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Datasheet for the decision of 29 November 2024

Case Number: T 2215/22 - 3.3.03

Application Number: 13712069.7

Publication Number: 2928978

IPC: C09J183/04

Language of the proceedings: EN

Title of invention:
SILICONE GEL ADHESIVE WITH HYDROPHILIC AND ANTIMICROBIAL PROPERTIES

Patent Proprietor:
Solventum Intellectual Properties Company

Opponent:
Mölnlycke Health Care AB

Relevant legal provisions:
EPC Art. 54, 56, 100(b)

Keyword:
Grounds for opposition - insufficiency of disclosure (no)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
G 0003/14, T 1845/14, T 1553/16

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Case Number: T 2215/22 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 29 November 2024

Appellant: (Opponent)	Mölnlycke Health Care AB Gamlestadsvägen 3C 402 52 Göteborg (SE)
Representative:	Kransell & Wennborg KB P.O. Box 27834 115 93 Stockholm (SE)
Respondent: (Patent Proprietor)	Solventum Intellectual Properties Company 3M Center, 275-6E-21 2510 Conway Ave E Maplewood, MN 55144 (US)
Representative:	Mathys & Squire Theatinerstraße 7 80333 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 4 August 2022 rejecting the opposition filed against European patent No. 2928978 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	D. Semino
Members:	O. Dury
	M. Millet

Summary of Facts and Submissions

I. The appeal of the opponent is against the decision of the opposition division rejecting the opposition filed against European patent No. 2 928 978.

II. The following documents were, among others, cited in the decision under appeal:

D1: WO 2010/056544 A1
D4: WO 2011/129759 A1
D9: Laboratory report n° R-20210921-03, filed by the opponent with letter of 27 September 2021
D10: Laboratory report n° R-20220406-07, filed by the opponent with letter of 28 April 2022
D11: Additional information about D9, S. Areskoug, dated 28 April 2022, filed by the opponent with letter of 28 April 2022
D12: Experimental report, K. Tse, filed by the patent proprietor with letter of 6 May 2022

III. As far as relevant to the present case, the following conclusions were, among others, reached in the decision under appeal:

- Documents D9 to D12 were admitted into the proceedings.

- The patent in suit met the requirements of sufficiency of disclosure.

- The subject-matter of the claims as granted was novel over examples 3, 5 and 6 of D4.

- The subject-matter of the claims as granted involved an inventive step when either document D1 or document D4 was taken as the closest prior art.

In view of the above, none of the objections put forward by the opponent were successful and the opposition was rejected.

IV. The opponent (appellant) appealed against the above decision.

V. With their rejoinder to the statement of grounds of appeal the patent proprietor (respondent) filed several sets of claims as auxiliary requests 26 to 33.

VI. The parties were summoned to oral proceedings and a communication pursuant to Article 15(1) RPBA indicating specific issues to be discussed at the oral proceedings was then sent to the parties.

VII. With letter of 29 October 2024 the respondent filed additional sets of claims as auxiliary requests 34 to 53.

VIII. Oral proceedings were held on 29 November 2024.

IX. **The final requests of the parties were as follows**:

(a) The appellant requested that the decision under appeal be set aside, that the case be not remitted to the opposition division and that European patent No. 2 928 978 be revoked.

(b) The respondent requested that the appeal be dismissed (main request) or, in the alternative, that the case be remitted to the opposition

division for further prosecution or, in the alternative, that the patent be maintained in amended form according to any of the following auxiliary requests:

- auxiliary requests 1 to 25 filed with letter of 23 September 2019;

- auxiliary requests 1a to 6a and 8a to 25a filed with letter of 13 August 2020;

- auxiliary requests 26 to 33 filed with the rejoinder to the statement of grounds of appeal;

- auxiliary requests 34 to 53 filed with letter of 29 October 2024.

X. Claims 1 and 4 of the **main request** (claims as granted), which are the sole claims relevant to the present decision, read as follows:

"1. An adhesive composition comprising:

a) a silicone gel comprising a crosslinked poly(diorganosiloxane) having terminal groups of formula $-O-Si(R^1)(R^2)_2$ wherein R^1 is hydroxyl, alkyl, or aryl and each R^2 is independently alkyl or aryl;

b) a hydrophilic component dispersed in the silicone gel, wherein the hydrophilic component is a carbohydrate having at least 3 hydroxyl groups, a carbohydrate derivative having at least 3 hydroxyl groups, or a combination thereof; and

c) an antimicrobial agent dispersed in the silicone gel, wherein the antimicrobial agent comprises

elemental copper, elemental silver, a copper-containing compound, a silver-containing compound, or a combination thereof;

wherein less than 10 weight percent of the hydrophilic component is extractable from the adhesive composition into a phosphate buffer saline solution at pH 7 within 24 hours at room temperature."

"4. The adhesive composition of any one of claims 1 to 3, wherein the silicone gel is crosslinked using an electron beam or gamma radiation."

XI. The appellant's arguments, in so far as they are relevant to the present decision, may be derived from the reasons for the decision below. They are essentially as follows:

(a) The patent in suit did not meet the requirements of sufficiency of disclosure.

(b) The subject-matter of claim 1 of the main request was not novel over the disclosure of example 5 of D4.

(c) The subject-matter of claim 1 of the main request did not involve an inventive step when either D1 or D4 was taken as the closest prior art.

XII. The respondent's arguments, in so far as they are relevant to the present decision, may be derived from the reasons for the decision below. They are essentially as follows:

(a) The patent in suit met the requirements of sufficiency of disclosure.

(b) The subject-matter of claim 1 of the main request was novel over the disclosure of example 5 of D4.

(c) The subject-matter of claim 1 of the main request involved an inventive step when either D1 or D4 was taken as the closest prior art.

Reasons for the Decision

Main request (patent as granted)

1. Sufficiency of disclosure: Article 100(b) EPC

1.1 In order to meet the requirements of sufficiency of disclosure, an invention has to be disclosed in a manner sufficiently clear and complete for it to be carried out by the skilled person, without undue burden, on the basis of the information provided in the patent specification, if needed in combination with the skilled person's common general knowledge. This means in the present case that the skilled person should be able to prepare an adhesive composition according to claim 1 as granted, which was contested by the appellant.

1.2 Claim 1 as granted is a product claim which is characterised by a combination of structural features related to the definition of the components which have to be mandatorily present in the composition being claimed (as defined in features a) to c)), with the additional functional feature that "less than 10 weight

percent of the hydrophilic component is extractable from the adhesive composition into a phosphate buffer saline solution at pH 7 within 24 hours at room temperature" (said feature is referred to in the following as "**the extractability parameter**"). In the present case, there are no reasons to consider that the latter functional feature - which is central for the appellant's objection of lack of sufficiency of disclosure - is implicitly satisfied by all the compositions falling under the structural definition of claim 1 (see also point 2.2, third paragraph, below). Therefore, the question to be answered is whether or not the patent in suit, optionally in combination with common general knowledge, provides sufficient guidance how to prepare, with a good chance of success and without undue burden, compositions as defined in structural terms in operative claim 1 which further satisfy the extractability parameter. In that respect, the appellant's objection was based on two separate lines of arguments, which are dealt with hereinafter.

Unusual parameter and method of determination

1.2.1 The appellant argued that the extractability parameter was an unusual parameter whose method of determination was not sufficiently disclosed to allow a reliable measurement thereof (statement of grounds of appeal: bottom of page 6 to top of page 15).

1.2.2 In that regard, independently of whether or not the extractability parameter that is specified in claim 1 as granted is a usual parameter (as was considered by the opposition division but which was in dispute between the parties), it was not shown by the respondent that said parameter could be determined

using a well accepted method in the art. Therefore, it cannot be held that the skilled person could merely rely on common general knowledge to determine said parameter. Rather, this can only be done on the basis of the information provided by the patent in suit.

1.2.3 In that respect, at least some information how the extractability parameter may be determined is given in paragraphs 57 and 58 of the patent in suit (see indications regarding amount and some dimensions of the samples, amount of extraction fluid, procedure of determination of the extracted species). Further information, e.g. regarding the dimensions of the samples to be prepared, are indicated in the examples (thickness of support and adhesive film; irradiation type and dose; see e.g. last two sentence of paragraph 64).

a) It is correct that apart from the indication of the nature of the extraction fluid, of the temperature of measurement and the duration of the extraction, no reference is made in claim 1 as granted to any other details of the method of measurement (either directly or by reference to the description), which means that said parameter should be read in its broadest sense, albeit in a manner that is technically sensible for the skilled person working in the field of adhesive composition, which is the object of said claim 1. However, in the present case, considering that at least some information how to carry out the measurement of the extractability parameter is provided in the description, the fact that limited amount of information regarding the determination method of the extractability parameter is specified in claim 1 as granted is solely related to the determination of the scope of the claims (i.e. when is the skilled person

working within or outside the claim?), which is rather a matter of clarity than sufficiency of disclosure. In that regard, such a clarity issue cannot be addressed at the present stage of the proceedings since the extractability parameter is already present in claim 1 as granted (see decision G 3/14). In particular, the arguments put forward by the appellant are not sufficient to conclude that the ambiguity regarding the determination method of the extractability parameter is such as to amount to a lack of sufficiency of disclosure for the following reasons:

b) Although it is correct that the pH and the nature of the buffer used in the examples of the patent in suit are different from the corresponding features specified in claim 1 as granted (statement of grounds of appeal: page 8, last paragraph), the Board is satisfied that the skilled person could modify these disclosures of the experimental part of the patent in suit in order to carry out a method of determination according to the one specified in claim 1 as granted. In addition, the appellant has not shown that the method used in the experimental parts of the patent in suit even led to results that are significantly different from the ones that would be obtained using a method according to claim 1 as granted.

c) Although the formulae indicated in paragraph 58 of the patent in suit might be somewhat "confusing" for the reasons indicated by the appellant (statement of grounds of appeal: page 9), the Board is also satisfied that the skilled person would know how to calculate the "initial weight of hydrophilic additive" and "percent weight loss of hydrophilic additive" using basic mathematics, i.e. without the need to rely on these formulae.

d) The appellant put forward that the method indicated in the patent in suit failed to define the thickness of the adhesive during the test (statement of grounds of appeal: page 10, first full paragraph). Considering that it was accepted by the respondent that the results of the extraction method depended on the thickness of the adhesive layer, that deficiency amounted to a lack of sufficiency of disclosure, so the appellant.

In that regard, the Board agrees with the appellant that there is no reason to limit the method of measurement in the light of passages of the description (e.g. in respect of the dimensions of the sample of adhesive layer on which the measurement is made in the examples of the patent in suit; see also paragraphs 52 and 57 of the patent in suit for information regarding suitable ranges for the thickness and main surface of the sample). As an aside, it is noted that it was not even argued by the respondent that claim 1 as granted should be read in that manner. However, the consequence of that lack of information in claim 1 as granted only means that the claim has to be read in its broadest, technically meaningful sense. In the present case, it makes in particular no doubts that the skilled person would know, at least in view of e.g. paragraphs 52, 57 and 64 of the patent in suit mentioned above how s/he could proceed to suitably prepare a sample on which the extractability parameter could be determined.

e) The appellant further holds that the patent in suit failed to disclose any pre-drying step to compensate for the initial water content of the components (statement of grounds of appeal: page 10, second full paragraph).

However, should it be held that the skilled person knows that components b) as defined in claim 1 as granted are hygroscopic, s/he would also certainly take that knowledge into account when determining the extractability parameter. In that respect, it is further noted that in the patent in suit, the samples are first subjected to an "absorption capacity test" and then evaluated for "sample integrity" (page 9, lines 5-6). In the absence of any additional indication in that passage of the patent in suit regarding e.g. waiting time/storage, it is reasonable to consider that both tests were carried out one (directly) after the other.

f) The appellant further argued that the test method disclosed in the patent in suit was only suitable to measure the content of all the components that were extracted but did not allow to differentiate the sole hydrophilic components defined in claim 1 as granted (whose amount is to be less than 10 wt.%) from any other components, different from said hydrophilic components, that could simultaneously be extracted by the method of the patent in suit (statement of grounds of appeal: page 10, last paragraph to page 11, second paragraph).

That objection was already rebutted by the opposition division in the decision under appeal (reasons: point 37). While it was agreed that, in view of the co-extraction issue mentioned by the appellant, the method according to paragraphs 57 and 58 of the patent in suit did not allow to determine directly the extractability parameter, it was held that the disclosure of the patent in suit could be adapted, using common general knowledge, to arrive at a method that accounted only for component b) as defined in claim 1 as granted (e.g.

by first determining the amount of component c), for which independent methods of measurements were known in the art, in the extracted material and then subtracting said amount from the total amount of extracted material determined according to the patent in suit).

However, the reasoning of the opposition division does not appear fully convincing because the composition according to claim 1 as granted is defined in an open manner ("comprising") and allows for the presence of any other component different from the ones specifically mentioned therein, in any amounts (claim 1 as granted contains no limitation regarding the amount of any component present therein). Under these circumstances, it appears that the amount of component b) according to claim 1 cannot be determined by the method proposed by the opposition division for all compositions according to claim 1 as granted.

Nevertheless, should any other component be co-extracted together with component b) as defined in claim 1 as granted - as put forward by the appellant -, obtaining a total amount of co-extracted components of less than 10 wt.% would impose that less than 10 wt.% of components b) *per se* is extracted (as apparently even considered by the appellant in their novelty objection: see statement of grounds of appeal, page 18, last paragraph, last sentence). Therefore, the fact that there is no guidance in the patent in suit about correcting any type of co-extraction is not held by the Board to hinder the skilled person from preparing an adhesive composition according to claim 1 as granted.

In addition, as correctly put forward by the respondent during the oral proceedings before the Board, the skilled person who has prepared the adhesive

composition being claimed knows exactly which components are present and may be co-extracted. In particular, there is no evidence on file showing that s/he would have any difficulty to determine if and in which amount any of these - known - components is co-extracted. This is particularly true for the antimicrobial agents specifically disclosed in the patent in suit (paragraphs 26-28).

In view of the above, also the fact that claim 1 as granted does not specify any ratio between the amounts of the hydrophilic component b) and the antimicrobial agent c) and the fact that dependent claim 8 as granted allows the antimicrobial agent c) to be up to four time higher than the amount of hydrophilic component b) (appellant's letter of 24 October 2023: paragraph bridging pages 2 and 3) was not shown to lead to a lack of sufficiency of disclosure.

g) In the statement of grounds of appeal (bottom of page 11 to bottom of page 13), the appellant addressed an argument put forward by the respondent during the opposition proceedings, whereby the respondent had argued that the method of determination of the extractability parameter had to be such that the maximum amount of hydrophilic component b) was extracted. However, according to the appellant, the patent in suit provided no guidance to ensure that said maximum amount of hydrophilic component b) was extracted. For that reason also, the patent in suit was insufficiently disclosed.

In that regard, the Board notes that neither claim 1 as granted, nor the patent specification makes any reference to the fact that the extractability parameter is related to the "maximum amount" of extracted

species. Therefore, it is not clear to the Board how said issue can be relevant for the assessment of sufficiency of disclosure. Indeed, the question to be answered is, as indicated above, if the patent in suit, if needed complemented by common general knowledge, provides sufficient information as to how to determine said parameter.

h) During the oral proceedings before the Board, the appellant further elaborated their objection by relying on the Case Law related to completeness of disclosure (Case Law of the Boards of Appeal of the EPO, 10th edition, 2022, II.C.5.5.3), in particular with reference to the passage related to decision T 1553/16. However, the latter case dealt with a different situation than the present one, in which a parameter mentioned in a claim, which was not unclearly delimited but was in itself very specific, was to be determined using a procedure whose method of measurement had been kept secret. In contrast, the present case is directed to a parameter which is alleged to be unclearly delimited but for which at least some information regarding its determination method is provided in the patent specification. In view of this, the circumstances of the present case differ in a significant manner from the ones of T 1553/16 and there is no reason to consider that the findings of this decision must also apply to the present case. Therefore, the appellant's argument based on T 1553/16 is rejected.

i) For these reasons, the appellant's argument that the patent in suit did not provide sufficient information to determine the extractability parameter did not convince.

Insufficiency according to T 1845/14

1.3 The appellant argued that, in view of the lack of information regarding the determination method of the extractability parameter, the definition of said parameter was ambiguous, so that the subject-matter of claim 1 as granted had to be read in its broadest sense. However, the teaching of the patent in suit was not sufficient to enable the skilled person to carry out the invention over the whole breadth of the claim, since e.g. it was highly questionable that a 1 µm thick sample that exhibited less than 10 wt.% extraction could be prepared. Following the findings of decision T 1845/14, this amounted to a lack of sufficiency of disclosure (statement of grounds of appeal: pages 15-17).

1.3.1 In that respect, according to established case law, an objection of insufficiency of disclosure presupposes that there are serious doubts, substantiated by verifiable facts, and the burden of proof is primarily on the opponent(s), here the appellant. However, in the present case, the appellant's objection is not supported by any evidence.

1.3.2 In addition, claim 1 as granted does not contain any feature related to a sample thickness of 1 µm thickness. Also, the subject-matter of claim 1 as granted is directed to an adhesive composition. Therefore, the determination of the extractability parameter mentioned in said claim 1 only makes sense if it is read in relation to that use, as further derivable from the fact that the relevant amount should be extractable "from the adhesive composition". In that regard, it was not shown that a sample thickness of

1 µm is representative of such a use.

1.3.3 For these reasons already, the appellant's objection is not persuasive and there is no need to address the relevance of the findings of T 1845/14 for the present case.

1.3.4 The appellant noted that in support of the submission that decision T 1845/14 did not apply to the present case, the respondent had put forward that the patent in suit showed how to prepare the claimed adhesive compositions in particular using irradiation curing, whereby it was further mentioned in paragraph 46 of the patent in suit that said irradiation curing led to a covalent bond being formed between the hydrophilic component and the silicon gel, thereby preventing extractability of the hydrophilic component (rejoinder: page 11, first paragraph). However, the appellant pointed out that while such an irradiation curing was the object of dependent claim 4 as granted, it was not reflected at all in claim 1 of the main request. Therefore, the respondent's argument based on the fact that the patent in suit showed that the adhesive composition of claim 1 as granted could be prepared by an irradiation process was only possibly relevant for claim 4 as granted but not for claim 1 as granted. That argument was pursued at the oral proceedings before the Board, during which the appellant considered that the respondent's argument showed that claim 1 as granted encompassed means of realisation that did not imply irradiation curing for which the patent in suit failed to indicate how to proceed. For that reason, the absence of a mention of irradiation curing in claim 1 as granted led to a lack of sufficiency of disclosure, so the appellant.

a) However, the Board shares the respondent's view (that was put forward at the oral proceedings before the Board) that the question to be answered when assessing sufficiency of disclosure is whether the patent in suit provides sufficient information as to how to prepare the adhesive composition being claimed. In that regard, at least the examples of the patent in suit show how to proceed. In addition, paragraphs 40-45 of the patent in suit provide general information how to prepare the adhesive compositions by radiation curing and the examples provide more specific information regarding irradiation type and dose (see e.g. paragraph 64). In addition, it is explained in paragraph 46 of the patent in suit that through such an irradiation process, the hydrophilic component is covalently bonded to the silicone component making it less extractable. Therefore, paragraph 46 of the patent in suit establishes a direct link between the (low) level of extractability mentioned in claim 1 as granted and irradiation curing and undoubtedly provides the information necessary to prepare an adhesive composition satisfying the extractability feature specified therein (see rejoinder: page 13, second full paragraph).

b) In the Board's view, claim 4 as granted is considered to constitute a mean chosen by the respondent to possibly distinguish the subject-matter of claim 1 as granted from the prior art by means of a product-by-process feature, should it be needed at some stage of the proceedings. The question if and how claim 4 as granted may effectively distinguish the subject-matter being claimed from the one of claim 1 as granted is a question that could have been relevant if novelty of both claims had had to be assessed, which however was not the case.

c) For these reasons, the appellant's argument that the absence of a mention of irradiation curing in claim 1 as granted led to a lack of sufficiency did not convince.

1.3.5 Under these circumstances, the appellant's objection of lack of sufficiency of disclosure based on T 1845/14 is rejected.

1.4 In view of the above, the Board is satisfied that the skilled person would be able, on the basis of the patent in suit and common general knowledge, to prepare an adhesive composition comprising the components mentioned in claim 1 as granted and meeting the extractability parameter defined in said claim 1 (notwithstanding the ambiguity related to the latter). For these reasons, the appellants' arguments do not justify that the Board overturns the decision of the opposition division regarding Article 100(b) EPC.

2. Novelty: Article 100(a) and 54 EPC

2.1 The appellant disagreed with the conclusion reached by the opposition division that the subject-matter of claim 1 as granted was novel over the disclosure of example 5 of D4. In a first line of argument, the appellant considered that the extractability parameter specified in claim 1 as granted was not a limiting feature and should be disregarded when assessing novelty. In a second line of argument, the appellant argued that even if that parameter were to be considered, it was implicitly met by the composition prepared in example 5 of D4. These objections did not convince the Board for the following reasons:

The extractability parameter is a limiting feature

2.2 Although it had been rejected by the opposition division (reasons: points 40-41), the appellant pursued in appeal their line of argument that the extractability parameter was so ill-defined that it should not be considered as a limiting feature (statement of grounds of appeal: footnote 3 on page 18).

2.2.1 However, the Board shares the view of the opposition division that the ambiguity regarding the definition of the extractability parameter is not so severe that the parameter should be completely disregarded. Indeed, as derivable from the analysis regarding sufficiency of disclosure, the Board considers that the extractability parameter can for instance be determined by the skilled person on the basis of the information provided in the patent in suit and, if needed, common general knowledge. Therefore, although only limited information regarding the determination method for that parameter is specified in claim 1 as granted, said parameter does imply some limitation on the definition of the adhesive composition being claimed.

2.2.2 In addition, the appellant's considerations that the extractability parameter should be disregarded because it could be expected that it would be met by any compositions meeting the structural requirements of claim 1 (statement of grounds of appeal: page 18, first paragraph) is not convincing. Indeed, this is neither derivable from the patent in suit, nor supported by any evidence, nor was it ever argued by the respondent. Also, considering that the composition according to claim 1 as granted contains no explicit limitations regarding the amounts of each of components a) to c)

defined therein, the Board considers that the skilled person would not expect that any composition according to the structural features of claim 1 as granted would mandatorily meet the extractability parameter.

2.2.3 For these reasons, the appellant's arguments are rejected and the extractability parameter is hereinafter considered as a limiting feature of claim 1 as granted.

Burden of proof

2.3 In the statement of grounds of appeal (middle of page 22) and during the oral proceedings before the Board, the appellant referred to the Case Law (*supra*, I.C.5.2.3) to argue that the extractability parameter being an unusual parameter, the burden of proof was on the respondent to show that said feature was not met by the composition of example 5 of D4.

However, the Board does not share the appellant's view since in (appeal) opposition proceedings the burden of proof primarily lies on the opponent, here the appellant, to show that the relevant prior art relied upon effectively discloses all the features of the claims objected to lack novelty. In that respect it is noted that at the end of the passage of the Case Law referred to by the appellant, reference is made to Chapter III.G.5.2.2 "Cases in which the burden of proof was reversed". In section d) of that Chapter (which is related to "unusual parameters") it is stated that the burden of proof may be reversed (from the opponent to the patent proprietor) "once the opponent had established a strong presumption that unusual parameters as those used to define the claimed subject-matter were inherently disclosed in the prior art". The

present Board agrees with that finding and therefore considers that the first point to clarify is whether or not the opponent, here the appellant, has established a strong presumption that the subject-matter of claim 1 as granted is anticipated by the composition prepared in example 5 of D4, which is done hereinafter.

Implicit disclosure of the extractability parameter?

2.4 The appellant was further of the opinion that it was derivable from D9 to D11 that the extractability parameter was implicitly met by the composition prepared in example 5 of D4 (see e.g. statement of grounds of appeal: page 18, third paragraph).

2.4.1 Regarding the issue of implicit disclosure, it is established case law that a prior art document takes away the novelty of a claimed subject-matter if the latter is directly and unambiguously derivable from that document, including any features implicit to a person skilled in the art, whereby an alleged disclosure can only be considered "implicit" if it is immediately apparent to the skilled person that nothing other than the alleged implicit feature forms part of the subject matter disclosed (Case Law, *supra*, I.C.4, I.C.4.1 and I.C.4.3).

2.4.2 As already indicated in section 1 above, the extractability parameter of claim 1 as granted has, in the absence of any information in the claim regarding e.g. the dimensions of the sample and/or the relative amount of extraction fluid as compared to the exposed surface of the sample on which the parameter has to be determined (which features are undisputedly relevant for the determination method of the extractability parameter), to be read in its broadest, technically

meaningful sense.

2.4.3 In that respect, the main issue in dispute between the parties in appeal was whether the method of determination of the extractability used by the appellant in D9-D11 was technically meaningful.

Said method consisted in preparing about 180 g of a cured composition as disclosed in example 5 of D4 in a jar with a bottom diameter of about 11.2 cm and then to add 400 ml of a phosphate buffer saline solution at pH 7 on top of it (D10: bottom of page 1 and Appendix 1; D11: point 3). It was common ground that in doing so, the cured composition consisted of a layer of about 2-3 cm height located at the bottom of the jar (2.9 cm in D12, see page 2, line 3; the jar used in D9-D10 had similar but different dimensions with respect to the ones used in D12, see point 3 of D11 and page 1, last paragraph of D12). The jar was then kept for 24 h at room temperature and the amount of hydrophilic component extracted in the phosphate buffered saline solution was determined and found to be of 6.6 %, i.e. within the range specified in claim 1 as granted.

2.4.4 In that regard, the opposition division held that it would not make technical sense to the skilled person to consider that any extraction method would be suitable to measure the extractability parameter, in particular because the skilled person knew that the amount of extractables depended on the experimental conditions. According to the opposition division, the conditions used in D9-D11 were very unfavourable to extraction because the contact surface between the sample and the extraction fluid was very small and the sample thickness was very large (reasons: page 11, first

paragraph and point 43).

2.4.5 In that respect, no evidence was provided in appeal by the appellant to show that the conclusion reached by the opposition division was incorrect, e.g. by showing that the experimental conditions used in D9-D11 to determine the extractability parameter were already used for a similar aim and/or that these conditions would be held to make technical sense by a skilled person working in the field of adhesive compositions (said person being different from their own technicians, who drafted D9-D11).

2.4.6 In addition, regarding the conditions under which said extraction takes place, the Board took into consideration that the subject-matter of claim 1 as granted is not merely directed to a composition *per se* but to an "adhesive composition" which has to satisfy certain requirements in terms of the extractability of one of its component. Therefore, the conditions under which said extractability is determined should, in order to make technically sense, be related in a reasonable manner to the application specified in claim 1 as granted, namely the application as an adhesive composition.

a) In that regard, it makes no doubt that such adhesive compositions are commonly used as thin layers. Although paragraphs 49-51 of the patent in suit make reference to various applications (including e.g. denture, hairpieces and various substrates such as metal or glass), the Board agrees with the respondent that such applications, read in the context of the patent specification as a whole, indicate that for such applications, use can be made of the adhesive compositions being claimed. In view of this, the Board

considers that the skilled person would consider that, in the context of claim 1 as granted, a method of determination in which the extractability parameter is determined on a layer of 2-3 cm height such as the one used in D9-D11, would not be reasonable.

b) During the oral proceedings before the Board, the appellant argued that although adhesive compositions may commonly be used as thin layers, the description of the patent in suit did not impose any limitation regarding the thickness of the sample on which the extractability parameter was to be determined. According to the appellant, it was further derivable from paragraphs 6 and 49-54 of the patent in suit that the use of the claimed adhesive compositions as thin layer was only directed to the "second embodiment" of the patent in suit. This was further confirmed by the fact that according to paragraph 52 of the patent in suit the thickness of the adhesive layer was "not particularly limited". Therefore, there was no reason to disregard the determination method used in D9-D11, so the appellant.

However, the Board does not share the appellant's view for the reasons indicated in the preceding paragraph. In addition, the fact that the thickness of the adhesive compositions is "not particularly limited" cannot be read to mean that "any thickness" without upper limit would be considered by the skilled person. Rather, that expression has to be read in the context of adhesive compositions to mean that any thickness that would be contemplated by the skilled person working in the field of adhesive compositions may be considered, i.e. thin layers.

2.4.7 Furthermore, the Board considers that the skilled person working in the field of adhesive compositions and confronted with claim 1 as granted would understand that the extractability parameter, which is defined in terms of a range defined by a single, relatively low upper limit ("less than 10 weight percent") is meant to define that a rather low amount of hydrophilic component should be extractable from the adhesive composition. Therefore, such as parameter only makes sense if the method of extraction allows to extract an amount of the component of interest which is sufficiently high to be meaningful. This, however, does not mean that said method should extract the "maximum" amount of the relevant component (see point 1.2.2.g above).

In that regard, the respondent showed in D12 that determining the extractability parameter using either i) small samples of a thin (125 µm) coating of a composition prepared according to example 5 of D4 immersed in 1 litre of a phosphate buffer solution (sample 2 of D12, method according to the patent in suit) or ii) a thick layer (2.9 cm) of the same composition topped by 400 ml of the same buffer solution (sample 1 of D12, method according to D9-D11) led to significantly different results in terms of extracted species (sample 1: 5.9 %; sample 2: 36 %). It is correct that, because co-extraction cannot be excluded (see point 1.2.3.f above), these results cannot unambiguously demonstrate that whereas the experimental conditions used for sample 1 of D12 did not satisfy the extractability parameter, the ones used for sample 1 of D12 did. However, the results of D12 at least allow to conclude that the two methods of determination led to significantly different results whereby the method used in D9-D11 surely led to a

significant underestimation of the (total) amount of extracted species, including hydrophilic components, during the duration of the test. The Board considers that this finding further confirms that, since the method used in D9-D11 eventually led to a rather limited extraction of the extractable components, it would not be considered as a reasonable method of determination of the extractability parameter.

2.4.8 In view of the above, although the extractability parameter has to be read in the broadest sense allowed by the relevant features of claim 1 as granted, the Board arrived at the conclusion, taking into account the parties' arguments and the evidence on file, that the method of determination used by the appellant in D9-D11 to determine that feature was not reasonable and would not be considered to constitute an appropriate method by the skilled person working in the field of adhesive compositions.

2.4.9 In view of the above, the data of D9-D11 are not suitable to demonstrate that the composition prepared in example 5 of D4 implicitly satisfies the extractability parameter specified in claim 1 as granted. For that reason, it cannot be concluded that the appellant has established a strong presumption that the composition according to example 5 of D4 implicitly satisfies the extractability parameter according to claim 1 as granted. As a consequence, the circumstances of the present case do not justify that the burden of proof be reversed and remains on the appellant/opponent (see point 2.3 above). However, since the Board arrived at the conclusion that the extractability parameter was not shown to be inherently disclosed in the prior art, the appellant's objection of lack of novelty cannot succeed at least for that reason.

Further considerations

2.5 During the oral proceedings before the Board, both parties had a different reading of the disclosure of document D4 regarding the adhesive properties of the compositions prepared therein: whereas the respondent held that D4 was directed to the preparation of cured silicone gels that were so little adhesive that they did not adhere too much to the skin (as already mentioned on page 18, second full paragraph of the rejoinder), the appellant considered that the cured silicone gels according to D4 undoubtedly had adhesive properties and, therefore, were adhesive compositions according to claim 1 as granted (as already hinted at on page 8, first paragraph of their letter of 24 October 2023).

In that respect, the Board notes that most of the passages of D4 that were referred to by the appellant during the oral proceedings before the Board in support of their line of argument (D4: page 18, lines 15-16; page 22, lines 12 and 26-30; page 26: lines 17-22) do not disclose that the cured silicon compositions of D4 *per se* can suitably be used as adhesive compositions but rather teach that said compositions may be used by application on a substrate, including substrates that have adhesive properties (e.g. "adhesive", "adhesive tape"). The only passages of D4 mentioned by the appellant that effectively deal with the adhesion properties of the cured silicone gels of D4 *per se* are claim 18, page 17, lines 19-23 and page 22, lines 26-30. However, these passages disclose a range of relatively low adhesive properties (adhesion with steel of between 0.1 and 2 N as determined with ASTM D 3330/D3330M-04, method F) and point to the aim of

providing gels that ensure "patient comfort and compliance", which in the field of wound dressings according to D4 (see e.g. page 1, lines 5-7) and in the context of the cited passages is understood by the Board to mean sufficiently low adhesion to avoid pain on removal of said gels. In particular, it was not shown that D4 discloses any information regarding the adhesive properties of the composition prepared in example 5 thereof and no evidence in that regard was submitted by any of the parties. Also, there is no evidence on file for the Board to refute the respondent's view that the data concerning the peel adhesion of the adhesives of D4 were lower than the ones of the opposed patent (rejoinder: page 18, second full paragraph). Under these circumstances, the Board shares the concerns of the respondent and considers that there are at least some reasonable doubts whether the cured silicone compositions according to D4, including the one prepared in example 5 of D4, can effectively be considered as "adhesive compositions".

2.6 For these reasons, the Board arrived at the conclusion that the appellant's arguments did not justify that the decision of the opposition division regarding novelty of the subject-matter of claim 1 as granted over example 5 of D4 be overturned.

3. Inventive step: Article 100(a) and 56 EPC - D1 as the closest prior art

3.1 Starting point and distinguishing feature(s)

It was common ground between the parties that:

- Examples 22 to 24 of D1 constituted a promising starting point for the assessment of inventive

step;

- The subject-matter of claim 1 as granted differed from the disclosure of said examples 22 to 24 of D1 only in that the compositions being claimed must contain components b) and c) as defined therein.

The Board has no reason to be of a different opinion.

3.2 Problem effectively solved over the closest prior art

3.2.1 The respondent considered that the examples and comparative examples of the patent in suit showed that the effects achieved by the above indicated distinguishing features were an antimicrobial activity and hydrophilic property without loss of adhesive capacity and loss of sample integrity (rejoinder: page 16, first five full paragraphs).

3.2.2 The appellant did not agree with that view and held that the experimental section of the patent in suit itself showed that the part of the problem related to "without loss of adhesive capacity" was not solved. Therefore, the problem effectively solved should not be based on that effect, so the appellant (statement of grounds of appeal: bottom of page 27 to page 29, second paragraph).

a) In that respect, the Board agrees with the appellant. Indeed, the compositions prepared in examples 1, 2 and 5 of the patent in suit only differ from the one according to comparative example CE1 in that they contain a hydrophilic component and an antimicrobial agent as defined in claim 1 as granted (see table 1 of the patent in suit, whereby it is derivable therefrom that these compositions contain a

comparable weight ratio of the same silicone material OHX-4070 and tackifier BELSIL TMS-803; see also the table on page 7 of the appellant's letter of 24 October 2023). However, it is shown in table 2 of the patent in suit that the composition according to example 5 exhibits a loss of adhesive capacity (180° Peel Adhesion) as compared to the one according to comparative example CE1. The same conclusion may be drawn when comparing examples 3 and 4 with comparative example CE2 of the patent in suit (see table on page 7 of the appellant's letter of 24 October 2023; rows "greyed"). Under these circumstances, the problem effectively solved over D1 cannot be formulated using the term "without loss of adhesive capacity".

b) However, the respondent considered that the peel adhesion shown in table 2 of the patent in suit could at least be retained as being "good", i.e. sufficient for an adhesive composition (rejoinder: page 16, third full paragraph). This was not contested by the appellant (no argument in that sense was in particular put forward in the appellant's submission dated 24 October 2023 or in the submissions made in reaction to the Board's communication in which that point was mentioned) and the Board sees no reason to be of a different opinion.

3.2.3 Regarding the part of the problem related to "without loss of sample integrity", the Board agrees with the respondent (rejoinder: page 16, fourth full paragraph) that comparative example CE3 of the patent in suit shows that the specific hydrophilic components defined in claim 1 as granted show, using the specific test of the patent in suit, less extractability as compared to other hydrophilic components such as e.g. polyethylene glycol (PEG). In addition, although there is some

ambiguity in relation to the definition of the method of determination of the extractability parameter indicated in claim 1 as granted, is is derivable from the assessment of sufficiency of disclosure and novelty made above that the method provided in the patent in suit at least provides a mean to assess in an objective manner if the criterion mentioned by the respondent, namely "without loss of sample integrity", is met or not. Also, in view of the conclusion reached on novelty that the method used in D9-D11 by the appellant to determine the extractability parameter was not reasonable, it cannot be concluded that the skilled person is not in the position to determine when a composition may be held to solve that problem or not. Under these circumstances, there is no reason for the Board to disregard the effect "without loss of sample integrity" relied upon by the respondent for the formulation of the problem effectively solved.

3.2.4 In view of the above, the problem effectively solved over D1 is seen as to reside in the provision of an adhesive composition that exhibits antimicrobial activity and hydrophilic properties together with satisfying adhesive capacity and without loss of sample integrity.

3.3 Obviousness

3.3.1 The question remains to be answered if the skilled person, desiring to solve the problem(s) identified as indicated above, would, in view of the closest prior art, possibly in combination with other prior art or with common general knowledge, have modified the disclosure of the closest prior art in such a way as to arrive at the claimed subject matter.

3.3.2 In that respect, while the appellant's objection was based on the combination of D1 with the teaching of D4, the respondent considered that the skilled person would not consider combining these documents in view of the difference in adhesive strength and of the curing methods involved therein (rejoinder: page 18, second full paragraph; the objection being further elaborated at the oral proceedings before the Board).

a) In that regard, it is correct that D1 and D4 both at least belong to neighbouring fields of compositions comprising silicone gels that can be suitably used for wound dressings: compare D1, claims 1, 11, 13 and paragraphs 2, 3, 19, 37, 41-48 vs. D4, claims 1, 19, 26, 29, page 1, lines 5-7, page 3, lines 10-18, page 6, lines 8-11, page 17, lines 19-28 and page 22, line 27 to page 23, line 2. It is further derivable from these passages that D4 also deals with some of the effects underlying the problem to be solved over D1 (antimicrobial activity; hydrophilic property; adhesive capacity; see also statement of grounds of appeal: bottom of page 30 to page 32). However, as already indication in section 2.5 above, the Board shares the respondent's view that D1 and D4 do not mandatorily both disclose cured silicone compositions having the same level of adhesive properties. In particular, there are at least some doubts that the skilled person would consider that the compositions prepared in D4 are adhesive compositions in the sense of D1. Already for that reason, it is questionable if the combination of D1 with D4 considered by the appellant may be held to be obvious.

b) Should such a combination be nevertheless considered, it is further noted that the polymeric and curing systems of the two documents D1 and D4 are

significantly different (D1: radiation curing of siloxanes without using a catalyst, see paragraphs 62 and 63; D4: two components siloxanes cured under heat in the presence of a catalyst, see e.g. claims 1, 13 and 19). In addition, while the whole teaching of D4 is related to the use of a combination of a silver salt as antimicrobial additive with a hydrophilic component as a swelling agent to enhance the release of the silver component (D4: claim 1; page 10, line 24 to page 11, line 28), it is rather specific in terms of the definition of the polymeric matrix to be used: claim 1 thereof in particular defines specifically a composition "comprising at least one alkenyl- and/or alkynyl substituted polysiloxane, at least one polysiloxane comprising silicon-bonded hydrogen atoms, and at least one hydrosilylation catalyst". The description and the examples of D4 were also not shown to provide different information (see e.g. page 8, last paragraph to page 10, first paragraph). Such compositions are, however, significantly different from the curable silicone compositions used in examples 22-24 of D1 constituting the closest prior art. Under these circumstances, the Board considers that the combination of D1 with D4 contemplated by the appellant is even less obvious in view of the different polymeric systems involved in the two documents.

c) In that respect, although the appellant is correct that D1 explicitly allows for the present of additives (statement of grounds of appeal: page 32, second full paragraph; page 33, last paragraph), in particular pharmaceutical/antimicrobial agents and hydrophilic polymers such as the ones disclosed as essential components of the invention of D4 (D1: paragraph 43; D4: claim 1), the concerns regarding the combination of D1 with D4 indicated above remain nevertheless valid

because, in view of the different disclosures of these documents in terms of both the polymeric systems and the adhesive properties, the skilled person would have no reason to expect that any teaching derivable from D4 would mandatorily apply to any disclosure of D1 (in particular the one according to examples 22-24 thereof).

d) For these reasons, on the basis of the considerations indicated in above paragraphs a) and b), the Board considers that the combination of D1 with D4, which was relied upon by the appellant for their objection of lack of inventive step, is not obvious.

3.3.3 In addition, even if based on the disclosure of D4 the skilled person were to consider using a silver salt and a hydrophilic component as taught therein (D4: see e.g. claim 1; page 3, lines 10-18 and 20-28) in the composition according to examples 22-24 of D1 with the aim of providing an adhesive composition that exhibits antimicrobial activity and hydrophilic properties, s/he would have had no hint how to prepare such a composition which does not exhibit a loss of sample integrity. In that respect, it is in particular noted that, whereas all the silver salts defined in D4 correspond to an antimicrobial agent according to component c) of claim 1 as granted (which include any "silver-containing compound"), the most general definition of the hydrophilic component disclosed in D4 encompasses both compounds that are either according to component b) of claim 1 as granted or not (see e.g. D4: claim 3, which in particular discloses mannitol and CMC that are used as hydrophilic component b) in the examples of the patent in suit but also other components that do not satisfy the definition of said component b), such as polyethylene glycol). In that

regard, as already indicated in point 3.2.3 above, comparative example CE 3 of the patent in suit shows that not all hydrophilic components disclosed in D4 solve that part of the problem. In addition, the statement made in paragraph 46 of the patent in suit provides (regarding formation of a crosslinking between the silicone component and the hydrophilic component defined in claim 1 as granted upon irradiation) renders credible that the improvement in terms of sample integrity cannot be achieved when using any hydrophilic component according to the teaching of D4 (but only with the ones that may undergo said crosslinking upon irradiation). Under these circumstances, the Board agrees with the respondent that, in view of the evidence on file, the problem posed is credibly solved by the adhesive compositions according to claim 1 as granted but not by all the combinations of antimicrobial agent and hydrophilic components taught in D4 (as shown by comparative example 3 of the patent in suit).

3.3.4 The appellant noted that it was derivable from table 6 of D4 that, among the hydrophilic components tested in D4, either CMC or mannitol - which are components b) according to claim 1 as granted - led to the best properties of the gels prepared therein. In view of this, CMC and mannitol were components of choice in D4 and their selection was not based on hindsight (statement of grounds of appeal: page 34, first half; letter of 24 October 2023: paragraph bridging pages 8-9).

However, even if the appellant's arguments were to be followed, it was not shown that the skilled person would have had any reason to select CMC or mannitol in order to provide improved sample integrity, which

problem is not addressed at all in D4. In addition, as already noted above, there is no reason to expect that the beneficial effects shown in D4 would be mandatorily obtained for the cured silicon compositions of D1, which are of a different nature. For these reasons, the appellant's arguments did not persuade.

3.3.5 For these reasons, the subject-matter of claim 1 as granted amounts to a purposive selection within the ambit of D4 which leads to the claimed technical effect of improved sample integrity.

3.3.6 In view of the above, the appellant's arguments do not justify that the Board overturns the decision of the opposition division in regard of inventive step in view of D1 as the closest prior art.

3.3.7 As an aside, it is noted that the respondent requested that a new argument, which was put forward by the appellant for the first time in their statement of grounds of appeal in respect of the obviousness of the combination of D1 with D4, be not admitted (rejoinder: section II.b). However, said argument was put forward by the appellant in support of their objection of lack of inventive in case the objective problem would include "without losing adhesion properties" (statement of grounds of appeal: page 32, second full paragraph). Since the Board arrived at the conclusion that the problem could not be formulated on the basis of that property (see point 3.2.2.a above), there is no need for the Board to decide on the admittance of that argument.

4. Inventive step: Article 100(a) and 56 EPC - D4 as the closest prior art

4.1 Starting point and distinguishing feature(s)

4.1.1 It was common ground between the parties, once the decision on novelty had been taken, that:

- Example 5 of D4 constituted a promising starting point for the assessment of inventive step;

- The subject-matter of claim 1 as granted differed from the disclosure of said example 5 of D4 at least in that the compositions being claimed must satisfy the requirements in terms of the extractability parameter, for which it was derivable from the conclusion reached by the Board in respect of novelty that this was not the case for the relevant composition of D4 when reasonable extractability conditions were used.

4.1.2 The Board has no reason to be of a different opinion. In particular, although the respondent expressed some concerns during the oral proceedings before the Board whether D4 was a suitable document to be taken as the closest prior art (for the reasons indicated in point 2.5 above), the respondent did not formally object to the selection of document D4 as the closest prior art. Under these circumstances, D4 is considered hereinafter as a suitable document to be taken as the closest prior art, which position is to the appellant's benefit.

4.2 Problem effectively solved over the closest prior art

Considering the conclusion reached on novelty in section 2 above according to which the composition prepared in example 5 of D4 does not meet the requirement of claim 1 as granted in terms of the

extractability parameter, it can only be considered here that the problem solved over example 5 of D4 resides in the provision of an antimicrobial composition with improved sample integrity.

4.3 Obviousness

4.3.1 Regarding the question of obviousness of the solution, the appellant's objection was based on the combination of D4 with D1.

4.3.2 However, for the same reasons as the ones outlined in section 3.3.2 above, the combination of D4 with D1 contemplated by the appellant cannot be held to be obvious in view of the disclosure of the two documents related to the nature of the polymeric systems and of the adhesive properties of the compositions prepared therein.

4.3.3 In addition, it was not shown that either D4 itself, or D1 contains any information regarding sample integrity, let alone an improvement thereof. Therefore, the combination of D4 with D1 *in order to solve the problem posed* as defined in point 4.2 above cannot be held to provide a solution to the problem posed, let alone a solution that is obvious. Rather, such a combination of D4 with D1 can only be based on hindsight, which is not allowable.

4.3.4 The appellant argued that the threshold of "less than 10 weight percent" indicated in claim 1 as granted for the extractability parameter was purely arbitrary and, as such, could not contribute to an inventive step (statement of grounds of appeal: page 37, second half; further elaborated at the oral proceedings before the Board).

However, in view of the conclusions reached in respect of sufficiency of disclosure and novelty, the Board is satisfied that the extractability parameter according to claim 1 as granted is related to an effect that can be quantified and retained in the formulation of the problem solved over the closest prior art (improved sample integrity). For that reason, the appellant's argument is not convincing.

4.3.5 For these reasons, the appellant's arguments do not justify that the Board overturns the decision of the opposition division in regard of inventive step in view of D4 as the closest prior art.

5. In view of the above, none of the appellant's objections is successful and the appeal is to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe D. Semino

Decision electronically authenticated