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Datasheet for the decision of 16 March 2018

Case Number: T 0176/15 - 3.3.09

Application Number: 04820386.3

Publication Number: 1697480

IPC: C09J153/02, C09J153/00,

A61L15/58, A61L24/04, A61L24/08

Language of the proceedings: ΕN

Title of invention:

An adhesive composition and wound dressings or ostomy appliances comprising such adhesive composition

Patent Proprietor:

Coloplast A/S

Opponent:

Hollister Incorporated

Headword:

Relevant legal provisions:

EPC Art. 83, 54, 56

Keyword:

Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)
Late-filed documents - admitted (no)

Decisions cited:

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 0176/15 - 3.3.09

DECISION
of Technical Board of Appeal 3.3.09
of 16 March 2018

Appellant: Hollister Incorporated (Opponent) 2000 Hollister Drive

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Representative: Høiberg P/S

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Respondent: Coloplast A/S

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(Patent Proprietor)

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 17 November 2014 rejecting the opposition filed against European patent No. 1697480 pursuant to

Article 101(2) EPC

Composition of the Board:

Chairman M. O. Müller

Members: J. Jardón Álvarez

D. Prietzel-Funk

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Summary of Facts and Submissions

- I. This decision concerns the appeal filed by the opponent against the decision of the opposition division to reject the opposition filed against European patent No. 1 697 480.
- II. The opponent had requested revocation of the patent in its entirety on the grounds of Article 100(a) (lack of novelty and inventive step) and (b) EPC. The following documents were cited during the opposition proceedings:

D1: US 2002/0077420 A1;

D2: WO 2005/032610 A1; and

D3: US 6 558 792 B1.

- III. The granted patent included fifteen claims, independent claims 1, 14 and 15 reading as follows:
 - "1. An adhesive composition comprising rubbery elastomeric matrix comprising a block-copolymer and a homopolymer where the block-copolymer contains one or more block(s) of a polymerised mono alkenyl arene monomer and one or more block(s) consisting of a linear or branched saturated hydrocarbon chain characterized in that the homopolymer is a linear or branched saturated hydrocarbon chain made from the same monomer as said block(s) consisting of a linear or branched saturated hydrocarbon chain."
 - "14. An ostomy appliance with an adhesive wafer comprising an adhesive composition according to any of claims 1-13."

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"15. A wound dressing comprising an adhesive composition according to any of claims 1-13."

Claims 2 to 13 were dependent claims.

- IV. The opposition division's decision may be summarised as follows:
 - The patent in suit disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The lack of an essential feature objected to by the opponent was an issue under Article 84 EPC, not falling under sufficiency of disclosure.
 - The combination of features of claim 1 was not disclosed in any of D1, D2 and/or D3. Concerning D1, the opposition division held that this document did not disclose a homopolymer as required by claim 1, because the polymer of D1 additionally contained a silicon group.
 - D3 represented the closest prior-art document, in particular the embodiment of example 7. The technical problem underlying the patent was to provide an adhesive composition with improved cohesion. This problem was solved by using a composition as claimed, wherein the homopolymer was made from the same monomer as the block(s) of the block copolymer. The skilled person did not find any suggestion to this solution in D3 or D1. Consequently, the claimed subject-matter involved an inventive step.
- V. This decision was appealed by the opponent (in the following: the appellant) which requested that the

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opposition division's decision be set aside and that the patent be revoked in its entirety. The statement setting out the grounds of appeal included the following further evidence:

- Al: Internet page: "http://scholar.google.dk/scholar? hl=da&q=%22end-capped+homopolymer%22&btnG=" dated 16 March 2015 (2 pages); and
- A2: Internet page: "https://www.google.dk/?
 tbm=pts&gws_rd=cr,ssl&ei=ePcGVdy3FMTaOJP4gOgP",
 dated 16 March 2015 (2 pages).
- VI. With its reply, the patent proprietor (in the following: the respondent) disputed the arguments of the appellant and requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained in amended form on the basis of the claims according to auxiliary requests A to C submitted therewith.
- VII. In a communication dated 16 August 2017, the board indicated the points to be discussed during the oral proceedings.
- VIII. Both parties replied to the communication of the board.

 The reply of the respondent included the following further evidence:
 - Annex A: Polymer Chemistry, An Introduction; Malcom P. Stevens, Oxford University Press 1999; page 7;
 - Annex B1: Organic Chemistry Fourth Edition; Allyn and Bacon, Inc. 1983; page 43; and

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Annex B2: General Chemistry Second Edition; Scientific American Books 1992, pages 74 - 75.

The reply of the appellant included the following documents:

D4: US 5 714 225 A; and

D5: US 6 437 038 B1.

- IX. On 16 March 2018, oral proceedings were held before the board.
- X. The appellant's relevant arguments may be summarised as follows:
 - The patent was insufficiently disclosed. An essential feature of the claimed adhesive compositions appeared to be the use of a physically cross-linked styrene-isobutylene-styrene block copolymer. However, the patent did not teach how to physically crosslink the block copolymer. Moreover, claim 1 encompassed block copolymers that were not physically cross-linked and the patent did not teach how to avoid physical crosslinking.
 - Examples 5 and 6 of D1 anticipated the subjectmatter of claim 1. In these examples, an
 isobutylene polymer containing end-capped silicon
 groups was used. The patent did not exclude that
 the homopolymer used might be somehow modified,
 e.g. through the attachment of end-capped groups.
 The Google searches in A1 and A2 demonstrated that
 the term "end-capped homopolymer" was used by
 persons skilled in the art, confirming that the

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polyisobutylene used in D1 was a homopolymer according to claim 1 of the patent.

- The claimed subject-matter lacked inventive step starting from either D3 or D1 as the closest prior art. Independently of which document was seen as the closest prior art, the evidence on file was not sufficient to show any improvement across the whole scope of the claim. In particular, example 4 of the patent performed worse than comparative example 3, and it was not credible that any embodiment covered by the scope of the claims would show improved properties. Thus, the problem to be solved by the patent was the provision of an alternative adhesive. The claimed solution represented an arbitrary selection of elastomers already well known for their adhesive properties and obvious for the skilled person.
- XI. The respondent's arguments may be summarised as follows:
 - Newly filed documents A1 and A2 were *prima facie* not relevant and should not be admitted into the proceedings. In fact, the term "end-capped homopolymer" searched in A1 and A2 was not used in the patent or in the appealed decision.
 - The invention was sufficiently disclosed. The patent included a variety of adhesive compositions falling within the scope of the claim. Evidence to the contrary had not been provided by the appellant, which had the burden of proof.
 - Claim 1 of the patent was novel over D1 because D1 did not directly and unambiguously disclose a

homopolymer as claimed. Claim 1 mandatorily required that the homopolymer be a linear or branched saturated hydrocarbon chain, and thus made exclusively of hydrogen and carbon atoms. Any polymer incorporating silicon, as those used in D1, was excluded from the scope of the claim.

- The closest prior art was D3, as it was the only document concerning adhesives suitable for medical purposes. The claimed adhesive compositions differed from those of D3 (i) in that the block copolymer comprised a saturated hydrocarbon chain and (ii) in that the homopolymer was a linear or branched saturated hydrocarbon chain made from the same monomer as said block(s) consisting of a linear or branched saturated hydrocarbon chain. The technical problem to be solved by the patent was the provision of an adhesive with an improved balance between the properties of adhesion and cohesion resulting in extended wear time of the wound dressings. The examples and comparative examples in the patent showed the improvements over the adhesive compositions of D3, and the prior art gave no hint at the claimed solution.
- XII. The appellant requested that the decision under appeal be set aside and that European patent No. 1 697 480 be revoked in its entirety. It further requested that annexes A1 and A2 filed with the statement setting out the grounds of appeal be admitted into the proceedings, and that auxiliary request C not be admitted into the proceedings. If auxiliary request C were admitted, then new prior-art, in particular D4 and D5, should also be admitted into the proceedings, and, were they to be admitted, the case should be remitted to the opposition division for further consideration.

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The respondent requested that the appeal be dismissed (main request), or that the patent be maintained in amended form on the basis of one of auxiliary requests A to C, all filed with the reply to the statement of grounds of appeal. It also requested that A1, A2, D4 and D5 and the submissions of the appellant dated 14 February 2018, insofar as they concerned the auxiliary requests, not be admitted into the proceedings.

Reasons for the Decision

- 1. Admission of A1 and A2
- 1.1 The appellant filed A1 and A2 with its statement of grounds of appeal in order to support its argument that an "end-capped homopolymer" was a specific form of homopolymer. In its view, the result of searches for this term in Google Scholar (see A1) and Google Patents (see A2) demonstrated that this term was used by persons of skill in the art.
- 1.2 The respondent requested that A1 and A2 not be admitted into the proceedings as both were the results of Internet searches carried out on 16th March 2015. They were neither state of the art nor prima facie relevant for the appeal proceedings.
- 1.3 The board agrees with the respondent that A1 and A2 are not relevant to clarify the question whether D1 anticipates the subject-matter of claim 1. The fact that the term "end-capped homopolymer" is used in the art as shown by the Google searches does not add any information to the question as to whether or not the

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isobutylene polymer containing a methyldimethoxysilyl group used in D1 falls within the definition of a homopolymer used in claim 1. In fact, the wording "end-capped homopolymer" is not used in either D1 or the patent in suit.

1.4 The board therefore decided not to admit A1 and A2 into the proceedings.

MAIN REQUEST (granted claims)

- 2. Sufficiency of disclosure
- 2.1 The invention is directed to adhesive compositions comprising a rubbery elastomeric matrix comprising a block copolymer and a homopolymer (see claims 1 to 13) and to wound dressings and ostomy appliances comprising these adhesive compositions (see claims 14 and 15).
- The patent specification gives information as to suitable block copolymers and homopolymers to be used to achieve physical crosslinking (see paragraphs [0030] to [0045], in particular paragraphs [0033] to [0035]), and includes several working examples of the preparation of the claimed adhesive compositions. In fact, apart from this teaching in the patent, it is common general knowledge that physical crosslinking in block copolymers results from physical crosslinks created by a dispersed glassy or crystalline phase, e.g. in the case of a styrene-isobutylene-styrene block copolymer, from the glassy styrene blocks.
- 2.3 The appellant did not show that the examples of the patent could not be reproduced or that an embodiment of the invention could not be carried out. There is no

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evidence on file that an adhesive composition as claimed cannot be prepared by the skilled person.

- 2.4 Notwithstanding the above, the appellant considered the invention insufficiently disclosed, because in its view an essential feature for providing an adhesive having the desired technical effects, namely the use of physically cross-linked styrene-isobutylene-styrene, was missing from claim 1.
- 2.5 The board acknowledges that physical crosslinking is required only by dependent claim 4. Hence, claim 1 indeed covers embodiments without any physically crosslinked block copolymer. However, contrary to the appellant's assertion, in the patent specification (see paragraph [0033]), physical crosslinking is disclosed merely as a preferred rather than as an essential feature of the invention. Furthermore, as pointed out by the opposition division in its decision, lack of an essential feature in an independent claim is normally to be dealt with under clarity and support requirements, that is to say under Article 84 EPC, (see Case Law of the Boards of Appeal of the EPO, 8th edition, 2016, Section II.A.3.2), rather than under sufficiency of disclosure.
- 2.6 For these reasons, the board is satisfied that the requirements of sufficiency of disclosure are met.
- 3. Novelty
- 3.1 Claim 1 is directed to an adhesive composition comprising rubbery elastomeric matrix comprising
 - (a) a block copolymer and
 - (b) a homopolymer where

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- (a1) the block copolymer contains one or more block(s) of a polymerised mono alkenyl arene monomer and
- (a2) one or more block(s) consisting of a linear or branched saturated hydrocarbon chain characterized in that
 - (b1) the homopolymer is a linear or branched saturated hydrocarbon chain made from the same monomer as said block(s) consisting of a linear or branched saturated hydrocarbon chain.
- 3.2 The novelty of the subject-matter of this claim is contested by the appellant in view of examples 5 and 6 of D1.
- 3.3 D1 is directed to a pressure sensitive adhesive comprising:
 - (A) a block copolymer having at least one kind of block formed from an aliphatic hydrocarbon compound and
 - (B) an isobutylene polymer having a silicon group bound to a hydrolysable group or a hydroxyl group (see claim 1).
- 3.3.1 Example 5 discloses an adhesive composition comprising inter alia 100 weight parts of a styrene-isobutylene-styrene block copolymer as (A) component and 50 weight parts of isobutylene polymer containing a methyl-dimethoxysilyl group at a molecular terminus as (B) component, the silicon group content per molecule measured by ¹H-NMR method being 1.5 to 1.9. Example 6 discloses a similar composition but including 100 weight parts of a similar isobutylene polymer containing also a methyldimethoxysilyl group as (B) component.

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- 3.3.2 The presence of a reactive silicon group is an essential feature of the adhesive compositions of D1 (see paragraphs [0020] to [0029]). At least one reactive silicon group, preferably 1.1 to 5 reactive silicon groups, exists per molecule of the isobutylene polymer on an average and it may occur terminally and/or internally in the isobutylene polymer chain (see paragraph [0026]).
- Indisputably, the adhesive compositions of D1 include a block polymer, namely styrene-isobutylene-styrene block copolymer, according to features (a), (a1) and (a2) of claim 1. It remains to be investigated whether the "isobutylene polymer having a silicon group bound to a hydrolyzable group or a hydroxyl group" therein used represents a homopolymer according to feature (b1) of the claim.
- 3.5 Claim 1 of the patent mandatorily requires that "the homopolymer is a linear or branched saturated hydrocarbon chain made from the same monomer as said block(s) consisting of a linear or branched saturated hydrocarbon chain" (emphasis by the board), that is to say, it is made solely from carbon and hydrogen atoms. Therefore, it cannot contain silicon atoms and it does not embrace the isobutylene polymer having a silicon group used in D1.
- 3.6 The appellant argued that the wording of the claim did not exclude the presence of end groups in the polymer used. In its view, the skilled person would understand that the homopolymer used in D1 is a specific form of a homopolymer, a modified homopolymer, not excluded from the scope of the claim.

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- 3.7 The board is not persuaded.
 - First of all, it is not disclosed in D1 that the methyldimethoxysilyl group in the isobutylene polymer is present only as a terminal group. As stated above, the silicon group may occur terminally and/or internally in D1.
 - But even if it were exclusively a terminal group, the subject-matter of claim 1 would still be novel because, as stated in point 3.5 above, the wording of the claim does not allow for the presence of silicon atoms in the homopolymer. Only carbon and hydrogen are present in a "linear or branched saturated hydrocarbon chain". In other words, the term "homopolymer" as used in claim 1 is not to be understood as embracing "substituted and unsubstituted" homopolymer, wherein any further atom could be present as substituent. This possibility is not covered by the wording of the claim.
- 3.8 For this reason alone, the subject-matter of claim 1 is novel over the disclosure of D1.
- 3.9 During the oral proceedings before the board, the respondent argued for the first time in appeal proceedings that a further distinguishing feature of the claimed compositions over examples 5 and 6 of D1 was that the compositions of these examples were not adhesive compositions.

At the request of the appellant, the board did not admit this new line of argumentation into the appeal proceedings (see Article 13(3) RPBA). Since in any case the board acknowledges novelty of the claimed subject-

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matter for the reasons given above, no detailed reasons for the non-admittance of this new argument need to be given.

- 4. Inventive step
- 4.1 Closest prior art
- 4.1.1 The appellant relied in its written submissions on D1 and/or D3 as the closest prior art. During the oral proceedings, it only argued on the basis of D3 as closest prior art, but maintained its written arguments starting from D1.
- 4.1.2 In the board's judgement, the disclosure of D1 does not represent a suitable starting point for the assessment of inventive step. According to the case law of the Boards of Appeal, the closest prior art for assessing inventive step is a prior-art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention, and having the most relevant technical features in common.
- 4.1.3 Unlike the patent, which is directed to adhesive compositions for medical purposes (see point 2.1 above), D1 relates to curable compositions suited for use as a rubbery material, for example a tire, a sealant, a gasket, an adhesive, a pressure sensitive adhesive or a damping material (see paragraph [0001]).
- 4.1.4 Although in paragraph [0046] of D1 it is stated that the compositions of D1 can also be used in other fields such as food related, miscellaneous goods for daily use, toys, etc. including medical supplies such as various catheters, there is no mention in D1 that for

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these uses the adhesive properties of the compositions are needed.

- 4.1.5 In fact, D1 aims to mitigate the reductions in physical properties at high temperatures of block copolymers having at least one block species formed from (an) aliphatic hydrocarbon compound(s) (see paragraph [0004]). It does not deal with the problems encountered with the adhesive compositions used for securing ostomy appliances to the skin that the patent in suit aims to improve.
- 4.1.6 Thus, D1 is not directed to the same purpose or effect as the claimed invention, and therefore does not qualify as the closest prior-art document.
- 4.1.7 On the other hand, D3 relates, like the patent in suit, to pressure sensitive adhesive compositions suitable for various medical applications, and especially suitable for adhesion to the skin, in particular in the field of ostomy care (see column 1, lines 10 to 13; see also column 2, lines 53 to 58). Consequently, D3 is the most appropriate starting point for the assessment of inventive step.
- 4.1.8 D3 (claim 1) discloses a pressure sensitive adhesive composition which is suitable for medical purposes and which comprises a rubbery component, a mixture of water soluble or water swellable hydrocolloids and optionally, inter alia, a cohesive strengthening agent.

The rubbery component may be a conjugated butadiene polymer, preferably polyisobutylene (see column 4, lines 28 to 31), and the cohesive strengthening agent, if present, may suitably be a physically cross-linked elastomer selected from block copolymers comprising

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styrene and one or more butadienes (see column 4, lines 32 to 41). In examples 5 and 9, the adhesive composition includes polyisobutylene (PIB) and styrene-isoprene-styrene (SIS) copolymer.

The styrene blocks of the block copolymer of D3 correspond to the one or more blocks of a polymerised mono alkenyl arene monomer of the block copolymer as defined in claim 1. The remaining block of the block copolymer of D3 is, however, different from that of claim 1. More specifically, the remaining block of the block copolymer of D3 consists of a linear or branched unsaturated hydrocarbon chain (butadiene or isoprene blocks), while claim 1 requires a linear or branched saturated hydrocarbon chain.

- 4.2 Problem to be solved and its solution
- 4.2.1 According to the respondent, some drawbacks encountered when using adhesive compositions such as those of D3 are that while, on one hand, absorption of fluid is desirable for adhesive properties, on the other hand, too much fluid absorption leads to excessive swelling, with concurrent loss of integrity/cohesion. The technical problem to be solved by the patent in view of D3 is the provision of an adhesive with improved balance between the properties of adhesion and cohesion (see reply to the appeal, points 3.13 and 3.14) resulting in extended wear time.
- 4.2.2 The question whether the above problem has been credibly solved by the claimed compositions was disputed between the parties. While the respondent relied on the examples and comparative examples in the patent to show the improved properties of the claimed compositions, the appellant questioned whether an

improvement would be achieved at all and, even if an improvement were attained for some embodiments, it questioned whether it would be obtained over the whole scope of the claims.

4.2.3 In view of the evidence on file, the board is satisfied that the above problem has been credibly solved. The examples and comparative examples in the patent show that there is significantly reduced disruption of the physical cross-linking in the SIBS network from the PIB polymer as compared with a SIS network. This gives rise to increased cohesion in the adhesive (see paragraph [0038].

Examples 2 and 3 apply SIBSTAR 102T and SIBSTAR 073T, which are both styrene-isobutylene-styrene block copolymers. The isobutylene block in these block copolymers is a linear saturated hydrocarbon chain as required by claim 1. Comparative examples 2 and 3 apply Kraton D1161, which is a styrene-isoprene-styrene block copolymer. The isoprene block in this block copolymer is unsaturated and thus represents the teaching of D3. The SIBS based compositions of examples 2 and 3, when compared with the respective SIS based compositions of comparative examples 2 and 3 (see Table 2), show initially similar water absorption rates (see Table 3 entries from 30 to 240 minutes), but, on prolonged immersion, the absorption of the compositions comprising SIBS slows down (see Table 3, entries for 1440 minutes), preventing deterioration due to increasing water content. Breakdown of the appliance due to the absorption of excessive body fluids is therefore reduced. Unlike the compositions comprising SIBS, the comparative compositions with SIS show a significant increase in water absorption on prolonged immersion.

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- 4.2.4 Similarly, the results in Table 4 (see entries for "% shrinkage hole" and "% expansion, disc" of examples 2 and 3 versus comparative examples 2 and 3) reveal that the compositions comprising SIBS (examples 2 and 3) show improved resistance against deterioration over those compositions comprising SIS and the results in Table 5 show overall improved gel strength (see paragraph [0097]).
- 4.2.5 From these results, it can be concluded that compositions as claimed provide further safety and extended wear time when compared with those of D3.
- 4.2.6 This finding cannot be called into question simply because, for some properties, the adhesive composition of example 4 of the patent does not perform as well as the adhesive composition of comparative example 3 (see for instance Table 3, water absorption after 1440 minutes). According to established jurisprudence, the nature of comparison with the closest state of the art must be convincingly shown to have its origin in the distinguishing feature of the invention. The composition of example 4 differs from the composition of comparative example 3 not only by the type of block copolymer used (i.e. the distinguishing feature over D3), but also by the amounts used. Example 4 is therefore not directly comparable with comparative example 3, so the comparison of these two examples is not meaningful.

Similar considerations apply to the doubts of the appellant concerning the question whether all the embodiments covered by the claim would solve the above problem. In the absence of any experimental evidence to the contrary, the board is satisfied from the

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experimental evidence in the patent discussed above that the above problem has been credibly solved over the whole scope of the claim.

4.3 Obviousness

- 4.3.1 It remains to be decided whether, in view of the available prior art, it would have been obvious for the skilled person to solve the technical problem as defined above by the means claimed.
- 4.3.2 Certainly, D3 itself does not give any hint to the claimed solution. Apart from the fact that the use of the cohesive strengthening agent in D3 is not mandatory (see claim 1 of D3), all physically cross-linked elastomers mentioned in D3 for this agent are derived from one or more butadienes and thus contain blocks that are unsaturated. They cannot give any hint to the block copolymers with saturated blocks as required by claim 1. In this context, the board cannot see how the apparently erroneous mention of the saturated polymer polyisobutylene as conjugated butadiene polymer (an unsaturated polymer) in the definition of the rubbery component in column 4, lines 28 to 31 of D3 could have any impact in the definition of the cohesive strengthening agent. These are two independent definitions not related to each other.
- 4.3.3 Also, D1 cannot give any hint to the claimed solution. The fact that SIBS could be used in the curable compositions of D1 to mitigate reductions in physical properties at elevated temperatures (see paragraph [0058] of D1) would not give any hint to the skilled person to modify the adhesive compositions of D3, as they are quite different from those of D1, in particular because the adhesives of D1 additionally

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include an isobutylene polymer having a silicon group, that is not foreseen in the adhesives of D3.

- 4.3.4 In summary, there is no incentive in the prior art for the skilled person to modify the adhesive compositions of D3 by using a block copolymer as defined in claim 1. The objection of the appellant is made with knowledge of the invention.
- Insofar as the appellant relied on D1 as the closest prior art document, the board has already noted that D1 does not qualify as the closest prior art. The appellant's objections based on D1 are clearly made ex post facto in the knowledge of the invention. In any case, the skilled person would not be motivated by the disclosure of D1 to use an isobutylene polymer without the terminal silicon group, because the presence of such group is an essential feature of the invention of D1 (see, for instance, claim 1).
- 4.5 For these reasons, the subject-matter of claim 1, as well as dependent claims 2 to 13, involves an inventive step. This conclusion also applies to the ostomy appliance and wound dressing of claims 14 and 15 that comprise the adhesive compositions of claims 1 to 13.

AUXILIARY REQUESTS A TO C

5. Since the main request is allowable, there is no need for the board to deal with these requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Cañueto Carbajo

M. O. Müller

Decision electronically authenticated