of the discovery of an unexpected benefit for, in my judgment, the skilled person would have been well aware from his or her common general knowledge that a woven material offers a greater resistance to external forces due to its interlaced structure. The claimed benefit was, in my judgment, the obvious consequence of the use of a woven material. I cannot see that it involved any inventive step.

110. Further, in my judgment, the fact that wovens had not previously been used to provide this increased resistance to external forces does not suggest that the idea to use a woven to achieve that objective was inventive. This was not a case where the idea solved an unrecognised problem. Rather, the reason for such non-use was that there was no real need to provide for a greater resistance to such forces. The only documentary evidence suggesting that there was any problem with existing comfort layers was the comment in Dircks (at [0007]) that non-woven comfort layers "can snag on clothing at times" and Salts' advertisement referred to above suggesting (indirectly) that ostomy bags with non-woven integrated comfort layers did not stay in as good a condition as those with woven integrated comfort layers. It is true that Ms Becke said that she believed (based on her experience with other products) that snagging and pilling in particular were an issue. However, she accepted that, despite her efforts, she had been unable to find any evidence of tearing, snagging or pilling occurring in real life but simply general references to "user comfort". In my judgment, the reason for this lack of evidence of a problem is that there was no real problem. In this regard, I accept Mr van der Leden's evidence that:

> "There is nothing wrong with the comfort layer. I am more than 40 years in the business. I have never seen these problems that you say here."

He went on to qualify this slightly by referring to a single exception when, as a result of using a non-woven of a lower density, he had received complaints (albeit only of pilling). He also said that he had seen users in psychiatric hospitals trying

to remove a stoma and destroying a pouch and he suggested (in my view, with his tongue firmly in cheek) that there may be a problem if a user wished to wear "clothes with sharp edges". However, otherwise and in normal use, he was clear that he could see no advantage in the use of a woven to give an ostomy bag greater resistance to external forces. It was, he said "simply not a problem". He concluded that:

> "I deny that before that there was a lot of problem with bobbling, fraying, snagging, pilling… I have not seen them".

111. For these reasons, I have concluded that the claims of the Patent did not involve any inventive step. I should note, however, that I do not accept Mr Campbell's argument that the Patent is invalid insofar as claim 4 was referring to a characteristic that was aesthetic rather than technical. As Mr Lykiardopoulos said, the technical contribution was the use of a woven material. If that contribution had been inventive, then the fact that it had only had an aesthetic result would not have prevented the grant of the Patent. The Patent would have been to protect the technical idea that led to that aesthetic result and not the result itself. It is not like, for example, an idea that a bag should be blue in colour. Similarly, I do not see that it matters that the claims themselves do not expressly suggest that use of a woven integrated comfort layer provides greater user comfort and/or resistance to tearing, snagging and pilling. Again, had the technical contribution (the use of a woven) been inventive, there was no need to spell out in the claims the benefits that that contribution would provide.

112. I turn now to consider obviousness in the light of the particular pieces of prior art relied on by Salts. I will deal with these in the order in which Mr Campbell relied on them in his closing submissions, namely, Watkins, the Dansac Novalife, the ND13, Dircks and, finally, Willis.

Obviousness in the light of the prior art - Watkins

113. Watkins was a UK patent published on 23 January 1985 and based on an application which had been filed on 9 December 1980 and published on 17 June 1981. It was, therefore, around 30 years old at the priority date of the Patent. It was for an "ostomy device" and was described by Mr van der Leden as "brilliant" and as "the basis of modern pouches". In closing, Mr Lykiardopoulos said that Watkins "would have been considered

a foundational patent in the ostomy industry" and that it had "effectively predicted where the industry would go over the next 30 years".

114. The first aspect of the invention in Watkins (see pages 2 to 6) related to an adhesive flange to connect the device to the stoma. Nothing turns on this. However, it is worth noting that Watkins only contemplated the use of a non-woven fibre material for the flange.

115. The next aspect of the invention in Watkins was intended to address the problems described at pages 6 – 7, namely that the main body of ostomy devices, being made of an impermeable material, suffered from moisture and perspiration and could feel unpleasant against the skin and could "emit an embarrassing rustle when flexed". Having described earlier attempts to solve these problems by the use of removable fabric covers or of integral covers attached to the device by adhesives, Watkins went on (at page 7) to teach a different solution (reflected in its claims 5 and 6). This was that the impermeable plastic film should have:

> "a cover… made from one of two sheets of a woven or non-woven material in which the fibre and any binder used is non-dielectric, the film and the one or two sheet of fibre material being all united together at their edges with a radio frequency welded seam."

The reference to this cover being made from "a woven or non-woven fibre material" was repeated (twice) on page 8, where the point was also made that the material should be "not dielectric" and "not thermoplastic at the heat sealing temperature of the film".

116. On page 9, Watkins provided for a variant on the invention whereby the cover (yet again said to be made of a "woven or non-woven fibre material") should be similarly bonded to "a composite element" (rather than to just a film). However, the essence of the invention remained the use of a woven or non-woven integral cover.

117. Finally, on page 10, Watkins noted that:

> "The only requirements for the woven or non-woven fibre material is that it shall be made from a non-dielectric fibre and that any binder shall also be non-dielectric. Non-

> woven materials are preferred for costs reasons. Examples of suitable materials are those made from polyester fibres or cellulose fibres, for example viscose rayon fibres."

118. Turning then to *Pozzoli* questions (3) and (4). The two sides adopted different approaches to these questions. Mr Campbell sought to identify differences between Watkins and the individual claims of the Patent and to explain why, in his submission, those differences did not involve an inventive step. In contrast, Mr Lykiardopoulos submitted that:

> "In terms of the *Pozzoli* analysis, Watkins discloses the use of a polyester woven material to form the comfort layer and teaches welding it around the periphery of the pouch with RF welding. The question remains (a) whether a Skilled Person would be motivated to do anything differently from the CGK on being shown Watkins and, if so, what that might be."

He then went on argue that, although Watkins disclosed the use of a polyester woven material, those were simply options. He noted that, in the 30 years since Watkins, wovens had not been used and that there was nothing in Watkins to tell the Skilled Person *why* he may want to change this and nothing which might encourage the Skilled Person "to think of giving wovens a try". He also argued that if the skilled person did decide to follow Watkins, the obvious material to use would have been a non-woven polyester given that "Watkins teaches that the same material should be used for the comfort layer as for the flange… and only a nonwoven material is disclosed for the flange". However, he then submitted that most manufacturers (Coloplast and Dansac being the exceptions) were not interested in using polyester because "it would not fit their existing processes". Overall, his position was that there was "no reason on reading this 30-year-old document why the Skilled Person would switch to using a polyester comfort layer".

119. It seems to me that Mr Lykiardopoulos' approach is contrary to that set out in *Pozzoli* and contrary to the guidance from the authorities that I have summarised in paragraphs 93 to 97 above. The question is not whether or not the skilled person reading Watkins would have been led or motivated actually to take the step in question (or, in Mr Lykiardopoulos' words "to do something differently" or to give it "a try" or to make "a switch"). Rather, the question is whether, on reading Watkins,

the relevant step would have appeared obvious to the skilled person or whether it required any degree of invention and, in answering that question, the focus must be on technical issues and on whether the step had added something to the existing stock of knowledge. As Birss J pointed out in *Hospira* (see paragraph 94 above), "… the well-known 9 ½ inch plate is not something a skilled person would make. It is more accurate to say that it is not patentable because the skilled person could make it without any inventive step." Similarly, as Aldous LJ pointed out in *Asahi* (see paragraph 95 above), "If the step from the prior art lacked invention, then it mattered not whether anybody would have thought of implementing it."

120. In my judgment, the step involved in this case (the idea of using a woven material for the comfort layer) was not inventive over Watkins and it added nothing to the existing stock of knowledge. A skilled person looking at Watkins (a "brilliant" or "foundational" patent) on the priority date in May 2012 would have noticed that Watkins specified the use of a non-woven for the flange but repeatedly referred to the use of a "woven or non-woven fibre material" for the integral cover. In view of this, it is difficult to argue that the idea of using a woven material (something expressly disclosed in Watkins) was nevertheless inventive. That difficulty is all the greater given that Watkins did not suggest that were any technical difficulties in using a woven and instead made clear that the only reasons for preferring non-wovens were "costs reasons". It seems to me that Mr Lykiardopoulos' approach requires the skilled person to ignore the teaching of Watkins and I do not accept that that would be what the skilled person would have done, particularly given the foundational status of that Patent and the fact that its teaching with regard to wovens would have accorded with what was common general knowledge as at May 2012. In this regard, I reject Mr Lykiardopoulos' submission that, in using a woven (or for that matter a polyester), the skilled person would be doing something differently from the common general knowledge and, hence, that such use was inventive. As I have found, the possibility of using a woven was common general knowledge and the skilled person would have known that the reason why it had not actually been tried in the 30 years since Watkins was because there were commercial disadvantages and because there was no particular problem with existing ostomy bags with non-woven integrated comfort layers.

121. A further point made by Mr Lykiardopoulos was that Watkins:

> "does not tell the Skilled Person what weld zone characteristics he should be aiming for. There is therefore no reason to think that he would achieve the tactile or visual characteristics of integers 3.1 and 4.1."

Ms Becke made the same point, asserting that Watkins had not disclosed the inventive concept relied on because it did not teach the skilled person how to meet the objectives of the Patent. Again, I do not agree. In my judgment, the skilled person would have known that, in implementing Watkins using polyester and RF welding (as envisaged by Watkins), the resulting product would meet the requirements of integers 3.1 and 4.1 because the fibres of the comfort layer would not melt and would only be partly embedded. In this regard, Mr van der Leden said when using polyester and RF welding (as per Watkins):

> "…you have a higher chance that in the welding zone the tactile and the visual characteristics are the same or about the same as the rest of the pouch than the case that they are not."

Although he was referring here to a non-woven polyester, his point would apply equally to a woven polyester. Similarly, the skilled person would have known from his or her common general knowledge how to achieve these objectives using different forms of material or welding. Either way, given the common general knowledge of the skilled person as at May 2012, the difference between the disclosures in Watkins and the idea of using a woven material to meet integers 3.1 and 4.1 of the Patent did not involve any inventive step.

122. Finally, as regards Watkins, Coloplast (rightly) does not rely on the fact that Watkins provides for the comfort layer to be attached by means of peripheral welding, whereas the inventive concept of Patent involves a comfort layer with a welding zone(s) or "zone(s) of attachment" and does not refer to the periphery. Nor does Coloplast rely on the fact that Watkins provides for the comfort layer to be attached by RF welding whereas the claims of the Patent simply require it to be "attached". I cannot see that these differences involve any inventive step. In both cases, the Patent is simply less specific than Watkins and in implementing Watkins, the skilled person would end up within the claims of the Patent.

Obviousness in the light of the prior art – Dansac Novalife

123. The second piece of prior art relied on by Salts was the Dansac Novalife product. This was a drainable ostomy pouch with a non-woven comfort layer peripherally welded on both sides of the pouch and made (as was common ground in closing) of polyester. It was common ground that it meets the peel strength requirements of claim 2 and that the surface of the comfort layer in its weld zone had the same tactile and visual characteristics as its surface outside the weld zone and would, therefore, also meet claims 3 and 4 of the Patent.[7]

124. On this basis, the only issue as regards obviousness over the Dansac Novalife was whether the step from using a non-woven to using a woven as the material for the integrated comfort layer was an inventive step. As Mr Lykiardopoulos submitted, this really raises two separate questions; first, whether it was obvious to change from a non-woven to a woven and, if so, second, whether it was obvious to do so in such a way as to ensure that the tactile and visual characteristics of the comfort layer remained the same in and out of the weld zone (i.e. whether in a way that still satisfied claims 3 and 4).

125. As to the first of these questions, Mr Lykiardopoulos argued that the skilled person would not think of making any such change and would not want to make such a change. Indeed, he submitted that the only reason to make a change would be to meet the claims of the Patent which would involve improperly applying hindsight. He relied on Ms Becke's evidence that the skilled person would have had no motivation to make a change from a non-woven to a woven and on Mr van der Leden's evidence that neither he (Mr van der Leden) nor the skilled person would have considered changing the Dansac Novalife so as to use a woven.

126. It seems to me that, as was the case with regard to Watkins, this approach places too much emphasis on whether the skilled person would have made a change (i.e. on what he would have done or not done) rather than on asking the statutory question, namely whether the step involved was inventive. Given my finding that it was common general knowledge that a woven fabric could be used for an integrated comfort layer, I do not accept that the skilled person would have seen this change as inventive. I accept that Mr van der Leden said that he (and in his view the skilled person) would not have thought of changing

[7] In cross examination, Ms Becke said that there was a difference in one small area at the bottom of the clothes facing side of the bag. However, it appears that Coloplast are not taking any point on this.

the Dansac Novalife and would not have wanted to change it. However, he also made it very clear that this was because the existing product was perfectly satisfactory ("so nice, so soft", "the softest pouch in the business"), because a change would involve time and expense and because wovens were more expensive. In other words, for commercial reasons. In giving her evidence as regards the Dansac Novalife, Ms Becke accepted that using a woven would be more expensive and that existing examples where wovens were used involved using more plastic and to that extent were less environmentally friendly. In these circumstances, the fact that the skilled person would not have thought of changing and would not have wanted to change the Dansac Novalife product does not mean that he or she would have regarded such a change as inventive. It was simply that he or she would have seen a change as commercially unattractive and unnecessary.

127. I should also note that I reject Mr Lykiardopoulos' argument that the case for obviousness is based on a knowledge of what the claims of the Patent involve and, therefore, hindsight. The *Pozzoli* approach requires one to look at the claims of the Patent in order to identify how they differ from the prior art. Without doing so, it is impossible to determine the issue of obviousness. Simply doing this cannot amount to impermissible hindsight.

128. The second question identified by Mr Lykiardopoulos (see paragraph 124 above) was that, assuming it was obvious to modify Dansac so as to use a woven, was it also obvious to do so in such a way that the resulting product would still satisfy claims 3 and 4.

129. In this regard, Mr Lykiardopoulos pointed to Ms Becke's evidence that, if a woven was used, it would not automatically follow that claims 3 and 4 would be satisfied; it would require experimentation. He also referred to Mr van der Leden's evidence that to change the comfort layer of the Dansac Novalife from a non-woven to a woven would require tests as well as changes to production lines. He argued that it was only the teaching of the Patent that would tell the skilled person that he or she should seek to satisfy claims 3 and 4 and that, without that teaching, it would not have been obvious to use a woven in such a way as to satisfy claims 3 and 4.

130. Again, I reject these arguments as they again focus on what the skilled person would have done rather than on whether the step involved could properly be called inventive. In my judgment,

the idea of using a woven in way to satisfy claims 3 and 4 was not inventive. As I have already found, the skilled person would have been well aware that it was possible to change the tactile or visual characteristics of the weld zone depending on his or her choice of material (e.g. polyester, polypropylene or polyethylene) and of welding parameters (heat, pressure, time). The skilled person would have known that if the woven material was made of polyester, then under normal welding conditions, the result would satisfy claims 3 and 4.

131. Further, I do not accept that it was only the teaching of the Patent that would have led the skilled person to look to satisfy claims 3 and 4. This is because the Dansac Novalife as it stood clearly satisfied those claims. Even if the skilled person was motivated to change one aspect of the prior art (i.e. to change the non-woven for a woven), that does not mean that he or she has to change another aspect. There is no reason to assume that in deciding to change to a woven, the skilled person would also decide to abandon the existing (attractive and notable) characteristics of the surface of the comfort layer in the weld zone, let alone to decide to go back to the hard glossy surface that was typical in bags other than the Dansac Novalife. Whilst it may have taken experimentation to ensure that the new woven material produced a result that would still satisfy claims 3 and 4, such experimentation would have involved techniques that were well known to the skilled person. They may have required time and effort, but there is no suggestion that they would have required inventiveness.

132. For these reasons, I conclude that the Patent was also obvious over the Dansac Novalife product.

Obviousness in the light of the prior art – ND13

133. The third piece of prior art is Salts' own ND13 product. This was a drainable ostomy bag made with a non-woven comfort layer made from polyethylene. At the edge of this bag, there were three distinct sections to the weld zone:

    a. An outer section of varying width, never more than about a millimetre wide and, in places, almost non-existent. The surface of the comfort layer in this outer section was glossy and plastic-like.
    b. Next in from the edge was a raised section some 2.5mm wide and referred to during the trial as the ridge. The surface of the comfort layer in this section was similar in

terms of look and feel to the surface of the rest of the comfort layer outside the weld zone.

c. An inner section furthest in from the edge. This was roughly 1.5mm wide and the surface of the comfort layer in this inner section was (like that of the outer section) glossy and plastic-like.

134. There was a dispute as to the nature of the welding process which gave rise to these 3 sections and, in particular, whether it involved using 2 heating bars (as Ms Becke suggested in her written evidence) or a single "U" shaped heating bar (as Mr van der Leden said in the course of cross examination based, it seems, on a conversation he had had with a representative of Salts). To the extent that it matters, I think that Mr van der Leden is more likely to be correct. But, so far as I am aware, nothing actually turns on this.

135. Further, whilst it was common ground that the inner and outer (glossy) sections had been welded and that some but not all of the fibres of the comfort layer in these sections had been embedded in the barrier film material, there was a dispute as to whether any of the fibres of the comfort layer in the ridge section had become so embedded. Ms Becke's evidence was they had not. In contrast, Mr van der Leden said in oral evidence that there had been embedding and that his view in this regard had been confirmed when, sitting his hotel room during the trial, he had cut up a sample ND13 with scissors, evidence to which Mr Lykiardopoulos objected on the basis that it was an impermissible experiment.

136. In my view, it seems likely that some of the fibres in the ridge section would have been embedded, particularly in the areas which had been nearest to the heating bars. However, I do not think that I need to resolve this. I can see that whether the ridge was part of the zone(s) of attachment and whether the fibres in that section had become embedded in the barrier film would be relevant if the ND13 was being used to challenge the novelty of the Patent. However, although that was pleaded, it was not argued in Salts' opening or closing submissions, presumably because any novelty claim based on the ND13 must fail given that the ND13 did not disclose the use of a woven comfort layer. Further, as set out below, I cannot see that this dispute is relevant to the issue of obviousness.

137. As regards obviousness in relation to the ND13, both parties submitted that the position was the same as for the Dansac

Novalife. Subject to one point, I agree. On that basis, as with the Dansac Novalife, I find that there was nothing inventive in the idea of changing from the non-woven polyethylene of the ND13 to the woven material of the Patent. I also find that there would have been nothing inventive in the idea of carrying out the welding in a way that would satisfy claims 3 and 4. That was simply a matter of applying the common general knowledge and was relatively simple to achieve, particularly in the case of a polyester comfort layer under typical welding conditions. Given this, I do not think that it matters which welding method had been used to make the ND13 or how many fibres in the ridge section of the ND13 had been embedded. Either way, achieving claims 3 and 4 was a matter of applying techniques that were common general knowledge.

138. For these reasons, I conclude that the Patent was also obvious over the ND13 product.

139. The one point of difference between the positions as regards the ND13 and the Dansac Novalife was that in looking at the ND13 bag (unlike the Dansac Novalife) the skilled person was not starting from a product which already satisfied claims 3 and 4. Accordingly, the point which I made in paragraph 131 above does not apply to the ND13.

Obviousness in the light of the prior art - Dircks

140. Dircks was a US patent application filed on 4 June 2004 and published on 8 December 2005. As Mr Lykiardopoulos says, the skilled person looking at Dircks in May 2012 would have seen that it departed from much of what was conventional in ostomy pouch design. In particular, at [0013]-[0014] it taught the use of a laminated structure consisting of "three distinct material layers", a fabric layer, an adhesive layer and a film layer. It stated that "the adhesive layer is between and preferably co-extensive with the facing surfaces of the film layer and the fabric layer. The suitably thick, co-extensive adhesive layer adds bulk to the thin film layer and penetrates the fibers of the fabric layer." In effect, unlike most bags, in which the comfort (fabric) layer was attached around the edge of the bag, Dircks taught full face attachment of the comfort layer and the use of an adhesive layer.

141. Significantly, Dircks also taught that the fabric layer (i.e. the comfort layer) "can be formed of a knit fabric, a woven fabric or a non-woven fabric…. preferably composed of fibers or filaments of a synthetic material such as nylon, polypropylene,

polyester, low density polyethylene…" (see Dircks [0016] and [0041]). Clearly, therefore, Dircks disclosed the possibility that an integrated comfort layer could be made using a woven fabric.

142. The advantages of Dircks were said to be that it had "low noise characteristics, excellent 'hand' or 'feel' and significantly reduced water cling characteristics" (see Dircks [0015]). However, in reality, it was not a success. Mr van der Leden said he had seen a similarly constructed pouch some 15 years earlier and had thought it to be a "lousy pouch". He was clear that the skilled person looking at the idea would have concluded that:

> "The skilled person in our company in 1990, when we were approached with this type of pouch, we immediately say, 'This is not going to work'. It limits the noise and it limits the water cling from the front of the pouch, which is excellent when you have a shower to just put a towel on and it is dry, perfect. But the back of the pouch, that will be a disaster for patients."

The differences – Pozzoli (3)

143. In relation to *Pozzoli* (3), Mr Lykiardopoulos submitted that the differences between Dircks and the inventive concept of claims 6A, 6B or 6C of the Patent were that:

a. Under Dircks, the fibres of the comfort layer would become partially embedded in the adhesive layer and not (as required under claim 1 of the Patent) in the barrier film, and

b. Due to the full-face attachment of the comfort layer in Dircks, there could be no surfaces of the comfort layer outside the zone of attachment as required under claims 3 and 4 of the Patent. The whole comfort layer was in the zone of attachment.

144. Mr Campbell submitted that there were no such differences and that Dircks had disclosed the substance of each of claims 1, 3 and 4.

(a) The partial embedding issue

145. As regards the partial embedding issue, Mr Campbell had two bases for arguing that Dircks had disclosed partial embedding of the fibres of the comfort layer in the barrier film material, such that there was no difference between that and claim 1 of the Patent.

146. Mr Campbell's first basis was that at [0005]-[0009] Dircks described earlier attempts to solve the problems that it identified, attempts that had involved comfort layers (sometimes peripherally attached) whose fibres had been embedded in the barrier film. There was, he said, no material difference between Dircks [0006] with the Patent [0009]. The former said:

> "[0006] In a perhaps more accurate description, the interstices of the non-woven or other fibrous layer are filled with melted and solidified ostomy film material as a result of the thermal bonding process."

Whereas the latter ended with the words:

> "….. The melted barrier film material at least partly flows into the interlaced fibre filament structure of the threads of the textile and thereby creates a physical anchorage between the two layers without destroying the structure of the textile material."

147. I agree. In my judgment, the skilled person seeing this would conclude that those passages were describing the same result. Indeed, when asked about Dircks [0006], Ms Becke accepted that it did reinforce the conclusion that the earlier attempts had resulted in some but not all of the fibres of the comfort layer becoming embedded in the barrier film, although she maintained that whether this would actually have occurred would depend on the method of thermally securing used.

148. Mr Campbell's second point was that the invention claimed in Dircks also disclosed partial embedding of comfort layer fibres in the barrier film. This was a matter of dispute between the experts. Ms Becke's evidence was, in effect, that although material from the adhesive layer would have bonded with adhesive outer layer of the barrier film, it would not have mixed with it (there would still have been a "distinct line" between them). Hence, the material in which fibres from the comfort layer would have become embedded was material from the

adhesive layer and not from the barrier film. In contrast, Mr van der Leden (whilst admitting that Ms Becke knew "much more about how polymers are made and how they react to each other") believed that, in implementing Dircks (particularly in the case of a thin adhesive layer), fibres of the comfort layer could end up embedded in the barrier film.

149. In support of Mr van der Leden, Mr Campbell referred to the SEM images of a sample product known as the "D1" which had been made for the purposes of this litigation according, Mr Campbell said, to the method of Dircks. Professor Barron's evidence was that these SEM images showed three layers; 2 outer woven layers and between them a central layer made up of five sub-layers of two types ("A" and "B") in an A,B,A,B,A sequence of varying widths (as shown in image 2 in the Appendix to his first report). His conclusion was that these images showed the outer woven layers partially embedded in that central layer which he said was the barrier film.

150. Mr Lykiardopoulos argued that the SEMs were of no value. He argued, first, that the sample had not been made according to Dircks and was therefore irrelevant. In my judgment, whilst it is true that the materials used for the sample were not those specified in the preferred embodiment of Dircks, they were within the parameters of the Dircks disclosure. Mr Lykiardopoulos also argued that it was impossible to draw any reliable conclusions from these SEMs. Whilst I agree that (as I have already mentioned) the process leading to the creation of this SEM image was very much less than ideal, I do not feel that I can reject Professor Barron's evidence as to what they show. In this regard, I note that the A,B,A,B,A sequence which he was able to discern was consistent with what might occur if 2 pieces of barrier film material made up in accordance with Salts' Notice of Experiments were welded together.[8] The fact that the adhesive layer cannot be separately discerned is, presumably, because it had become mixed with the EVA of the barrier film as a result of the heat welding process.[9]

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[8] i.e. a barrier film made of 5 layers - (i) EVA (an adhesive); (ii) EVA; (iii) PVDC; (iv) EVA and (v) EVA. Assuming the EVA is type "A" and the PVDC is type "B", then the film has an A,A,B,A,A sequence. If 2 pieces of barrier film are placed together, the sequence would be A,A,B,A,A,A,A,B,A,A. On being heat welded, the adhesive layers (A) will merge to form the sequence of A,B,A,B,A to which Professor Barron referred.

[9] Possibly supported by the fact that in image 2, the outer "A" sub-layers in the central layer are slightly wider.

151. On these reasons, I agree with Mr Campbell that there was no difference between the disclosures contained in Dircks and the claims of the Patent as regards the partial embedding of fibres of the comfort layer in the barrier film material.

(b) The difference as regards claims 3 and 4

152. As regards the second suggested difference between Dircks and the claims of the Patent, the issue here is whether the fact that Dircks envisages a full-face attachment of the comfort layer, means that it had disclosed something different to claims 3 and 4, which envisage there being zone(s) of attachment and require a comparison between the tactile and visual characteristics of the surface of the comfort layer in such zone(s) and of its surface outside such zone(s).

153. In my judgment, there is clearly a difference in this regard. Moreover, I reject Mr Campbell's argument that the requirement in claims 3 and 4 that there be a comfort layer surface outside the zone(s) of attachment is merely a semantic point. The skilled person would not see this requirement as semantic particularly given that the entire point of Dircks was to move away from the existing practice that involved comfort layers with zone(s) of attachment and, instead, to comfort layers with full face attachment.

Did the differences involve steps that were obvious – Pozzoli (4)

154. Under *Pozzoli* (4), the issue is whether the differences between Dircks and the claims of the Patent involved an inventive step.

155. In my judgment, the difference which I have found existed (the difference between a comfort layer attached with full face welding and a comfort layer with zone(s) of attachment) was not inventive. Indeed, as the latter was what Dircks was teaching the skilled person to move away from, it might seem surprising to go back to it, but it could hardly be said to involve an inventive step. Mr Lykiardopoulos may well be right in saying that the skilled person would not have thought of taking Dircks forward (in the sense that he or she would have done nothing with it) but that is not the test. The test is whether, having read Dircks with interest, the skilled person would have seen this difference as involving an inventive step.

156. I should note that if (contrary to my finding in paragraph 151 above) there had been a difference between the disclosures in

Dircks and the claims of the Patent as regards the partial embedding of fibres of the comfort layer in the barrier film material, I would not have regarded the step involved as being inventive. Even assuming that Dircks had not disclosed the partial embedding in the barrier film, it was part of the common general knowledge that this was possible depending (as Ms Becke herself said) on the method of thermally securing that had been used and particularly if the skilled person decided to dispense with the additional adhesive layer and to use a material such as polyester and typical welding conditions.

157. Mr Lykiardopoulos submitted that if the skilled person were to abandon the full-face welding and had gone back to the known method of perimeter welding, he or she would also have gone back to using a non-woven material for the comfort layer. Again, it seems to me that this involves focussing, wrongly, on what the skilled person would have done rather than on whether there was an inventive step. As I have found, the possibility of using a woven was common general knowledge in May 2012.

158. For these reasons, I conclude that the Patent was also obvious over Dircks.

Obviousness in the light of the prior art - Willis

159. The final piece of prior art was Willis. This was an international patent application filed on 14 January 2008 and published on 18 September 2008.

160. Willis sought to build on Dircks and was primarily concerned with how to attach components to the surface of an ostomy bag. The problem being that the "'fuzzy' non-woven or fibrous or fabric-like exterior surface of body collection devices" tended to provide a weak point of anchorage. To address this, Willis taught using either a 3-layer laminate (as taught by Dircks) or a 2-layer laminate (dispensing with the separate adhesive layer) and to apply heat to a selected part of the surface which would result in a film like surface where an attachment could be made. In this sense, Willis was teaching the opposite to the Patent. It sought to make specific areas of the comfort layer more rather than less film-like.

161. Willis does not expressly mention that the comfort layer could be made of a woven material. It does, however, envisage the use of a woven fabric. First, it says (at [0011]) that preferably the comfort layer will be "a natural or synthetic fabric selected

from one of cotton, silk, cellulose tissue, nylon, polypropylene, polyester, polyethylene or other polyolefins or copolymers or blends thereof". Then, (at [0028]) it incorporates the features of the material disclosed in Dircks.

162. As regards the *Pozzoli* (3) and (4) analysis, so far as Willis envisaged the use of a 3-layer laminate, the position is effectively the same as that considered above in relation to Dircks. The only additional differences being as regards specific areas intended to take attachments which are for present purposes irrelevant.

163. As regards the alternative 2-layer laminate to which Willis referred, it is hard to see any relevant difference between Willis and the claims of the Patent. Without an adhesive layer, there can be no doubt that implementing Willis could result in the fibres of the comfort layer being embedded in barrier film material. Indeed, Ms Becke accepted that, depending on the nature of the welding processes used, one would get partial embedding. Further, it was clear from Willis that this was likely to be the case given that the "fuzzy" quality of the surface with which Willis was concerned would have been a result of partial embedding. If I am wrong in this regard, then there is even less reason to believe that any difference as regards embedding when using a 2-layer laminate involved an inventive step than there was with Dircks.

164. The only relevant difference when the 2-layer laminate was used was, again, that between full surface welding and welding of zone(s) of attachment. In this regard, what I found with regard to Dircks applies equally to Willis. It was not inventive to go back to the very method of welding that Dircks was teaching the skilled person to move away from.

165. Mr Lykiardopoulos submitted that if the skilled person were to abandon the full-face welding and to go back to the known method of perimeter welding, he or she would also have gone back to using a non-woven material for the comfort layer and to weld in accordance with the common general knowledge thereby creating a weld with a firm, glossy characteristics (i.e. not in accordance with claims 3 and 4 of the Patent). Once again, I do not agree that it is correct to ask what the skilled person would have done. The issue is whether the difference identified involved a step that was inventive. For the reasons already set out, I find that the step involved was not inventive.

166. For these reasons, I conclude that the Patent was also obvious over Willis.

Novelty

167. Under ss.1 and 2 of the Patents Act 1977, to be patentable, the claimed invention must be new, meaning that it did not form part of the state of the art. Thus, where a piece of prior art clearly and unambiguously discloses the features of a claim, or discloses matter which, if performed, would inevitably fall within the claim, then that claim is not novel. Thus, a lack of novelty is a ground for invalidating a patent.

168. In its pleadings, Salts challenged the validity of the Patent on the ground of novelty over each of the pieces of prior art mentioned above. By the time of opening submissions, the novelty argument had been limited to Watkins, Dircks and Willis. However, in its written closing submissions, Salts did not put forward any novelty argument and, orally, Mr Campbell confirmed that whilst he had no instructions to drop the issue of novelty, he was not pushing the issue.

169. In my judgment, Mr Campbell was right not to push the issue of novelty. Dealing with the matter briefly, I find that the Patent would not have lacked novelty over the prior art. In particular:

    a. Watkins says nothing about the embedding of comfort layer fibres in the barrier film material, about peel strength or about the tactile and surface characteristics of the surface in the weld zone and, as the experts agreed, it was not inevitable that in implementing Watkins, the skilled person would end up within the claims of the Patent in those regards.

    b. The disclosures of the Dansac Novalife and ND13 products would have been limited to the precise characteristics of those products. They did not therefore involve the use of a woven integrated comfort layer.

    c. As set out above, Dircks may teach the partial embedding of the fibres of the comfort layer in the barrier film material and the use of a woven. However, it says nothing expressly about peel strength. Moreover, as set out above, because Dircks requires full-face attachment of the comfort layer, there can be no surface of the comfort layer outside the zone of attachment. It does not, therefore, disclose claims 3 and 4.

d. The position was regards Willis is the same as that for Dircks.

Insufficiency

170. I will deal next with the attack on the Patent based on insufficiency.

171. Salts' pleaded case includes (at paragraph 3(a)-(d) of its Re-amended Grounds of Invalidity) a number of insufficiency arguments relied on as a "squeeze". Given the way in which Coloplast has put its case, these arguments do not arise. It appears, therefore, that it is only the insufficiency arguments raised in paragraphs 3(f) and 3(g) that are now relevant.

172. Starting with the argument in paragraph 3(g), this was, in essence, that the Patent was insufficient in that it failed to specify the processing conditions necessary for the skilled person to make an ostomy bag which would satisfy claims 3 and 4 (i.e. a bag where the surface of the comfort layer in the zone(s) of attachment had the same tactile and visual characteristics as its surface outside such zone(s)). The law in this regard was summarised by Lord Briggs in *Regeneron v Kymab* [2020] UKSC 27 at [56] (with emphasis added):

> "i) The requirement of sufficiency imposed by article 83 of the EPC exists to ensure that the extent of the monopoly conferred by the patent corresponds with the extent of the contribution which it makes to the art.
> ii) In the case of a product claim, the contribution to the art is the ability of the skilled person to make the product itself, rather than (if different) the invention.
> iii) Patentees are free to choose how widely to frame the range of products for which they claim protection. But they need to ensure that they make no broader claim than is enabled by their disclosure.
> iv) The disclosure required of the patentee is such as will, **coupled with the common general knowledge existing as at the priority date**, be sufficient to enable the skilled person to make substantially all the types or embodiments of products within the scope of the claim. That is what, in the context of a product claim, enablement means.
> v) A claim which seeks to protect products which cannot be made by the skilled person using the disclosure in the patent will, subject to de minimis or wholly irrelevant exceptions, be bound to exceed the contribution to the art

made by the patent, measured as it must be at the priority date.

vi) This does not mean that the patentee has to demonstrate in the disclosure that every embodiment within the scope of the claim has been tried, tested and proved to have been enabled to be made. Patentees may rely, if they can, upon a principle of general application if it would appear reasonably likely to enable the whole range of products within the scope of the claim to be made. But they take the risk, if challenged, that the supposed general principle will be proved at trial not in fact to enable a significant, relevant, part of the claimed range to be made, as at the priority date.

vii) Nor will a claim which in substance passes the sufficiency test be defeated by dividing the product claim into a range denominated by some wholly irrelevant factor, such as the length of a mouse's tail. The requirement to show enablement across the whole scope of the claim applies only across a relevant range. Put broadly, the range will be relevant if it is denominated by reference to a variable which significantly affects the value or utility of the product in achieving the purpose for which it is to be made.

viii) Enablement across the scope of a product claim is not established merely by showing that all products within the relevant range will, if and when they can be made, deliver the same general benefit intended to be generated by the invention, regardless how valuable and ground-breaking that invention may prove to be."

173. Applying these principles, the claimed contribution to the art was to enable the skilled person to use a woven fabric in such a way so as to form an integrated comfort layer within claims 1 to 4 of the Patent. The sufficiency issue is whether the disclosure of the Patent "coupled with the common general knowledge" would have allowed the skilled person to make the product(s) as claimed.

174. As set out above, in my judgment the Patent did not involve an inventive step because it was well known that a woven could be used in such a way as to achieve claims 1 to 4, and because the means of achieving the requirements of claims 1 to 4 involved using materials and techniques that were part of the common general knowledge. The corollary of this must be that the disclosure of the Patent was not insufficient.

175. In closing, Mr Campbell argued that the disclosure of a patent would not be sufficient if making the product would require

"undue effort" or prolonged research, enquiry or experiment. In this regard he referred to the evidence of Ms Becke to the effect that for the skilled person to be able to implement the Patent in a way that satisfied the claims would require "experimentation". However, that evidence was given by Ms Becke in support of her argument that the Patent involved an inventive step. It seems to me that it is difficult to conclude that the degree of experimentation required meant that the Patent was insufficient given that I have rejected the argument that that degree of experimentation showed that there had been an inventive step. Moreover, in other evidence, Ms Becke made clear that she did not regard the Patent as being insufficient because:

> "… it does set out the requirements, so you would be able to do your experiments knowing what the requirements are and therefore you would be able to get to the result…."

176. Turning to the insufficiency argument raised in paragraph 3(f) of the Re-Amended Grounds of Invalidity, this was that the Patent is insufficient because it fails to teach the skilled person how to ascertain whether the surface of the comfort layer in the zone(s) of attachment has the same tactile and visual characteristics as its surface outside such zone(s). This is, in effect, an argument that the Patent is insufficient because it is uncertain (the word "uncertainty" being preferred to the word "ambiguity" which was formerly used, see *Anan Kasei Co. Ltd v Neo Chemicals and Oxides Limited* [2019] EWCA Civ 1646 at [25]).

177. What "uncertainty" means for these purposes was considered in *Generics (UK) Limited v Yeda Research and Development Co. Ltd*. At first instance ([2012] EWHC 1848 (Pat)), Arnold J stated at [162] that:

> "… it is necessary to distinguish between claims that are difficult to construe or that have a "fuzzy boundary" (in the words of Lord Hoffmann in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46, [2005] RPC 9 at [126]) on the one hand from claims that are truly ambiguous on the other. It is regrettably common for claims to be difficult to construe, but the court will nevertheless strive to give such claims a sensible meaning having regard to the inventor's purpose. It is also common for claims to have a fuzzy boundary, because an integer

> of the claim involves some question of degree or an imprecise functional limitation. It is well established that is not itself objectionable. If a claim is truly ambiguous, so that it is unclear what is the correct test to determine whether or not a product or process infringes, however, then the claim is insufficient…"

178. Then, on appeal ([2013] EWCA Civ 925), Floyd LJ said at [78]:

> "It is sometimes difficult to determine where the precise boundary of a claim lies. In such cases what matters is whether the skilled person knows what the test is he has to apply to determine infringement."

179. Mr Campbell argued that claims 3 and 4 were not just fuzzy around the edges but were uncertain because they provided no means by which it could be ascertained whether a product did or did not fall within those claims. This was not, he said, a construction issue, but a testing issue.

180. I will deal with the construction point below when dealing with infringement. However, in my judgment, claims 3 and 4 are not uncertain. The test is clear; it is whether the tactile and visual characteristics of the surface of the comfort layer are the same in and out of the zone(s) of attachment. It seems to me that it is no more unclear than (for example) the statutory tests for novelty and individual character in design law[10] and for registration and infringement of a trade mark.[11] As Mr Lykiardopoulos points out, neither Ms Becke nor Mr van der Leden had difficulty ascertaining what was required under claims 3 and 4.

***AgrEvo* obviousness**

181. I will deal now with Mr Campbell's argument that the Patent was invalid on the basis of principles derived from the decision of an EPO Board of Appeal in *AgrEvo* (T939/92). The issues that arise in this regard are often referred as *AgrEvo* obviousness.

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[10] Whether an "identical design has been made available to the public" and whether "the overall impression [a design] produces on the informed user differs from the overall impression produced on such a user by any design which has been made available to the public….". See Registered Designs Act 1949, ss.1B(2) and (3) and the Community Designs Regulation (6/2002), Arts.5 and 6.
[11] Whether the mark is identical or similar to another mark, see Trade Marks Act 1994, ss.5 and 10.

182. The law as regards *AgrEvo* obviousness was summarised by Floyd LJ in *Generics (UK) Limited v Yeda Research and Development Co. Ltd* [2013] EWCA Civ 925 at [49]:

> "i) Article 56 of the EPC is in part based on the underlying principle that the scope of the patent monopoly must be justified by the patentee's contribution to the art;
> ii) If the alleged contribution is a technical effect which is not common to substantially everything covered by a claim, it cannot be used to formulate the question for the purposes of judging obviousness;
> iii) In such circumstances the claim must either be restricted to the subject matter which makes good the technical contribution, or a different technical solution common to the whole claim must be found;
> iv) A selection from the prior art which is purely arbitrary and cannot be justified by some useful technical property is likely to be held to be obvious because it does not make a real technical advance;
> v) A technical effect which is not rendered plausible by the patent specification may not be taken into account in assessing inventive step;
> vi) Later evidence may be adduced to support a technical effect made plausible by the specification;
> vii) Provided the technical effect is made plausible, no further proof of the existence of the effect is to be demanded of the specification before judging obviousness by reference to the technical effect propounded."

183. The overlap between *AgrEvo* obviousness and the issue whether a claim is inventive is apparent from that summary. Indeed, in his oral closing submissions, Mr Campbell stated that *AgrEvo* "is on the boundary between obviousness and insufficiency" and in his written closing submissions he noted that "What has become known as *AgrEvo* obviousness is to be regarded as an approach to the assessment of inventive step under s.1(1) of the Patents Act 1977, and not as any separate statutory test for invalidity."

184. On the facts of this case, I do not think that *AgrEvo* adds anything to the grounds of obviousness as against the common general knowledge and insufficiency with which I have dealt above. However, in case I was wrong in finding that the Patent involves no inventive step (i.e. if I was wrong in finding that the Patent made no contribution to the art), I should deal with Mr

Campbell's argument that the Patent was nevertheless invalid under the *AgrEvo* principles as set out by Floyd LJ because its claims went beyond its alleged technical contribution. This, he argued, was because the contribution reflected in claims 1 to 4 is not something that all wovens offer; it will depend on the nature and specification of the material used and the welding conditions used, none of which are specified in the claims.

185. I reject this argument. In my judgment, Coloplast's claimed technical contribution does not relate to all uses of all wovens. It relates only to the use of wovens in a way that will meet claims 1 to 4. In the words of Floyd LJ, those claims are "restricted to the subject matter which makes good the technical contribution" and are not, therefore, invalid on the *AgrEvo* basis. As regards Mr Campbell's argument that the materials and welding conditions were not specified, I have already rejected this argument when dealing with the insufficiency issue.

186. Accordingly, if (contrary to my finding) the Patent had involved an inventive step, I would not have concluded that the Patent was nevertheless invalid on the basis of *AgrEvo* obviousness.

Added Matter

187. The final basis on which Salts challenges the validity of the Patent is for added matter.

188. The law in this regard was summarised by Floyd LJ in *AP Racing Limited v Alcon Components Limited* [2014] EWCA Civ 40 at [9], where he said that:

> "In the end the question is the simple one posed by Jacob J (as he then was) in Richardson Vick's Patent [1995] RPC 568 at 576 (approved by him as Jacob LJ in Vector Corporation v Glatt Air Techniques Ltd [2007] EWCA Civ 805; [2008] RPC 10 at [4]):
>
> > "I think the test of added matter is whether a skilled man would, upon looking at the amended specification, learn anything about the invention which he could not learn from the unamended specification.""

And by Kitchin LJ in *Nokia OYJ (Nokia Corporation) v IPCom GMBH & Co. KG* [2012] EWCA Civ 567, who said that:

> "59. It follows that it is not permissible to introduce into a claim a feature taken from a specific embodiment unless the skilled person would understand that the other features of the embodiment are not necessary to carry out the claimed invention. Put another way, it must be apparent to the skilled person that the selected feature is generally applicable to the claimed invention absent the other features of that embodiment.
> 60. Ultimately the key question is once again whether the amendment presents the skilled person with new information about the invention which is not directly and unambiguously apparent from the original disclosure. If it does then the amendment is not permissible."

189. In effect, in a case such as the present, the court is required to construe the application and the patent, looking through the eyes of the skilled person, to see whether the latter discloses something not clearly and unambiguously disclosed by the former. The comparison is a strict one but the relevant disclosure can be implied, in the sense that it is something that the skilled person would take for granted (a stricter test than the "obviousness" test considered above). See, generally, *European Central bank v Document Security Systems* [2007] EWHC 600 per Kitchin J at [97]-[102].

190. It should be noted that, for these purposes, the claims of the application as filed form part of its disclosure (see section 130(3) of the 1977 Act).

191. Salts' claim is that claim 1 of the Patent has added matter over that which was contained in the application in that it has sought to take a feature from the disclosures in the application but without the context in which that feature had been so disclosed – a process referred to as "intermediate generalisation" (see, for example, *Palmaz' European Patents* [1999] RPC 47 per Pumfrey J at [71]). The particular words complained of are the words "some but" which were added to Claim 1 in the Patent. The issue, therefore, is whether these words are telling the skilled person anything which he or she could not have learned from the application.

192. The starting point, therefore, is to look at the application. This contains the following (with emphasis added):

    a. On p.2, lines 10 to 15, the application stated that the claimed invention relates to a comfort layer made of "a

textile material having a number of threads each comprising a plurality of fibre filaments, and such textile material is attached to said barrier film in one or more zones of attachment such that **not all** of the fibre filaments of the textile material in said zone(s) are embedded in the barrier film material".

b. At p.2, line 23 to p.3, line 8 the application provided more detail as to the means and nature of the attachment and the point was made that the textile material has a higher melting point than the barrier film. Importantly, here, the disclosure was that the comfort layer maintained its structure "because **some, but not all,** of the fibre filaments of the threads are wholly or partially embedded in the melted barrier film material".

c. Claim 1 of the application was for: "A collecting bag for human body waste comprising a barrier film covered by a comfort layer, wherein the comfort layer is a textile material having a number of threads each comprising a plurality of fibre filaments, and said textile material is attached to said barrier film in one or more zones of attachment such that **not all** of the fibre filaments of the textile material in said zone(s) are embedded in the barrier film material."

193. This needs to be compared with the Patent. The Patent contains the following:

a. Para.[0006] which is in identical terms to the passage in the application quoted in paragraph 192(a) above. In other words, it uses the words "**not all**".

b. Paras.[0009]-[0013] which are in identical terms to the passage in the application which I have summarised in paragraph 192(b) above. In other words, they contain the words "**some, but not all**".

c. Claim 1 of the Patent is identical to Claim 1 of the application, save that the words "**not all**" are replaced by the words "**some, but not all**".

194. In my judgment, this change to Claim 1 does not tell the skilled person anything beyond what had been disclosed in the application. It seems to me that the skilled person reading the passages of the application referred to in paragraphs 192(a)

and (b) above would have assumed that the phrases "not all" and "some, but not all" were intending to describe the same result. The skilled person would have concluded that the application had adopted the words from the former but could just as well as adopted the words of the latter. In so far as there was any doubt as to what the words used in claim 1 of the application meant, the skilled person would have construed those words in the light of the detailed description which had used the words "some but not all".

195. As a separate point, it seems to me that insofar as there was any difference between the different wordings, the difference was as to whether (at a minimum) the required attachment was of only one filament or of two filaments. As the Opposition Division of the EPO found in rejecting Salts' added matter argument, the skilled person would not have thought that there was any technical difference between these. They were both unworkable as forms of attachment for the product in issue.

196. The Patent, therefore, adds nothing to the application. In substituting for the words "not all" the words "some, but not all", the Patent was simply using different words to describe the same result. Certainly, no new technical matter had been added.

197. Mr Campbell argues that this is a case of an intermediate generalisation because the words "not all" have been added stripped from their context (i.e. the context provided by the various requirements summarised in paragraph 192(b) above). I do not accept this argument. If the words of claim 1 of the Patent stripped the words used from their given context, then so too did claim 1 of the application. I cannot see, therefore, that the Patent has added anything to the application.

198. It seems to me that Mr Campbell's intermediate generalisation argument is exactly the argument that which was rejected by the Opposition Division in para.2.1 of its decision. Mr Campbell then points out "An argument of intermediate generalisation succeeded" in para.4.2 of that decision. However, the argument that succeeded in para.4.2 of the Opposition Division's decision did not relate to claim 1 as it was before me but instead to a proposed amended version of claim 1 as set out in an auxiliary request intended to counter a novelty challenge to claim 1. The proposed amendment involved adding a passage to claim 1 to reflect five out of the six features disclosed in the paragraphs of the application which I have summarised in paragraph 192(b)

above. The point that the Opposition Division made in para.4.2 of its decision was that in omitting one of those six features, the proposed amendment was adding matter to the claim because it was not making that claim in the full context in which it had been disclosed. As para.4.2 deals with a different (proposed) version of claim 1, I do not see how this helps Mr Campbell.

199. It may be that Mr Campbell's objection relates to the fact that Coloplast's case now requires Claim 1 to be read as a dependency of claim 6. In effect, claim 1 is now to be read as including a requirement that the material in question should be a woven (and not just a textile). However, I do not see that this involves adding anything to claim 1. Rather, it narrows it.

Infringement

200. I turn now to deal with the issue of infringement of the Patent. This is, of course, only relevant if I am wrong in concluding that the Patent is invalid.

201. As already mentioned, by the time of the trial, Coloplast's case had narrowed such that it relied only on Claim 6 with three different dependencies based on Claims 1, 2, 3 and 4. For convenience, these were referred to as Claims 6A, 6B and 6C and the integers of these Claims were summarised in the following table taken from Ms Becke's first report.

Claim Integers		Claim 6A	Claim 6B	Claim 6C
1.1	A collecting bag (1) for human body waste comprising	□	□	□
1.2	a barrier film (20a, 20b)	□	□	□
1.3	covered by a comfort layer	□	□	□
1.4	wherein the comfort layer is a textile material (10) having a number of threads (15) each comprising a plurality of fibre filaments (17, 18)	□	□	□
1.5	and said textile material (10) is attached to said barrier film (20a, 20b) in one or more zones of attachment	□	□	□
1.6	characterized in that some but not all of the fibre filaments (18) of the textile material (10) in said zone(s) are embedded in the barrier film material (20a, 20b)	□	□	□
2.1	wherein the peel strength between said comfort layer and said barrier film (20a, 20b) is above 5 N/12.5mm width in said zone(s)	□	□	□
3.1	wherein those fibre filaments (18) that are not embedded in the barrier film material (20a, 20b) provide a surface of the comfort layer having the same tactile characteristics as the surface of the comfort layer outside the zone(s) of attachment	□	□	□
4.1	wherein those fibre filaments (18) that are not embedded in the barrier film material (20a, 20b) provide a surface of the comfort layer having the same visual characteristics as the surface of the comfort layer outside the zone(s) of attachment	□	□	□

6.1	wherein said textile material (10) is a woven material.	□	□	□

202. As can be seen, claim 6C is the narrowest claim and requires Coloplast to establish that Salts' Confidence BE product satisfies all of the claim integers identified above. By contrast, claim 6A omits integer 4.1 (relating to the visual characteristics of the surface of the comfort layer) and claim 6B omits integer 3.1 (relating to tactile characteristics of the surface of the comfort layer).

203. It is common ground that Salts' Confidence BE products satisfy integers 1.1, 1.2 and 1.3. This is admitted by Salts in its Response to the Claimant's Notice to Admit Facts.

204. Whilst it is not formally admitted, it is clear from the images in Coloplast's Notice of Experiments and from Professor Drummond-Brydson's unchallenged evidence with regard to those images, that Salts' Confidence BE products also satisfy integer 1.4.

205. That integers 1.5 and 6.1 are satisfied with respect to Salts' Confidence BE products is clear from Salts' Re-Amended Product Description.

206. In its opening Skeleton Argument, Salts indicated that it had issues as regards integer 1.6. However, those issues were not pursued at trial or in Salts' Closing Submissions. To the extent that there is any doubt, I find that the SEM image of a Salts' Confidence BE product which is included in Coloplast's Notice of Experiments and Professor Drummond-Brydson's evidence in relation to that image clearly show that integer 1.6 is satisfied as regards the Confidence BE products and this appears also to have been accepted by Professor Barron.

207. Salts did not formally admit that integer 2.1 was satisfied. However, it did not advance any case with regard to this integer at trial and, given Coloplast's Notice of Experiments and Ms Becke's evidence, it is clear that the Confidence BE products satisfy integer 2.1.

208. At trial, the issues on which Salts focused with regard to infringement related to integers 3.1 and 4.1. The issues here are, in essence, whether the surface of the comfort layer of the Confidence BE products in the welding zone(s) has the same tactile characteristics (claim 3.1) and/or the same visual characteristics (claim 4.1) as the surface of the comfort layer

outside the welding zone(s). In this regard, the parties were agreed that the issue was one to be determined by the court and, although Mr Campbell referred me to evidence given by the experts, I did not find that evidence to be of any real assistance on this issue.

a. Professor Drummond-Brydson's evidence as regards the tactile characteristics was qualified (as regards the front of the bag, "it feels fabricy in the centre. It may feel different at the outside"; as regards the back, it "feels similar"). As regards the visual characteristics, the question he was asked mischaracterised the test in that he was not asked to concentrate on "the surface". In any event, his answer was again qualified ("They scatter the light differently, but then again there is also areas in the centre of the bag that scatter the light").

b. Ms Becke accepted that the tactile characteristics were "somewhat different" on the clothes facing side of the bag but not on the skin facing side. She also concluded that there were no visual differences. Mr Campbell criticised this conclusion saying, first, that she had based her conclusion on the fact that she could see the woven fibres and, second, that the very fact that "she could perceive the location of the weld zone … could only mean that its visual characteristics were in fact different". For the reasons set out below, I reject these criticisms. Indeed, with regard to the second criticism, it is interesting that, giving evidence with regard to the Dansac Novalife bag on which the location of the weld zone is perfectly apparent, Mr van der Leden was able to say with certainty that "you cannot see the difference between the weld and the non-welded area." Clearly, his view of the test to be applied was different to that of Mr Campbell.

c. Mr van der Leden's evidence was that a blind man could feel and see the difference in the tactile and visual characteristics. However, it was unclear to me on what basis this difference was so obvious given his view that there were no such differences in the case of the Dansac Novalife bag.

209. Ultimately, as both sides submitted, this is a matter for the court, applying the test laid down by the Patent. Mr Campbell urged me to take a strict approach as to what was meant by

the words “the same”, such that the test would not be satisfied in any case where the location of the weld could be perceived. For the reasons set out below, I do not accept that that would be the correct approach.

a. The Patent at [0003] makes clear that the invention is seeking to move away from ostomy bags with the characteristics of a “relatively hard or non-flexible welding zone” and welding which is “quite visible because all material in the welding zone is mixed and results in a relatively uniform surface after cooling, thus compromising the visual appearance of the collecting bag”.

b. At [0005], the Patent asserts that the invention will result in a bag with “improved visual and tactile characteristics”.

c. More specifically, at [0013] the Patent refers to the invention giving rise to a structure where “the feel or tactility of the welded zone or area, is softer than is the case with the welding zone of non-woven material, partly because the textile material stays intact and only bonds with the barrier film instead of melting into a continuous mass, and partly because not all of the fibre filaments are embedded in the melted barrier film material.” For these purposes, the word “softer” is said to mean “that the resulting attachment or welding zone is less rigid, or more flexible” when using a textile according to the invention than if a non-woven had been used.

d. Finally, at [0036], the Patent notes that the comparison between the different surface areas may be based on physical criteria such as the degree of light reflection and/or tendency to pilling or snagging but may also be based on subjective criteria evaluated by a team on the basis of “criteria such as visual appeal and softness to the skin on, e.g., a 1-5 step scale”.

210. In my judgment, these are all indications that the Patent does not require a strict application of the words “the same”. Indeed, it seems to me that the references in [0036] to “may” and to “subjective criteria” and to “a 1-5 step scale” are clearly contrary to such a construction. Nor, it seems to me, is there any support for Mr Campbell’s argument that the test requires that one should not be able to perceive the weld zone.

211. Instead, it seems to me that, for the purposes of integer 3.1, the subjective criterion that I should apply is whether, as a result of the weld, the surface in the weld zone is no longer as "soft" as the remainder of the surface and has become more rigid and inflexible (as it would where the comfort layer used a traditional non-woven material). In my judgment, whilst as a result of the weld the comfort layer of Salts' Confidence BE products is clearly anchored to the barrier film in the weld area, I do not perceive this to result in the surface of the comfort layer in that area being less soft or in its being more rigid or inflexible than its surface outside that area. Accordingly, in my judgment, the surface of the comfort layer in the weld area has the same tactile characteristics as the remainder of the comfort layer and integer 1.3 is satisfied by the Confidence BE products.

212. Similarly, for the purposes of integer 4.1, the subjective criterion that I should apply is whether, as a result of the weld, the surface in the weld zone no longer has the appearance of the textile from which the comfort layer was made and has instead acquired a "uniform" appearance or the appearance of a "continuous mass" in which separate fibre filaments of the textile are not apparent. In my judgment, applying this test, the surface of the comfort layer in the weld area of the Confidence BE products has the same visual characteristics as the remainder of the comfort layer in that the fibre filaments on the surface in the weld zone remain perfectly visible and distinct. The surface does not appear to be a "continuous mass" any more than the surface of the rest of the comfort layer does.

213. As a cross check, I have looked at the samples of other sample products included in the trial bundles (such as Coloplast's "Original" SenSura Mio product and Salts' ND13 product) where a non-woven fabric has been used for the comfort layer. With these products, the surface of the comfort layer in the weld zone clearly has a uniform or continuous mass appearance which is quite different to its surface outside the weld zone.

214. I should note, in response to a further point raised by Mr Campbell, that my assessment of the tactile and visual characteristics of the comfort layer of Salts' Confidence BE products is unaffected by the colour of the relevant product and applies equally to the product in the colour black.

215. For these reasons, had the Patent been valid, I would have found that Salts' Confidence BE products fall with each of claims 6A, 6B and 6C and infringed the Patent.

Conclusion

216. For the reasons set out above, whilst I reject Salts' claims that the Patent was invalid on the grounds of novelty, insufficiency or added matter, I accept Salts' claim that the Patent was invalid in the ground of obviousness because the concept relied on by Coloplast under the Patent was not an inventive concept. The idea that a woven material could be used as the material for an integrated comfort layer of an ostomy bag in a way that fell within each of claims 6A, 6B and 6C of the Patent was obvious over the common general knowledge of the skilled person and also over the specific prior art disclosures relied on by Salts.

217. For the reasons set out above, I will dismiss this action and I will grant appropriate relief as sought in the Counterclaim.