Patents Act 1977 **Opinion Number** **02/26**

OPINION UNDER SECTION 74A

Patent	GB 2585265 B
Proprietor(s)	Oakmed Ltd
Exclusive Licensee	
Requester	Salts Healthcare Ltd
Observer(s)	
Date Opinion issued	30 April 2026

The request

1. The Comptroller has received a request from Salts Heathcare Limited (the requester) to issue an opinion on the validity of GB 2585265 B (the patent).

2. The patent has a filing date of 24 March 2020 and a claim to an earlier priority date of 29 March 2019. The patent was granted on 17 August 2021 and it remains in force.

3. No observations were received and consequently there were no observations in reply.

4. A European patent EP 3801656 B1 was granted which claims priority from the same priority application. The European patent was revoked in opposition proceedings before the European Patent Office which held that the claims of the European patent lacked novelty.

5. The request questions the validity of the patent based on the disclosures of US 2007/0020319 A1 (O1 - published 25 January 2007) or WO 2017/158340 A1 (D1 - published 21 September 2017).

6. Additional prior art documents to support the requester's arguments are referred to as follows:

   O2: US 2007/0212314 A1 published 13 September 2007
   O3: US 2007/0078197 A1 published 5 April 2007
   O4: Handbook of Pharmaceutical Excipients, 6th edition; Rowe R. C., Sheskey P. J. & Quinn M. E. (Eds); Pharmaceutical Press, 2009.

7. The numbering reflects that used in the opposition proceedings.

8. All the documents were published prior to the priority date of the patent.

Preliminary matters

9. D1 was cited as background art during pre-grant processing of the application. For opinion requests, the Office may refuse to consider documents already considered unless there is a *new question*.

10. The requester has provided new evidence in the form of new prior art (O3) and has argued that the claims lack an inventive step based on a combination of D1 and O3. *Prima facie* this is a *new question* which will require consideration as part of the opinion. In order to determine inventiveness, I will necessarily have to consider what differences exist between the claims and D1, i.e. novelty will inevitably also be considered.

11. D1 and O1 were also cited in opposition proceedings at the European Patent Office in relation to the EP equivalent patent EP 3801656 B1. The opposition proceedings found that the patent lacked novelty.

12. There is a question of whether I should issue the opinion in view of the decision in the opposition proceedings. Firstly, I do not consider that I am bound by that decision as it relates to a different albeit very similar patent. Although the independent claims are substantially identical, there are differences in the remaining claims. Secondly, if I were to refuse the opinion it would potentially frustrate operation of Section 73(1A) which allows the comptroller to revoke a patent if an opinion finds it clearly invalid. I note also that the opposition proceedings were not contested by the proprietor and there was no hearing. I therefore consider it appropriate to issue the requested opinion.

The patent

13. The patent relates to an adhesive composition for adhering articles to the skin. In particular, it describes an adhesive for securing an ostomy appliance to the peristomal skin region of an ostomate.

14. Typically, collection bags for ostomates having a colostomy, ileostomy or urostomy are secured by an adhesive disc to the abdomen of the user such that they surround the stoma. It may be necessary to remove the collection bag for emptying several times daily. Such frequent removal causes irritation and can damage the skin. In order to reduce the frequency of removing the collection bag from the skin, two piece systems are known which comprise a base layer or wafer attached to the skin and a coupling part attached to the collection bag. The coupling part mates with cooperating regions of the base layer to attach the collection bag to the user. The collection bag may then be removed without having to remove the adhesive connection to the skin.

15. Regardless of whether a one or two piece system is used, a suitable compromise is required for the adhesive between the strength and security of the adhesion, comfort and ease of release when the disc or base layer needs to be changed. The patent

specifies an adhesive composition which is stated to provide improved security of adhesion and release characteristics.

16. In particular, the invention is based on a silicone polymer network adhesive which includes a water soluble permeability modifying polymer.

Claim construction

17. As a first step in determining validity I must correctly construe the claims. This means interpreting them in the light of the description and drawings as instructed by Section 125(1). In doing so I must interpret the claims in context through the eyes of the person skilled in the art. Ultimately the question is what the person skilled in the art would have understood the patentee to be using the language of the claims to mean. This approach has been confirmed in the decisions of the High Court in *Mylan v Yeda*[1] and the Court of Appeal in *Actavis v ICOS*[2].

18. There are two independent claims. Claim 1 is directed to an adhesive component comprising a silicone polymer network adhesive with a water soluble permeability modifying polymer. Claim 19 is directed to a method for manufacturing an adhesive component including the step of incorporating a water soluble permeability modifying polymer.

19. Claim 1 reads:

> *1. A skin compatible component attachable to mammalian skin comprising:*
>
> *a silicone polymer network derived from the addition curing of a first part including a vinyl functionalised siloxane polymer and a second part including a silicon hydride containing crosslinker, in the presence of a metal catalyst; and*
>
> *a superabsorbent particulate distributed within the polymer network configured to absorb moisture from the skin; and*
>
> *a permeability modifying polymer distributed within the polymer network, the permeability modifying polymer being a water soluble polymer having hydrophobic domains.*

20. Claim 19 reads:

> *19. A method of manufacturing a skin compatible component attachable to mammalian skin comprising:*
>
> *mixing a first part including a vinyl functionalized siloxane polymer with a second part including a silicon hydride containing crosslinker to form a mix;*
>
> *incorporating within the mix a superabsorbent particulate;*

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[1] *Generics UK Ltd (t/a Mylan) v Yeda Research and Dev. Co. Ltd & Anor* [2017] EWHC 2629 (Pat)
[2] *Actavis Group & Ors v ICOS Corp & Eli Lilly & Co.* [2017] EWCA Civ 1671

incorporating within the mix a water soluble permeability modifying polymer having hydrophobic domains; and

curing the mix via a metal catalyst;

wherein the superabsorbent particulate and the permeability modifying polymer are distributed within the resulting addition cured silicone polymer network.

21. Although the claims refer to a *component*, it is clear that this need be nothing more than an adhesive composition. In particular, claim 16, which is directed to an ostomy coupling, requires "*a skin compatible component as claimed in any preceding claim attached to a second surface of the support layer*." As such the *component* itself does not include the support layer, i.e. wafer or base layer.

22. Claim 1 is defined in part as a product by process (addition curing). This process is governed by the nature of the materials. Two-part silicone adhesives containing a platinum catalyst will undergo addition curing. No issues are considered to arise as a consequence of this definition.

23. There are not considered to be any other issues relating to claim construction.

24. The full list of claims is provided as an appendix.

Prior art – O1 US 2007/0020319 A1

25. O1 discloses a skin-friendly silicone based adhesive.

26. Example 8 of O1 (paragraph [0066]) discloses an adhesive composition as follows:

EXAMPLE 8

Adhesive with Improved MVTR Prepared by Using PEG

95 parts of silicone 7-9800 and 5 parts of silicone 7-4300 dissolved in n-hexane were mixed with 25 part of CMC, and 25 parts of polyethylene glycol 600 were added and gently stirred to favor the formation of microdroplets, after 3 minutes of stirring. The mixture was coated on a PU film, and cured. When the coating was cured the film was exposed to vacuum for 30 min. The MVTR was increased from 900 gr/m2/24 h to 1100 gr/m2/24 h.

27. The following chemicals are referred to:

Silicone 7-9800 – two part hydrophobic silicone resin with a component A comprising a catalyst (Pt [0061]) and component B comprising a cross-linking agent [0056].

Silicone 7-4300 - hydrophilic silicone resin from Dow Corning [0055]

CMC – carboxy methyl cellulose. Claim 4 of the patent refers to

carboxymethyl cellulose as a superabsorbent particulate.

28. Further evidence of the composition of silicone 7-9800 is provided in O2. It is described as follows (Table 1 footnote):

> ******7-9800*** *is the reaction product of a dimethylvinylsiloxy terminated dimethyl siloxane, trimethylsiloxy terminated dimethyl, methyl hydrogen siloxane and a hydrogen terminated dimethyl siloxane in the presence of a platinum catalyst.*

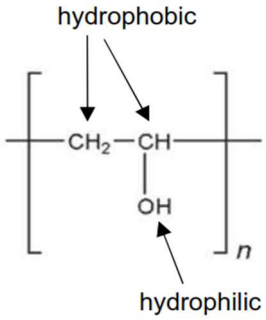
29. O1 teaches a number of embodiments of skin compatible adhesives. Those that include silicone 7-9800 comprise a silicone polymer network derived from the addition curing of a first part including a vinyl functionalised siloxane polymer and a second part including a silicon hydride containing crosslinker. The embodiment of example 8 also includes CMC, and therefore also comprises a superabsorbent particulate configured to absorb moisture from the skin.

30. The final part of claim 1 requires a water soluble permeability modifying polymer which has hydrophobic domains.

31. One example of such a polymer given in the patent is polyvinyl alcohol.

32. The requester observes that polyvinyl alcohol must accordingly have hydrophobic domains. They also observe that claim 7 of the patent requires that the permeability modifying polymer has hydrophilic domains, and polyvinyl alcohol must also possess these domains. Their explanation for the presence of the hydrophilic and hydrophobic domains in polyvinyl alcohol is as follows:

> *5.6 The patent lists polyvinyl alcohol (PVA) as an example of a permeability modifying polymer (see page 11, lines 24 to 25 and page 12, lines 11 to 12). Furthermore, Example 2 of the patent comprises polyvinyl alcohol as the permeability modifying polymer (see Table 2, page 23).*
>
> *5.7. Polyvinyl alcohol has the following structural formula (which is an annotated version of the structural formula from page 564, section 5 of O4).*



> *5.8. Hydroxyl (OH) groups are hydrophilic. Methine (CH) and methylene (CH_2) groups are non-polar and generally considered to be hydrophobic. Accordingly, the methine (CH) and/or methylene (CH_2) groups must be considered to be the hydrophobic domain(s) of the polyvinyl alcohol.*

5.9. Indeed, this must be the case, otherwise the patent, in particular Example 2, discloses permeability modifying polymers which fall outside the scope of the claims.

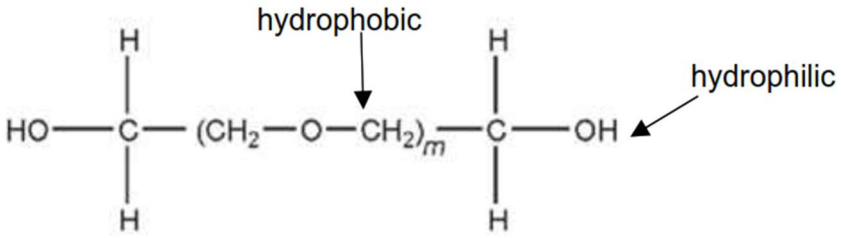
5.10. Therefore, the patent must be interpreted such that a methine (CH) and/or a methylene (CH_2) group of the permeability modifying polymer constitutes a "hydrophobic domain" and a hydroxyl (OH) group of the permeability modifying polymer constitutes a "hydrophilic domain".

33. I do not agree with this assessment. Polyvinyl alcohol is normally produced by hydrolysis of polyvinyl acetate. It is typically not fully hydrolysed (e.g. 80-90 mol%), and it is the remaining acetate groups which provide the hydrophobic domains. I consider that the skilled person would recognise that the hydrophobic domains of polyvinyl alcohol are provided by the remaining vinyl acetate groups, and the hydrophilic domains are provided by the vinyl alcohol groups.

34. This is relevant to the requester's arguments about additional polymers which might be considered to have hydrophobic domains. The requester argues that <u>any</u> polymer with a methine (CH) or methylene (CH_2) group should be considered to possess hydrophobic domains. I do not consider that to be the case. Whilst it may be true for some polymers, I do not consider it to be true for all polymers comprising CH or CH_2 groups.

35. In relation to the anticipation of claim 1, the requester argues that PEG 600 added to Example 8 of O1 is a permeability modifying polymer with hydrophobic domains as follows:

5.38. PEG has the following structural formula (which is an annotated version of the structural formula from page 517, section 5 and Table 1 of O4), wherein m is 13.2 for PEG 600.



5.39. As outlined above, based on the teachings of the patent, methylene (CH2) groups should be interpreted as hydrophobic domains. As such, PEG 600 comprises hydrophobic domains.

36. Given that I disagree with the requester's premise regarding the CH_2 groups in polyvinyl alcohol being hydrophobic domains, their argument in relation to PEG 600 does not follow. In particular, I am not persuaded that the skilled person would assume that all CH_2 groups represent hydrophobic domains. Furthermore, I am not persuaded that the skilled person would consider that PEG 600 has hydrophobic domains.

37. I consider that PEG 600 would be recognised by the skilled person as a hydrophilic

chemical lacking any hydrophobic domains, and that it does not meet the requirements of claim 1 of the patent.

38. I am not persuaded by the requester's argument that Example 8 of O1 falls within the scope of claim 1. Accordingly, I do not consider that claim 1 is anticipated.

39. This conclusion is inconsistent with the decision reached by the opposition division of the European Patent Office regarding claim 1 of the equivalent European patent EP 3801656. Claim 1 of the EP equivalent is substantially identical to claim 1 of the patent. Nevertheless, the requester's argument does not persuade me that I should follow that decision without further evidence.

40. Claim 19 is a method claim largely analogous to claim 1 and, for the same reasons, I also consider that it is novel based on O1. The dependant claims are also all novel by virtue of their dependency.

41. The requester has also argued that the claims lack an inventive step based on the disclosure of O1.

42. I consider the skilled person to be a chemist specialising in formulating skin contacting adhesives, suitable for use with dressings and ostomy appliances amongst other things.

43. O1 is not considered to disclose a silicone adhesive composition which includes a water soluble permeability modifying polymer that includes hydrophobic domains.

44. Paragraph [0051] of O1 lists a number of suitable chemicals for use as water absorbent materials, including carboxymethyl cellulose, polyoxy (ethylene-propylene) and derivatives or mixtures thereof.

> *[0051] The water absorbent material is preferably selected from the group of carboxy methyl cellulose (CMC) such as those sold by Hercules under the trade name Aquasorb(R) or cross-linked polyoxyethelenes, polyoxpropylenes, polyoxy (ethylene-propylene), such as those commercialized by Veramatrix A/S, under the generic name Versabeads(R), or crosslinked polyacrylates, known as super absorbing particles (SAP), such as those sold by Atofina under the trade name Norsocryl(R)., acrylates, alginates, chitosans, polysaccharides and derivatives or mixtures thereof.*

45. I agree with the requester that the skilled person would find it obvious to modify the composition of Example 8 of O1 to also include polyoxy (ethylene-propylene) as an additional absorbent material on the basis of the disclosure of paragraph [0051]. I.e. to formulate it with a mixture of carboxymethyl cellulose and polyoxy (ethylene-propylene) as water absorbing material.

46. Polyoxy (ethylene-propylene) is an example of a poloxamer. Poloxamers are known to be amphiphilic, i.e. they have both hydrophilic and hydrophobic domains. Additionally, poloxamers are identified as suitable permeability modifying polymers in the patent.

47. Accordingly, a silicone adhesive formulated according to Example 8 of O1 and additionally including polyoxy (ethylene-propylene) would have all the features of

claim 1 of the patent. I consider that claim 1 lacks an inventive step based on an obvious combination of compounds disclosed in O1.

48. Similar arguments apply in respect of claim 19, and I consider that it also lacks an inventive step.

49. Claim 4 requires that the superabsorbent particulate comprises carboxymethyl cellulose (amongst others), which is the absorbent specified in Example 8. This claim also lacks an inventive step.

50. Claims 5 and 20 require the further inclusion of an organosilicone resin and a cohesive strengthening agent. Silicone 7-9800 includes an organosilicone resin in the form of trimethylsiloxy terminated dimethyl methyl hydrogen siloxane (in addition to the vinyl functionalised siloxane polymer required by claim 1). O1 describes the use of reinforcing fillers including magnesium oxide. Reinforcing fillers are considered to act as cohesive strengthening agents. In any event, the patent suggests the use of non-polymeric metal oxides, which would include magnesium oxide, as cohesive strengthening agents. Claims 5 and 20 also therefore lack an inventive step.

51. The organosilicone resin and cohesive strengthening agent of claim 5 are further specified in claim 6 as being respectively an MQ resin and one of a list which includes non-polymeric metal oxides. O1 discloses that the silicone may be comprised of two components, a siloxane polymer and a silicate resin. As an example of a silicate resin it specifies trimethylsiloxy silicate (paragraph [0038]) which is an MQ resin. However, it is not clear that it is obvious to modify the silicone of Example 8 to include trimethylsiloxy silicate. It would seem to require a significant reformulation. I do not consider that claim 6 lacks an inventive step based on O1.

52. As discussed above, poloxamers are amphiphilic so polyoxy (ethylene-propylene) of O1 possesses the necessary hydrophilic domains to meet the requirement of claim 7. This claim also lacks an inventive step.

53. The requester's argument regarding claim 8 and O1 is based on the permeability modifying polymer being PEG 600. As I do not consider PEG 600 to have hydrophobic domains I have dismissed this line of argument. I do not consider that claim 8 lacks an inventive step based on O1.

54. Claim 9 requires that the permeability modifying polymer is a poloxamer, and so this claim lacks an inventive step.

55. Claim 10 specifies that the poloxamer is either poloxamer 407 ($E0_{100}P0_{65}E0_{100}$) or poloxamer P123 ($EO_{19}PO_{69}EO_{19}$). There are a very large number of poloxamers. Without further evidence I do not consider it obvious that the polyoxy (ethylene-propylene) referred to in D1/O5 should be one of these. This claim is not considered to lack an inventive step.

56. Claim 16 reads:

> *16. An ostomy coupling comprising:*

a moisture and gas permeable support layer;
an ostomy appliance or ostomy appliance connection provided at a first surface of the support layer; and
a skin compatible component as claimed in any preceding claim attached to a second surface of the support layer.

57. O1 discloses that the adhesive is suitable for ostomy appliances. The further featues of claim 16 are considered to be part of the skilled person's common general knowledge and this claim is considered to lack an inventive step based on O1 and common general knowledge.

58. The requester has also argued that claims 2, 3, 14, 15, 17, 18, 21, 22, 23, 24 and 25 are obvious over O1 alone and/or O1 in view of D1 without providing any detailed argument of why. In the absence of such argument I do not consider that they are obvious.

59. In summary, I consider that claims 1, 4, 5, 7, 9, 16, 19 and 20 lack an inventive step based on D1. I consider that claims 2, 3, 6, 8, 10, 14, 15, 17, 18 and 21 to 25 do not lack an inventive step.

Prior art – D1 WO 2017/158340 A1

60. D1 describes a skin compatible adhesive used for coupling an ostomy appliance to skin.

61. D1 has the same inventors as the patent, and, at least for the application stage, had the same applicant company.

62. The disclosure of D1 is very similar to the disclosure of the patent, except that there is no explicit mention of a permeability modifying polymer.

63. As an example of the similarities, it will be noted that, aside from the addition of a permeability modifying polymer in the patent, the specific formulation set out in Table 1 of D1 is substantially the same as the specific formulation of the patent.

Component	Concentration %w/w	Purpose	Supplier
Silicone Silpuran® 2122 part A	31-35	Part A silicone + catalyst	Wacker Chemie
Silicone Silpuran® 2122 part B	33-37	Part B silicone cross-linker	Wacker Chemie
Aquakeep (RTM) Sodium Polyacrylate	22-27	Moisture control, moisture transmission through silicone adhesive network	Sumitomo Seika Chemicals Co., Ltd
MQ Silanol Resin	3-7	Tackifier	Milliken™ SiVance LLC
Aerosil (RTM) (Fumed silica)	0.5-1.5	Cohesive strengthener	Evonik Industries AG
Permeability modifying polymer	0.1-2.0	Modify permeability	Sigma Oldridge Polymer Laboratories

Table 1 – starting materials of liquid phase non-cured mix

Component	Concentration %w/w	Purpose	Supplier
Silicone Silpuran® 2122 part A	33.60	Part A silicone + catalyst	Wacker Chemie
Silicone Silpuran® 2122 part B	35.40	Part B silicone cross-linker	Wacker Chemie
Aquakeep™ Sodium Polyacrylate	25.00	Moisture control, moisture transmission through silicone adhesive network	Sumitomo Seika Chemicals Co., Ltd
MQ Silanol Resin	5.00	Tackifier	Milliken™ SiVance LLC
Aerosil™ (Fumed silica)	1.00	Cohesive strengthener	Evonik Industries AG

Table 1 – starting materials of liquid phase non-cured mix example 1

64. More particularly, claim 1 of the patent and claim 1 of D1 are very similar. Claim 1 of D1 reads:

1. A skin compatible component attachable to mammalian skin comprising:

a silicone polymer network derived from the addition curing of a first part including a vinyl functionalised siloxane polymer and a second part including a silicon hydride containing crosslinker, in the presence of a metal catalyst; and

a superabsorbent particulate distributed within the polymer network configured to absorb moisture from the skin;

wherein the superabsorbent particulate has an average particle size less than 150 μm.

65. It will be noted that the only difference is that a size of the superabsorbent particles in specified in D1 rather than any requirement for a permeability modifying polymer.

66. The requester argues that a reference to polyvinyl alcohol as a superabsorbent particulate in D1 anticipates the permeability modifying polymer requirement of claim 1. This is in part based on the identification in the patent of polyvinyl alcohol as a suitable permeability modifying polymer as discussed further above.

67. The reference to polyvinyl alcohol in D1 occurs in a long list of chemicals identified as possible super absorbent particulates as follows (my underlining)(see page 3, line 31 to page 4, line 22):

The moisture control SAP may be a hydrocolloid including a naturally occurring semi-synthetic or synthetic hydrocolloid. Naturally-occurring hydrocolloids suitable for use with the subject invention include polysaccharides and cellulosic materials. Example polysaccharide hydrocolloids may comprise plant extracts including gums including in particular xanthan gum or pectin. Example cellulosic materials may comprise cellulose; carboxymethyl cellulose; carboxymethyl β-glucan; cross-linked sodium carboxymethyl cellulose; sodium carboxymethyl cellulose; methylcellulose; hydroxyethylcellulose and hydroxypropyl cellulose.

Semi-synthetic hydrocolloids may comprise starch or cellulose, such as starch- acrylonitrile graft copolymer; a starch polyacrylate salt, and sulfuric acid, vinyl sulfonate, methacrylic acid, vinyl alcohol, vinyl chloride copolymers; guar gums, esterified uronic acid containing polymers such as hyaluronates and alginates, hyaluronate polyvinyl alcohol blends; chitosans formed from partial or complete deacetylation of chitin and/or depolymerisation.

Synthetic hydrocolloids suitable for use with the subject invention may comprise polyvinyl pyrrolidone; carboxyvinyl polymers and polyethylene oxide polymers; polymers of methyl vinyl ether and maleic acid and derivatives; <u>polyvinyl alcohol</u>, high molecular weight polyethylene glycols and polypropylene glycols; or polyethylene oxides.

Preferably, the moisture control SAP comprises sodium polyacrylate…

68. Furthermore, in order to meet the requirement of claim 1 that there is a superabsorbent particulate *and* a permeability modifying polymer, I consider that there needs to be explicit disclosure of the use of polyvinyl alcohol *and* an additional superabsorbent particulate. That disclosure is considered to be found in claim 4 of D1 which specifies a combination of superabsorbent particulates as follows:

> *4. The component as claimed in any preceding claim wherein the superabsorbent particulate comprises any one or a combination of the set of:*
>
> *• a naturally occurring hydrocolloid;*
>
> *• a semi-synthetic hydrocolloid; or*
>
> *• a synthetic hydrocolloid.*

69. However, this results in a large number of of potential combinations of superabsorbent particles. It is not clear that the disclosure of D1 can be treated as a clear disclosure of all of those combinations.

70. In the absence of any further argument on this issue from the requester, I do not think I can reach a reasoned opinion. Suffice to say I am not persuaded by the requester's argument that D1 clearly discloses the necessary composition to fall within the scope of claim 1. Accordingly, I do not consider that claim 1 lacks novelty.

71. For similar reasons, I also do not consider that claim 19 lacks novelty. The dependant claims are also all novel by virtue of their dependency.

72. As with O1, this conclusion is inconsistent with the decision reached by the opposition division regarding the equivalent European patent EP 3801656. As with O1, the requester's argument does not persuade me that I should follow that decision without further evidence.

73. The requester has also argued that claim 1 lacks an inventive step based on the disclosure of D1.

74. In particular, the requester argues that it would be obvious to modify the adhesive of Example 6 of D1 to include polyvinyl alcohol as an additional super absorbent particulate.

Example 6 – MIX # 11

Component	Concentration %w/w	Purpose	Supplier
Silicone Silpuran® 2117/2140 part A	46.95	Part A silicone + catalyst	Wacker Chemie
Silicone Silpuran® 2117/2140 part B	46.95	Part B silicone cross-linker	Wacker Chemie
Sodium carboxymethylcellulose Aqualon CMC 7HF PH	5.00		
Aerosil™ (Fumed silica)	0.10	Cohesive strengthener	Evonik Industries AG
Glycerol	1.00		

Table 6 – starting materials of liquid phase non-cured mix example 6

75. Silicone Silpuran (RTM) 2117/2140 are referred to in both D1 and the patent. In both they are described as suitable examples of silicone polymer precursors. Sodium carboxymethyl cellulose is an example of a superabsorbent particulate. These components form the necessary silicone polymer network and superabsorbent particulate to meet these requirements of claim 1.

76. Example 6 does not include a permeability modifying polymer.

77. I agree with the requester's argument and consider that it would be obvious to include polyvinyl alcohol as an additional absorbent in the adhesive of Example 6 based on its suggested suitability at page 4, line 19 of D1 and the reference to combinations of naturally occurring hydrocolloids (e.g. carboxymethyl cellulose) and synthetic hydrocolloids (e.g. polyvinyl alcohol) in claim 4 of D1.

78. Polyvinyl alcohol is listed in the patent as a suitable water soluble permeability modifying polymer and it comprises both hydrophilic and hydrophobic domains. It therefore meets the requirements of claim 1.

79. The composition of Example 6 of D1 modified by the addition of polyvinyl alcohol has all the features necessary to fall within the scope of claim 1. I therefore consider that claim 1 lacks an inventive step in view of D1.

80. Claim 19 is similarly considered to lack an inventive step based on D1.

81. The features of claims 2 to 6, 16, 17, 18, 20, 21, 22, 23 of the patent are found in the claims of D1, and I consider that these claims also lack an inventive step.

82. Claim 7, 9, 12, 15, 24 and 25 relate to features of polyvinyl alcohol. They also lack an inventive step,

83. Claim 8 specifies that the permeability modifying polymer is not chemically bonded to the silicone polymer network. In the absence of any further evidence, I am not able to reach a conclusion on the inventiveness of this claim. I am not persuaded that it lacks an inventive step.

84. In summary, I consider that claims 1 to 7, 9, 12 and 15 to 25 lack an inventive step in view of D1.

Prior art US 2007/0078197 A1 (O3)

85. The requester has also argued that the claims lack an inventive step based on a mosaic of either D1 and O3 or O1 and O3, on the basis that they are all in the same technical field. Whilst this may be generally true, I do not consider that this alone is sufficient basis for mosaicking any of these documents together.

86. As set out by Laddie J in Pfizer Ltd's Patent [2001] FSR 16 (paragraph 66):

> *"When any piece of prior art is considered for the purposes of an obviousness attack, the question asked is "what would the skilled addressee think and do on the basis of the disclosure?" He will consider the disclosure in the light of the common general knowledge and it may be that in some cases he will also think it obvious to supplement the disclosure by consulting*

other readily accessible publicly available information. This will be particularly likely where the pleaded prior art encourages him to do so because it expressly cross-refers to other material. However, I do not think it is limited to cases where there is an express cross-reference. For example if a piece of prior art directs the skilled worker to use a member of a class of ingredients for a particular purpose and it would be obvious to him where and how to find details of members of that class, then he will do so and that act of pulling in other information is itself an obvious consequence of the disclosure in the prior art."

87. In the absence of any more specific argument about how/why the disclosure of O3 would be combined with either of D1 or O1, I am not persuaded that the skilled person would do so. Accordingly, I am not persuaded that claim 1 or any of the other claims lack an inventive step on this basis.

Opinion

88. Based on the arguments and evidence submitted, it is my opinion that claims 1 to 7, 9, 12 and 15 to 25 lack an inventive step based on D1.

89. Similarly, based on the arguments and evidence submitted, it is my opinion that claims 1, 4, 5, 7, 9, 16, 19 and 20 lack an inventive step based on O1.

90. Therefore, in my opinion, the patent is invalid.

91. I am not persuaded that any of the claims lack novelty in view of either D1 or O1.

Application for review

92. Under section 74B and rule 98, the proprietor may, within three months of the date of issue of this opinion, apply to the comptroller for a review of the opinion.

Matthew Jefferson
Examiner

NOTE

This opinion is not based on the outcome of fully litigated proceedings. Rather, it is based on whatever material the persons requesting the opinion and filing observations have chosen to put before the Office.

APPENDIX

Claims

1. A skin compatible component attachable to mammalian skin comprising: a silicone polymer network derived from the addition curing of a first part including a vinyl functionalised siloxane polymer and a second part including a silicon hydride containing crosslinker, in the presence of a metal catalyst;

a superabsorbent particulate distributed within the polymer network configured to absorb moisture from the skin; and

a permeability modifying polymer distributed within the polymer network, the permeability modifying polymer being a water soluble polymer having hydrophobic domains.

2. The component as claimed in claim 1 wherein the superabsorbent particulate has an average particle size less than 150 μm or an average particle size in the range 10 to 40 μm, 15 to 35 μm or 20 to 30 μm.

3. The component as claimed in claims 1 or 2 wherein the superabsorbent particulate is distributed within the polymer network at a concentration in the range 5 to 45 wt%, 10 to 40 wt%, 15 to 35 wt% or 20 to 30 wt%.

4. The component as claimed in any preceding claim wherein the superabsorbent particulate comprises any one or a combination of the set of:

- *a naturally occurring hydrocolloid;*
- *a semi-synthetic hydrocolloid;*
- *a synthetic hydrocolloid;*
- *a polysaccharide;*
- *a cellulose;*
- *hydroxyethylcellulose;*
- *carboxymethylcellulose;*
- *hydroxypropylcellulose;*
- *carboxymethyl β-glucan;*
- *cross-linked sodium carboxymethyl cellulose;*
- *sodium carboxymethyl cellulose;*
- *methylcellulose; or*
- *sodium polyacrylate.*

5. The component as claimed in any preceding claim wherein an organosilicone resin and a cohesive strengthening agent is included in the first or second part prior to addition curing.

6. The component as claimed in claim 5 wherein the organosilicone resin is an MQ resin and the cohesive strengthening agent comprises any one or a combination of the set of: fumed silica, fumed alumina, colloidal silica, nanoclays, silicates, silane treated organic polymers, polymeric metal oxides, and non-polymeric metal oxides.

7. The component as claimed in any preceding claim wherein the permeability modifying polymer further comprises hydrophilic domains.

8. The component as claimed in any preceding claim wherein the permeability modifying polymer is not chemically bonded to the silicone polymer network.

9. The component as claimed in any preceding claim wherein the permeability modifying polymer is any one of a combination of the following set of:

• polyvinyl alcohol (PVA);
• polyvinyl chloride (PVC);
• a poloxamer;
• a polyester; or
• polyvinyl pyrrolidone (PVP).

10. The component as claimed in claim 9 wherein the poloxamer comprises poloxamer 407 ($EO_{100}PO_{65}EO_{100}$) or poloxamer P123 ($EO_{19}PO_{69}EO_{19}$).

11. The component as claimed in claim 9 wherein the polyester comprise polycaprolactone (PCL).

12. The component as claimed in claim 9 wherein the permeability modifying polymer is PVA and comprises a molecular weight in a range 50,000 to 150,000; 60,000 to 120,000; 70,000 to 100,000; or 80,000 to 90,000.

13. The component as claimed in claim 9 wherein the permeability modifying polymer is PVP and comprises a molecular weight in a range 5,000 to 50,000; 10,000 to 40,000; 15,000 to 35,000; or 20,000 to 30,000.

14. The component as claimed in claim 9 wherein the permeability modifying polymer is PVC and comprises a molecular weight in a range 50,000 to 100,000 or 70,000 to 90,000.

15. The component as claimed in any preceding claim comprising the permeability modifying polymer at 0.1 to 5.0 wt%; 0.1 to 4.0 wt%; 0.1 to 3.0 wt%; 0.1 to 2.0 wt%; 0.2 to 1.8 wt%; 0.2 to 1.6 wt%; 0.2 to 1.2 wt%; 0.2 to 1.0 wt%; 0.2 to 0.8 wt%; 0.2 to 0.4 wt%; or 0.6 to 1.0 wt%.

16. An ostomy coupling comprising:

a moisture and gas permeable support layer;

an ostomy appliance or ostomy appliance connection provided at a first surface of the support layer; and

a skin compatible component as claimed in any preceding claim attached to a second surf ace of the support layer.

17. The coupling as claimed in claim 22 wherein the support layer comprises any one or a combination of the set of:

• a polyurethane
• a breathable silicone layer;
• a polyethylene block amide polymer;
• a polytetrafluoroethylene polymer;
• an acrylic latex polymer; or
• a polyolefin based layer.

18. The coupling as claimed in claims 16 or 17 wherein:

• the ostomy appliance comprises a bag or pouch attached to the support layer directly or via an intermediate layer; or

• the ostomy appliance connection comprises a first part of a bag or pouch connection assembly in which a second part of the connection assembly is mounted at a bag or pouch, the first part and the second part capable of releasable mating to detachably secure the bag or pouch to the coupling.

19. A method of manufacturing a skin compatible component attachable to mammalian skin comprising:

mixing a first part including a vinyl functionalized siloxane polymer with a second part including a silicon hydride containing crosslinker to form a mix;

incorporating within the mix a superabsorbent particulate;

incorporating within the mix a water soluble permeability modifying polymer having hydrophobic domains; and

curing the mix via a metal catalyst;

wherein the superabsorbent particulate and the permeability modifying polymer are distributed within the resulting addition cured silicone polymer network.

20. The method as claimed in any one of claim 19 wherein the first part or the second part further comprise an organosilicone resin and a cohesive strengthening agent.

21. The method as claimed in claim 20 wherein the organosilicone resin is an MQ resin, a silicic acid, trimethylsilylester with silanol functionality and the organosilicone resin is included in the mix at 0.2 to 10 wt%, 1 to 9 wt%, 2 to 8 wt%; 3 to 7 wt% or 4 to 6 wt%; and the cohesive strengthening agent comprises fumed silica included within the mix at 0.2 to 2.0 wt%, 0.3 to 2.0 wt%, 0.5 to 1.5 wt% or 0.8 to 1.2 wt%.

22. The method as claimed in any one of claims 19 to 21 wherein the superabsorbent particulate comprises a particle size less than 150 μm in a range 10 to 40 μm, 15 to 35 μm or 20 to 30 μm and wherein the superabsorbent particulate is included within the mix at 5 to 45 wt%, 15 to 35 wt% or 20 to 30 wt%.

23. The method as claimed in any one of claims 19 to 22 wherein the vinyl functionalized siloxane polymer comprises a vinyl-terminated polydimethylsiloxane (PDMS) and wherein the silicon hydride containing crosslinker comprises a hydride- terminated polydimethylsiloxane (PDMS); wherein the vinyl-terminated polydimethylsiloxane (PDMS) comprises a first vinyl-terminated PDMS having a mass average of 10,000 to 20,000 and a second vinyl-terminated PDMS having a mass average of 70,000 to 100,000.

24. The method as claimed in any one of claims 19 to 23 wherein the permeability modifying polymer is any one of a combination of the following set of:

- *polyvinyl alcohol (PVA);*
- *polyvinyl chloride (PVC);*
- *poloxamer 407 ($EO_{100}PO_{65}EO_{100}$) or poloxamer P123 ($EO_{19}PO_{69}E_{19}$);*
- *a polyester; or*
- *polyvinyl pyrrolidone (PVP).*

25. The method as claimed in any one of claims 19 to 24 wherein the permeability modifying polymer is incorporated within the mix at 0.1 to 5.0 wt%; 0.1 to 4.0 wt%; 0.1 to 3.0 wt%; 0.1 to 2.0wt%; 0.2 to 1.8 wt%; 0.2 to 1.6 wt%; 0.2 to 1.2wt%; 0.2 to 1.0 wt%; 0.2 to 0.8 wt%; 0.2 to 0.4 wt%; or 0.6 to 1.0 wt%.