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Datasheet for the decision of 23 February 2010

Case Number:	т 0540/07 - 3.2.06
Application Number:	98926363.7
Publication Number:	0987993
IPC:	A61B 19/08
Tanguage of the progeodings:	EN

Language of the proceedings: EN

Title of invention: Absorbent surgical drape

Patentee:

KIMBERLY-CLARK WORLDWIDE, INC.

Opponent:

Paul Hartmann AG SANTE ASSISTANCE PROMOTION/VYGON RKW SE

Headword:

-

Relevant legal provisions: EPC Art. 123(2), 84, 83, 56

Keyword:

"Amendments - agreed by Board of Appeal"
"Claims - clarity (yes)"
"Disclosure - enabling"
"Inventive step - (yes) exclusion of hindsight"

Decisions cited:

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Catchword:

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Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 0540/07 - 3.2.06

DECISION of the Technical Board of Appeal 3.2.06 of 23 February 2010

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Decision under appeal: Decision of the Opposition Division of the European Patent Office posted 16 February 2007 rejecting the opposition filed against European patent No. 0987993 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman:	P.	Alting Van Geusau	
Members:	G.	de Crignis	
	к.	Garnett	

Summary of Facts and Submissions

I. The oppositions against European patent No. 0 987 993 granted on application No. 98926363.7 were rejected by the opposition division by decision announced during the oral proceedings on 24 January 2007 and posted on 16 February 2007.

Claim 1 as granted reads:

"An absorbent surgical drape comprising a hydrophilic fabric and a liquid impervious film bonded to the hydrophilic fabric, characterized in that the hydrophilic fabric is a meltspun fabric made from hydrophobic polymeric material made hydrophilic by incorporating a hydrophilic chemical additive in or on the filaments, wherein the film has a dynamic coefficient of friction value, as measured by test method ASTM D1894, of greater than 0.4."

II. The decision of the opposition division was based on the finding that the subject-matter of claim 1 was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC) as in particular the skilled person would know how to carry out the test method ASTM D1894 in order to arrive, without undue burden and without inventive skill, at reliably reproducible data for the coefficient of friction. Moreover, the subjectmatter of claim 1 was considered to be novel over the disclosure in

> D2 US-A-4 379 192 and D5 US-A-5 540 979

because neither of these documents disclosed the claimed feature concerning a lower threshold value for the coefficient of friction of the film. With regard to the alleged prior use referred to by opponent 2, the opposition division was not convinced that sufficient evidence of the two products had been presented. With regard to the alleged prior use relied upon by opponent 3, the opposition division did not consider the evidence sufficient to establish the unconditional sale of finished surgical drapes to "a member of the public" before the priority date of the patent in suit. Concerning inventive step, none of the combinations which were considered as closest prior art, namely any of

D3 EP-A-0 474 123,
D5 US-A-5 540 979,
D9 GB-A-2 296 216 or
D11 FR-A-2 662 603

combined with the teaching of any of the following documents:

- D2 US-A-4 379 192,
- D4 EP-A-0 549 948,
- D6 GB-A-1 386 799,
- D7 Nonwovens and disposables (July 7-8, 1977),
- D8 EP-A-0 125 745 or
- D10 Proceedings of the lecture held at "New Plastics 96" on 30 October 1996 in Strasbourg

rendered the subject-matter of claim 1 obvious as none of these combinations suggested including a liquid impervious film having a specific lower threshold for the dynamic coefficient of friction value into a surgical drape.

Finally, the opposition division did not admit the late filed documents

- D20 Exxon Mobil Data sheets PP 4712E1 and PP 4792E1;
- D21 Excerpt from Plastics Technology, June 1993, p. 28, "New Olefin Copolymers Emerge"
- D22 EP-B-0 477 662
- D23 Evidences D1 D11 (a list of catalogue numbers and titles)
- D24 Evidence E Decision of the Commission of European Communities Nr. 61994B0322, 08.06.1994

into the proceedings as it was considered that none of these documents was *prima facie* highly relevant.

- III. On 29 March 2007 the appellant (opponent I) filed an appeal against the decision of the opposition division and on the same day paid the appeal fee. With its letter of 14 June 2007 the statement of grounds of appeal was filed, maintaining the objections concerning Articles 100(a) and (b) EPC.
- IV. On 25 April 2007 the appellant (opponent II) also filed an appeal against the decision of the opposition division and on the same day paid the appeal fee. With its letter of 22 June 2007 the statement of grounds of appeal was filed referring to lack of novelty and lack of inventive step (Article 100(a) EPC.
- V. With letter of 9 January 2008, the respondent (patent proprietor) requested the dismissal of the appeals and

filed inter alia an Annex B providing measurement data for the dynamic coefficient of friction of three film surfaces.

- VI. In a communication in preparation for the oral proceedings pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal dated 5 October 2009, the Board indicated that further consideration would need to be given to the objection under Article 83 EPC as the subject-matter of claim 1 did not appear to specify sufficiently the testing conditions for the coefficient of friction. With regard to novelty and inventive step no further comments were made.
- VII. With its letter of 22 January 2010, the respondent (patent proprietor) submitted amended sets of claims constituting a main request and first and second auxiliary requests. Additionally, Annex B was resubmitted in combination with Annex C indicating further details concerning the test method and materials.
- VIII. Oral proceedings were held before the Board on 23 February 2010, at the end of which the appellants requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested the decision under appeal be set aside and the patent be maintained on the basis of the main request filed with its letter dated 22 January 2010.

The other party did not attend the oral proceeding as had been announced with its letter of 10 November 2009.

Claim 1 according to the main request reads: "An absorbent surgical drape comprising a hydrophilic fabric and a liquid impervious film bonded to the hydrophilic fabric, characterized in that the hydrophilic fabric is a meltspun fabric made from hydrophobic polymeric material made hydrophilic by incorporating a hydrophilic chemical additive in or on the filaments, wherein the film has a dynamic coefficient of friction value, as measured by testing the drape's top side against the drape's bottom side using test method ASTM D1894, of greater than 0.4."

IX. In support of its requests the appellants essentially relied upon the following submissions:

> The amendment of claim 1 which specified the surfaces of the drape for the determination of the coefficient of friction was not sufficient to clarify all test conditions and the originally filed disclosure did not include such information either. The exact conditions for the measurement (*inter alia* md/cd direction) as well as the standard deviation should have been stated in the claim. Only in such a case would the limits within which the claimed lower limit was to be considered be clear and how it could reliably be reproduced.

D3 represented a suitable starting point as representing the closest prior the art. It did not disclose the feature "wherein the film has a dynamic coefficient of friction value, as measured by test method ASTM D1894, of greater than 0.4." The skilled person, trying to reduce slippage of the film side of the surgical drape disclosed in D3, would obviously consider the coefficient of friction of the outer surface of the drape. The coefficient of friction is a value which is dependent on the material. Accordingly, for the outer film surface a material having an appropriate coefficient of friction had to be chosen.

D6 was also a suitable starting point as representing the closest prior art, in particular when considering the embodiment including a coating. It referred to a surgical drape consisting of a nonwoven fabric and a polypropylene film as a backing. This backing was at least partially coated with pressure-sensitive adhesive. The problem in D6 was to maintain the drape in the correct position and this problem was solved by applying the pressure-sensitive adhesive at the appropriate edge portions. Accordingly, the skilled person only had to extend the application of the pressure-sensitive adhesive to the complete film backing, which modification did not involve an inventive step. The coefficient of friction for such pressure-sensitive adhesives inevitably lies above the claimed threshold.

D21 and D22 disclosed that "Catalloy" films had a high dynamic coefficient of friction and thus had suitable "anti-slip" properties. Accordingly, these documents were highly relevant for the argument concerning inventive step and should have been admitted into the proceedings. Although D22 did not specify the surface against which the coefficient of friction of the film should be tested, its example 2 referred to a kinetic coefficient of friction of 0.815, which thus was far beyond the claimed lower threshold. A corresponding disclosure was available in D10. D10 referred to ultra-low density metallocene polyethylene films and disclosed that their coefficient of friction was very high and stable (figure above point 7) and suggested the application of such films in laminates including nonwovens for use as surgical drapes.

A corresponding disclosure was also available in D9. D9 disclosed a laminate for use as a surgical drape and proposed a polymer film layer which already possessed the claimed the anti-slip properties due to their material components.

The method for the determination of the coefficient of friction disclosed in D2, relying upon a slip angle, was not a suitable reference for comparison. However, a relevant and well-known standard test method for the determination of the coefficient of friction of plastic films and sheeting was available via ASTM D1894. Such standard test methods belonged to the background knowledge of the skilled person. D4 related to a laminate of two nonwoven webs for use as a surgical drape. It was indicated that a coating could increase the coefficient of friction, which parameter could be determined according to test method ASTM D1894. This test method was applied to coated samples, which were tested against a specified aluminium plate as corresponding surface and the resultant coefficient of friction should be at least 0.8 (p. 7, 1. 26 - 29), which was far beyond the claimed threshold.

X. The respondent essentially argued as follows:

The subject-matter of claim 1 of the main request had been amended so as to include literally the disclosure on page 7, lines 56 - 58 of the description, which was identical to the passage as originally filed; the requirements of Article 123(2) EPC thus were met.

Due to this amendment it was clear how to carry out the test method and the results were reliably reproducible. No evidence had been put forward that the results of the test method differed, depending on whether it was performed in the machine direction or in the cross direction. ASTM D1894 referred to a test set-up based upon 5 samples and the corresponding standard deviation. There was nothing to show that in the patent in suit it was intended to differ from such a test set up. The requirements of Article 83 EPC were met.

Paragraphs [0014], [0019], [0044], [0047] and [0051] of the description confirmed that it could be either the film, the coating, or both, which has to have a dynamic coefficient of friction value which is greater than 0.4 and thus demonstrated that it is effectively the exposed surface - which is specifically so expressed in claim 9 - which has to have this lower threshold value. Accordingly, the requirements of Article 84 EPC were also met.

Concerning inventive step in claim 1, the feature distinguishing the subject-matter of claim 1 from the disclosure of all cited documents concerns the lower limit of the dynamic coefficient of friction. None of these prior art documents identifies a slippage problem related to the drape's bottom surface. The problem identified in the patent in suit starts from the need of a surgical drape to pass the class 1 flammability requirements, to have adequate tear strength, to be "lint free" and to reduce the slippage that is prone to occur between the exposed surfaces of a drape or adjacent drapes (paragraphs [0004], [0010]). Only when considering the balance of all these requirements, had the inventors become aware that in particular for the drapes having an outer film or coating side the slippage problem had to be solved in addition to the above requirements.

Irrespective of whether the problem/solution was analysed starting from D3 or D6, no such solution was obvious.

D6 was concerned with the correct position of the drapes and provided adhesive coating on the edge portions only. The problem of slippage did not exist for these drapes. The patent in suit, however, solves the problem of anti-slippage not only during use of the surgical drapes but also during storage or transport. No such concept is available when starting from D6.

D3 referred to a surgical drape having a composite laminate having an outer film side. No coefficient of friction nor its test method were disclosed. However, in view of its structural composition, it qualified as closest state of the art.

D21 and D22 indicated that there were commercially available films ("Catalloy") which exhibited a high coefficient of friction. This was not contested. The patent in suit relied on the combination of a hydrophilic fabric with such films. The relevance of D21/D22 concerned the existence of a variety of such commercially available films. Therefore, these documents could be admitted into the proceedings. However, these documents did not put any emphasis on the films being chosen according to their coefficient of friction. Only one inventive example was tested in this respect in D22. However, no lower threshold value could be based upon such an isolated value or would it indicate to the skilled person that such a threshold value was desirable.

D9 was not relevant at all as its disclosure was directed to various multilayer laminates which could be used for surgical drapes. No particular embodiment was disclosed which represented a two-layered laminate having on one of its outer surfaces a hydrophilic nonwoven and on the other outer surface a suitable polymer already having the necessary anti-slip properties.

Reasons for the Decision

1. The appeal is admissible.

2. Late-filed documents

Normally the board does not interfere with the discretion exercised by the opposition division which, in the present case, was not to admit D21 and D22. However, in view of the agreement of the parties to consider these documents in the appeal and in view of these documents having been referred to in the statement of grounds of appeal in support of the objection of lack of inventive step, there was ample time and opportunity to consider these documents and the corresponding arguments, the Board decided to consider D21 and D22 in the appeal proceedings.

- 3. Amendment Article 123(2) EPC
- 3.1 The subject-matter of claim 1 of the main request has been amended such that it is now more precisely specified how to determine the value for the dynamic coefficient of friction: "wherein the film has a dynamic coefficient of friction value, as measured by testing the drape's top side against the drape's bottom side using test method ASTM D1894, of greater than 0.4". [amendments in italics].
- 3.2 The amended feature is taken from the description, page 12, penultimate paragraph, of the PCT-publication, which passage corresponds to the one in paragraph [0051] of the patent in suit. The heading of this paragraph refers generally to the examples and accordingly, the test methods disclosed in this paragraph concern all the subsequent examples. In view of such support in the description, the requirements of Article 123(2) EPC are met.
- 4. Amendment Article 84 EPC Interpretation of claim 1
- 4.1 The objection concerning clarity related mainly to the above amended test method for the claimed drape, which method does not enable the coefficient of friction of the film to be determined when the film is coated.

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- 4.1.1 Such an objection would also have been valid for the subject-matter of claim 1 as granted. Clarity of the subject-matter of granted claims cannot be raised as a ground of opposition and thus cannot be raised in opposition appeal proceedings. Where the subject-matter of the claim suffers from a degree of uncertainty, it must nevertheless be interpreted, following which any other relevant issues can be examined.
- 4.1.2 Although the claim is not limited expressis verbis to the bottom side of the drape corresponding to the exposed side of the film (with or without coating), consideration of the specification as a whole leaves no other alternative. A determination of the coefficient of friction is not possible for the film of the surgical drape when it is covered by a coating. Accordingly, and also in accordance with the patent proprietor's view, it is the coefficient of friction of the exposed surface which has to be taken into account. This interpretation forms the basis of subsequent considerations in this decision.
- 4.2 Moreover, the subject-matter of claim 1 is not limited to the top side of the drape corresponding to the hydrophilic fabric. However, in particular with regard to the examples, and again in accordance with the patent proprietor's view, it is the hydrophilic fabric which constitutes the drape's top side. Again, this interpretation forms the basis of subsequent considerations in this decision.
- 4.3 Accordingly, the test method for determining the dynamic coefficient of friction is to be performed with

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the exposed surfaces of the surgical drape, namely the drape's bottom side, corresponding to the exposed surface of the film or its coated surface, and the drape's top surface, which is the hydrophilic fabric.

- 4.4 A further objection with regard to clarity which overlaps with the objection of insufficiency - concerns the question whether the test is to be applied in the machine direction or the cross direction.
- 4.4.1 ASTM D1894 refers in its point 4.5 (which concerns the frictional and slip properties of films) to the fact that film surface properties may differ depending on the equipment or the running conditions during manufacture. Point 6, note 4 highlights that due to anisotropy or extrusion effects, plastic films and sheeting may exhibit different frictional properties in their respective principal directions. However, this paragraph also notes that it is "more common practice to test the specimen ... with its long dimension parallel to the machine direction."
- 4.4.2 No evidence has been submitted which supports the view that for the claimed films such a dependency on the machine or cross direction, due to anisotropy or extrusion effects, exists. Accordingly, the board follows the explanation of the respondent that the skilled person would in case of doubt follow the instruction set out above, namely that the specimen should be normally tested in the machine direction. Thus at least a test result of greater than 0.4 has to be reached in one direction.

4.5 With regard to the number of specimens to be tested, ASTM D1894 indicates under point 6.5 that five specimen shall be tested for each sample. Since no contradictory indication is present in the patent in suit, there is no reason for the skilled person to deviate from this instruction.

4.6 The above clarity objections would also be relevant with regard to the subject-matter of claim 1 as granted. The skilled person would be able, however, in view of the overall description and in particular the examples, to give a clear and appropriate meaning as regards all points in issue. In conclusion, the board accepts that the claim can only be read such that the exposed surfaces have to be tested with regard to the claimed coefficient of friction. This is the only interpretation which makes any sense in view of the fact that the problem is related to slippage of the drape. The skilled person would identify this relationship and would not come to any other conclusion. Accordingly, the requirements of Article 84 EPC are met.

5. Article 83 EPC

- 5.1 An objection relating to sufficiency concerns the standard deviation and the reliable reproducibility of the test method with regard to a given film sample.
- 5.2 In order to verify that such a test set-up concerns a method which is reliably reproducible and has an acceptable standard deviation, annexes B and C were submitted by the respondent. These annexes concern the dynamic coefficients of friction (including the standard deviations) of three commercially available

films (LDPE, LLDPE and Catalloy) tested against the same film's surface and against a commercially available film laminate having a spunbond surface.

- 5.3 The test results demonstrate that the dynamic coefficient of friction for the test measuring the film surface against the film surface is higher than when measuring the same film surface against the spunbond surface of the laminate. Only in the case of film C (Catalloy film) does the coefficient of friction value of the film tested against the spunbond surface lie above the claimed threshold.
- 5.4 Accordingly, limiting the test method to the above interpretation (point 4.6 above) restricts the granted claim further (and is thus consistent with the requirements of Article 123(3) EPC). Moreover, such a feature clarifies the test conditions with regard to the application of the ASTM D1894 test method (Article 84 EPC). The standard deviation of the results is indicated. The data also support the reliable reproducibility of the test method with regard to a given film sample. Accordingly, no convincing arguments were provided which threw any real doubt on sufficiency of disclosure.

6. Novelty

6.1 Within the scope of claim 1 there are three embodiments which differ with regard to the film surface of the surgical drapes: either the film material itself meets the claimed friction requirement, or in order to meet the claimed friction requirement the material of the film has been specifically processed, or an outer coating has been uniformly applied to the film.

- 6.2 No objection of lack of novelty was raised in respect of any of these embodiments. The Board also sees no reason to think that any of the cited documents discloses the feature concerning the parametrically defined property of the outer surface.
- 7. Most relevant prior art
- 7.1 The patent in suit refers in its background of the invention to a multiplicity of prior art surgical drapes and indicates a variety of desired properties. These include the balanced combination of liquid absorptivity, liquid strike-through protection, flammability requirements and drape strength, (paragraphs [0002] to [0007] and Tables of the examples). Although, these characteristics are not present in the subject-matter of claim 1, they play a role when considering modification of the prior art surgical drapes.
- 7.2 With regard to the claimed surgical drape, the inventors acknowledged that the commercially available Klinidrape® Universal Set Drape of Moelnlycke (which was used as comparative example in Example 1) had adequate anti-slip properties. Hence, this drape was in particular appropriate for identifying suitable values for the desirable friction characteristics although it did not have the desired structural characteristics because in its three layer laminate the film layer is sandwiched between a nonwoven absorbent top ply and a cellulose wadding bottom ply. In view of this

structural discrepancy, this prior art surgical drape is not suitable as representing the closest prior art for the assessment of inventive step.

- 7.3 Also with regard to the claimed surgical drape, the inventors established criteria for defining the appropriate anti-slip properties of a drape which included the selection of an appropriate parameter (dynamic coefficient of friction), its test method (ASTM D1894) and test conditions for the identification of the appropriate range. Upon selecting the dynamic coefficient of friction as a suitable parameter, the availability of the corresponding ASTM method can be considered as being known by the skilled person. However, this method still includes a variety of options with regard to the specific test set up. In order to verify that the slippage during storage and during application is satisfactory, the friction has to be determined by testing the surfaces of the drape with respect to each other. Thus, no standard or reference surface has to be used for the test set up other than the top side and the bottom side of the drape. Testing the Klinidrape® with regard to its anti-slippage characteristics in this way, a value resulted for the dynamic coefficient of friction of 0.64, which accordingly was identified as being satisfactory.
- 7.4 In order to define a lower threshold for the dynamic coefficient of friction, a comparative example having unsatisfactory slippage behaviour had additionally to be identified and tested. For this, comparative example 2 was used. This example was represented by Kimberly-Clark's SMS Thermal Laminate which, contrary to the desired drape, is non-absorbent and comprises

thermally laminated polypropylene spunbond exterior plies and a centre ply of polypropylene meltblown. Testing the dynamic coefficient of friction of this laminate resulted in a value of 0.37. When considered in combination with example 1C - having a value for the dynamic coefficient of friction of 0.44 - the inventors concluded that a value for the dynamic coefficient of friction of 0.37 was too low, whereas a value of 0.44 was found to be satisfactory. Accordingly, the chosen claimed lower threshold for the value of the dynamic coefficient of friction was not arbitrarily but rather specifically chosen and evaluated.

7.5 Although D6 was cited as representing the closest prior art with regard to the third claimed embodiment, it does not qualify as such. It discloses a laminate of a nonwoven and a plastic film used as a surgical drape. For the plastic film which serves as a barrier to liquids and bacteria, the material of polypropylene, polyethylene or polyvinyl chloride is specified as being preferable. These plastic materials constitute one outer surface of the laminate. Such barrier films inherently have low coefficients of friction. In order to secure the drape during use (paragraphs [0020], [0048]), a strip of pressure-sensitive adhesive is applied to the laminate on the edge portions nearest to incisions. A release cover is provided in such positions during storage. Therefore, although it is well-known to the skilled person that each layer of pressure-sensitive adhesive implicitly meets the claimed anti-slip characteristics as it has a dynamic coefficient of friction which is substantially greater than 1, the pressure-sensitive adhesive cannot correspond to the claimed film layer as on the one hand it does not cover the (complete) outer surface and on the other it is covered by a release sheet during storage, which release sheet normally does not have anti-friction properties. Therefore, D6 is only concerned with the correct position of the drapes in use and a modification for the friction properties during storage would change the structural characteristics. Accordingly, D6 does not represent a suitable starting point for the assessment on inventive step. In any event, there is no apparent reason why the skilled person would depart from using pressuresensitive adhesive in this known surgical drape.

- 7.6 D3 discloses laminates used as surgical drapes having a film layer exposed on one of the outer surfaces adjacent to an absorbent nonwoven layer. The claimed surgical drape differs from the drapes disclosed in D3 by having defined slippage characteristics. Accordingly, D3 represents a suitable starting point for the assessment of inventive step.
- 8. Assessment of inventive step
- 8.1 With regard to the subject-matter of claim 1 and the advantages of the invention as set out in paragraphs [0010] and [0014] of the patent in suit, the technical result or effect of the claimed surgical drape is to reliably avoid slippage of the drape in use as well as during storage. This problem is solved by the combination of the features of claim 1.
- 8.2 D3 is concerned with the abrasion resistance, absorbency and fluid barrier properties in combination with good strength and delamination properties (page 2,

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1. 15 to 18) of the surgical drapes but does not refer to drape slippage at all. The outer surface of the film layer can be chosen from materials like polyolefin, polyethylene blends, thermoplastic elastomers, polyurethane and polyester (page 4, lines 33 - 42). The skilled person wishing to improve the anti-slippage properties during use and during storage would find no help in D3.

- 8.3 D2 refers to slip resistance but selects a completely different parameter and test method (slip angle degree), which is related to the upper surface of the drape and the angle of the plane at which a surgical instrument begins to slip. Accordingly, it is related to an alternative anti-slip property related to such a test method and does not concern the slipping of the drape itself but the slipping of instruments on top of the drape, which has no relation with the slippage of drapes with respect to each other.
- 8.4 D4 provides an anti-slip coating on the upper side surface layer of a surgical drape and specifies its coefficient of friction. The static and dynamic coefficients of friction of the coating are tested in accordance with ASTM D1894 against an aluminium plate having an anodized surface with a roughness of less than about 0.8 µm. The value for the dynamic coefficient of friction for the upper side coating is set to be at least about 0.8. Accordingly, this method is related to the anti-slip properties of the upper surface of the drape in comparison to a aluminium plate. Such a test set-up is not related to slippage of the drape itself either in use or in storage and cannot be considered to suggest a solution to the problem stated.

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8.5 D6 solves the problem of drape slippage by the use of pressure-sensitive adhesive which is placed in the edge portions of the towel (page 1, lines 56/57 and lines 57 - 65). Accordingly, D6 provides a solution to the part of the problem which concerns usage but does not necessarily provide any solution to the part of the problem which concerns storage, because pressuresensitive adhesive obviously has a number of drawbacks when used repeatedly in the environment of surgical drapes.

- 8.6 D9 discloses various multilayer laminates which could be used for surgical drapes. The laminates have on one of their outer surfaces a thermoplastic polymer skin layer laminated to a hydrophilic nonwoven support layer, the film (skin) layer already having the necessary anti-slip properties, which is evidenced by the examples which refer to the skin layers comprising substantial amounts of Catalloy polymer (which is also discussed below). The intention of D9 is to provide extremely thin multilayer laminates having specific strength and aesthetic properties. Neither any antislip properties nor test methods or criteria therefore are addressed. In combination with D3, the skilled person would be guided to provide very thin laminates, which contradicts to a considerable extent the concept of the patent in suit related to anti-slip properties.
- 8.7 D10 highlights the developments of metallocene resins in hygiene and medical films and refers to surgical drapes. It discloses that the coefficient of friction of such layers should be high for non-slip applications and points to the option of different coefficients of

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frictions on each side of an article. A graphic (shown under point 6) is disclosed, demonstrating the stability of the surface properties over time comparing metallocene VLDPE to conventional LLDPE with regard to an unspecified coefficient of friction. Reference is made to the fact that by addition of metallocene VLDPE to LDPE films, an increased coefficient of friction can be obtained (point 5). However, neither a test method is specified nor is it said whether the disclosed values correspond to the static or dynamic coefficient of friction. Accordingly, when taking this disclosure into account in addition to the teaching of D3, the skilled person could recognize that the coefficient of friction should be high for non-slip applications and that by addition of metallocene VLDPE to LDPE a film with an increased coefficient of friction could be obtained. However, no information is given with regard to the kind of specific test method (static or dynamic, test conditions) or the threshold of the value for the coefficient of friction which should be considered as relevant.

8.8 D21 highlights the use of novel olefin copolymer films and points to a high coefficient of friction of one of these films. No specific value or test method is disclosed. These novel olefin copolymer films are obtained by the Catalloy process and D21 shows in its Tables that there are a variety of film grades commercially available, all having low density but different melt flow ranges, tensile strengths and elongation at break. With regard to one particular film (Grade KS 077, which is referred to in Table 2 as having a melt flow rate of 0.8 g/10 min and being applicable for industrial bags), it is noted that "It also boasts high coefficient of friction to permit secure palletizing without need for adhesives" and this film is suggested for replacing certain LLDPE-films in medical/sanitary/hygienic film-applications.

- 8.9 The patent proprietor accepted that at least one of these Catalloy films would produce a value above the claimed lower threshold value (Annex B, film C) and confirmed that such a general disclosure was available for a film which was suitable for the claimed surgical drape. However, in the surgical drape claimed, the coefficient of friction between the film layer and the hydrophilic fabric layer is what is relevant and therefore palletizing of film or suitability of the film for use in medical applications does not give an indication to modify the surgical drape of D3 by replacing the known film layer by a Catalloy film layer.
- 8.10 D22, which is related to the same olefin copolymer films as the ones of D21, discloses the static and kinetic coefficient of friction for one such film (1.22/0.815) and compares these values to the ones of commercially available HDPE- and LLDPE-films (0.241/0.192 and 0.688/0.650). These six isolated values are obtained by the test method according to ASTM D 1894. However, there is no disclosure concerning the exact test conditions (thickness of sample, against which surface tested, principal direction tested, apparatus used). Considered in combination, D22/D21 highlight the advantages of these thermoplastic films, which have a low flexural modulus, high clarity, good tear strength (D22, p. 2, 1. 21/22; p. 11, 1. 27 - 30), and suggest the coefficient of friction as an important

parameter but can hardly be seen as relevant for suggesting a solution to the specific problem stated.

- 8.11 Accordingly, none of these documents, in combination with the teaching of D3 would suggest to the skilled person that the dynamic coefficient of friction should be determined specifically by means of the ASTM D1894 method such as to test the bottom film side against the top side of the same drape and arrive at the claimed range for the dynamic coefficient of friction. The ASTM D1894 itself refers with regard to this issue under its point 4.1 very generally to the fact that such measurements may be made on a film or sheeting specimen when sliding over itself or over another substance. It also concerns kinetic and static coefficient of friction without any preference being stated. Therefore, even at this point, the skilled person could select from a variety of possibilities.
- 8.12 Concerning the dynamic coefficient of friction, the respondent additionally provided comparative data for the film surface when tested against itself and when tested against a spunbond surface of a laminated structure (Annex B). From these data it emerges that the results vary significantly as regards testing against different surfaces. Such widely varying results are confirmed in the various cited documents: for example the coefficient of friction of a LLDPE-film is disclosed as being about 1.8 according to the graphic of D10 and as being 0.248 according to film B of annex B. Moreover, the coefficient of friction is not simply dependent on the film materials concerned but to a large extent dependent on the test set up, method, sample thickness and on whether it is the static or the

dynamic coefficient of friction which is measured. The appellants did not provide any data with regard to the films of the cited documents which put the above results in doubt.

- 8.13 The appellants argued that the problem was to provide a suitably high dynamic coefficient of friction. They based this view on the fact that the comparative example 1 of the patent in suit showed that a "suitable high coefficient of friction" was known. However, such definition of the problem is based on hindsight, as it already includes part of the claimed solution and does not correspond to the objective technical problem as set out above, i.e. avoidance of drape slippage during use and storage.
- 8.14 Hence, all documents and combinations lack any suggestion for determining appropriate anti-slip properties for the outer film surface of a surgical drape, let alone a lower threshold for the dynamic coefficient of friction. Accordingly, when starting from D3 and trying to solve the objective technical problem set out above the skilled person would have to identify and select an appropriate parameter and its determination method. The patent in suit relates the solution to the specific anti-slip property in form of the dynamic coefficient of friction, a specific determination method for this and a defined lower threshold value concerning the outer surface of the drape. Hence, the claimed subject-matter is not arrived at in an obvious manner when considering the combined disclosure of D3 with any of D2, D4, D9, D10 or D21/D22. The requirement of Article 56 EPC is thus fulfilled in respect of the prior art relied upon by the appellants.

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the opposition division with the order to maintain the patent on the basis of
 - (a) the claims 1 to 15 of the main request filed with letter dated 22 January 2010;
 - (b) the description, pages 2 to 11 filed during the oral proceedings.

The Registrar

The Chairman

M. Patin

P. Alting van Geusau