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**Datasheet for the decision  
of 29 October 2015**

**Case Number:** T 0373/12 - 3.2.08

**Application Number:** 05851833.3

**Publication Number:** 1814480

**IPC:** A61F2/78, // B29C33/40,  
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**Language of the proceedings:** EN

**Title of invention:**  
NOVEL ENHANCED COATING FOR PROSTHETIC LINERS PROCESSES,  
PRODUCTS AND IMPROVED UMBRELLAS

**Patent Proprietor:**  
Freedom Innovations, LLC

**Opponent:**  
Otto Bock HealthCare GmbH

**Headword:**

**Relevant legal provisions:**  
EPC Art. 56, 83, 84, 123(2)  
RPBA Art. 12(4)

**Keyword:**  
Sufficiency of disclosure  
Inventive step  
Amendments

**Decisions cited:**  
G 0003/14, T 1253/09

**Catchword:**



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Case Number: T 0373/12 - 3.2.08

**D E C I S I O N  
of Technical Board of Appeal 3.2.08  
of 29 October 2015**

**Appellant:** Freedom Innovations, LLC  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 19 December  
2011 revoking European patent No. 1814480  
pursuant to Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman:** P. Acton  
**Members:** M. Alvazzi Delfrate  
C. Schmidt

## **Summary of Facts and Submissions**

- I. By its decision posted on 19 December 2011 the opposition division revoked European patent No. 1814480.
- II. The appellant (patent proprietor) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. First oral proceedings before the Board of Appeal (in a different composition) were held on 2 April 2014. At the end of those oral proceedings the Board decided to refer some questions under Article 112 EPC to the Enlarged Board of Appeal, which decided upon them in decision G 3/14.

Second oral proceedings before the Board of Appeal were held on 29 October 2015. Since the composition of the Board had changed compared with the first oral proceedings, the parties were given the possibility to submit arguments also in respect of matters which, albeit not finally decided upon, were already debated during the first oral proceedings.

- IV. At the end of the second oral proceedings the requests of the parties were the following:

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request submitted with letter of 20 April 2012 or, in the alternative, in accordance with auxiliary request 1 filed at the oral proceedings on 29 October 2015.

The respondent (opponent) requested that the appeal be dismissed.

V. Independent claims 1 and 7 of the **main request** (corresponding to the claims as granted) read as follows:

"1. A prosthetic medical device, comprising:  
a prosthetic liner comprising an umbrella attachment, characterised in that said liner comprising at least one layer (47) of a protective and lubricious coating being coated on the periphery of the liner (38) whereby owing to the lowered coefficient of friction, the liner may be donned and doffed by physically challenged users, or by a user with only one hand; and said umbrella attachment is an enhanced umbrella (17, 8, 9, 10) attachment which reduces pistoning between the bottom of the liner and re-inforced sections adjacent to and above the same, wherein the prosthetic further comprises at least one layer of coating (47) containing Parylene."

"7. A process for creating a prosthetic liner (38) having an enhanced coating, comprising the steps of: plugging a female mold; inserting a pin umbrella (17, 8, 9, 10); covering a male mold with a cloth; saturating the cloth for integration into the resulting product; adding at least one aliquot of liquified silicone; inserting a male mold member into the female mold member; heating the assembled article; and coating at least one layer of a protective and lubricious coating (47) on the periphery of the liner (38), wherein, the coating is characterized in that it consists essentially of at least one Parylene selected from the group consisting of: Parylene N, Parylene D, Parylene C, Parylen HT and combinations thereof."

Independent claims 1 and 4 of **auxiliary request 1** read as follows (differences compared to the independent claims of the main request emphasised):

"1. A prosthetic medical device, comprising:  
a prosthetic liner comprising an umbrella attachment, characterised in that said liner comprising at least one layer (47) of a protective and lubricious coating being coated on the periphery of the liner (38) whereby owing to the lowered coefficient of friction, the liner may be donned and doffed by physically challenged users, or by a user with only one hand; and said umbrella attachment is an enhanced umbrella (17, 8, 9, 10) attachment which reduces pistoning between the bottom of the liner and re-inforced sections adjacent to and above the same, wherein the prosthetic further comprises at least one layer of coating (47) containing Parylene whereby the prosthetic liner (38) is coated over substantially all of its surface area."

"4. A process for creating a prosthetic liner (38) having an enhanced coating, comprising the steps of: plugging a female mold; inserting a pin umbrella (17, 8, 9, 10); covering a male mold with a cloth; saturating the cloth for integration into the resulting product; adding at least one aliquot of liquified silicone; inserting a male mold member into the female mold member; heating the assembled article; and coating at least one layer of a protective and lubricious coating (47) on the periphery of the liner (38), wherein, the coating is characterized in that it consists essentially of at least one Parylene selected from the group consisting of: Parylene N, Parylene D, Parylene C, Parylen HT and combinations thereof whereby the prosthetic liner (38) is coated over substantially all of its surface area."

VI. The following documents played a role for the present decision:

E1: WO -A- 01/67842;  
E2: WO -A- 03/051241; and  
E3: US -B- 6,231,617.

VII. The appellant's arguments can be summarised as follows:

*Main request - Sufficiency of disclosure*

The patent, in particular Figure 3 and the corresponding description, provided sufficient information for the person skilled in the art to carry out the invention. Therefore, the requirements of sufficiency of disclosure were satisfied.

*Main request - Inventive step*

E2 represented the closest prior art for the assessment of inventive step because it dealt, like the patent in suit, with the problem of providing a liner which could be easily donned and doffed. By contrast, E1 and E3 did not deal with this problem. Hence, they could not represent the closest prior art and the claimed device could not be obvious starting from those documents.

The liner shown in the closest prior art E2 exhibited a Parylene coating solely on its exterior surface. By contrast, the claimed device exhibited the lubricious coating on the "periphery" of the liner, i.e. on all its outside and inside area surface. Moreover, contrary to the liner disclosed in E2, it comprised an enhanced umbrella.

These distinguishing features eased the donning and doffing and reduced pistoning. There was a synergy between these two effects, because they both related to the use of the claimed device.

The prior art did not render it obvious to provide these effects by means of said distinguishing features. In particular, E3 was silent on the provision of a coating on the periphery of the liner. Moreover, it was not obvious to adopt the umbrella shown in this document for the liner of E2, since the user applied the latter by rolling, which would have been rendered impossible by the umbrella of E3.

Accordingly, the subject-matter of claim 1 involved an inventive step.

*Admission of the first auxiliary request into the proceedings*

The first auxiliary request had been submitted at the oral proceedings in opposition proceedings in reaction to the discussion at the hearing about the meaning of the term "periphery" and had been then re-submitted with the statement of grounds of appeal. As the importance of this issue had not been apparent before the oral proceedings and the decision of the opposition division, this request could not have been filed previously. Therefore, it should at least be admitted into the appeal proceedings.

*Auxiliary request 1 - Article 123(2) EPC*

Claim 1 of auxiliary request 1 was a combination of the originally filed claims. Therefore, it could not be in breach of Article 123(2) EPC. In any event, the



description too made it clear that the coating over substantially all the surface area of the liner was the Parylene coating.

*Auxiliary request 1 - Inventive step*

None of the prior-art documents disclosed a lubricious coating, in particular a Parylene coating, over substantially all of the surface area of the liner. This applied also to E2, because a coating applied only to the outer surface could not be considered to cover substantially all, i.e. at least almost all, of the surface.

This further distinguishing feature was advantageous, because it allowed the liner to be pulled on like a sock, resulting in easier use. The person skilled in the art had no reason to improve the lubricity of the prior-art coatings because the prior art, including E2, taught to wear the liner by rolling. Rather, in the prior art the inner surface of the liner was kept tacky, to reduce movement and milking.

Accordingly, it was not obvious to arrive at the liner of claim 1, and the subject-matter of this claim therefore involved an inventive step. The same applied to the subject-matter of claim 4.

VIII. The respondent's arguments can be summarised as follows:

*Main request - Sufficiency of disclosure*

Claim 1 stipulated that the Parylene layer was to be applied on the prosthetic, which was the element to be connected to the liner, without however defining where

this layer was to be applied. Figure 3 could not provide any help in this matter, because it showed a Parylene layer on the prosthetic liner and not on the prosthetic.

Nor did this drawing disclose how to realise an umbrella as defined in claim 1, since it did not show any re-inforced sections.

Hence, the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

*Main request - Inventive step*

The subject-matter of claim 1 did not involve an inventive step starting from E3, in view of the teaching of E2. E3 disclosed a prosthetic medical device, comprising a prosthetic liner with an enhanced umbrella attachment that reduced pistoning between the bottom of the liner and re-inforced sections adjacent to and above the same. E2 rendered it obvious to provide a lubricious coating of Parylene on the outer surface, i.e. the periphery, of this liner to facilitate donning and doffing. Therefore, the subject-matter of claim 1 did not involve an inventive step in view of the combination of E3 and E2.

Similar considerations applied starting from E1. Therefore, the subject-matter of claim 1 did not involve an inventive step in view of the combination of E1 and E2 either.

Moreover, starting from E2, it was obvious from the teaching of E3 to provide an umbrella as defined in claim 1 in order to reduce pistoning. Accordingly, the

subject-matter of claim 1 was also rendered obvious by the combination of E2 and E3.

*Admission of the first auxiliary request into the proceedings*

The first auxiliary request, which was submitted during the oral proceedings before the opposition division, had not been admitted into the proceedings by the opposition division. There was no reason to depart from this decision, since the opposition division had correctly assessed that the appellant had no reason to file this request at such a late stage. Accordingly, the first auxiliary request should not be admitted into the appeal proceedings either.

*Auxiliary request 1 - Article 123(2) EPC*

In any event, claim 1 of auxiliary request 1 did not comply with the requirements of Article 123(2) EPC.

According to this claim, the prosthetic further comprised at least one layer of coating containing Parylene whereby the prosthetic liner was coated over substantially all of its surface area. Accordingly, the claim stipulated that substantially all of the surface area of the liner was coated with Parylene. This feature was not disclosed in originally filed claim 3, which linked the coating over substantially all the surface in general to the features of claim 1 and not specifically to the Parylene coating.

Nor was this feature disclosed in the description, which did not mention "substantially all" the surface area.

Therefore, claim 1 comprised subject-matter which extended beyond the content of the application as originally filed.

*Auxiliary request 1 - Inventive step*

Furthermore, auxiliary request 1 was also not allowable for lack of inventive step.

The feature that the liner was coated over substantially all its surface area was so vague and undefined that it had to be disregarded. Hence, no difference in this respect could be seen over E2, which disclosed a Parylene coating over the external surface. Therefore, the subject-matter of claim 1 did not involve an inventive step for the reasons already given for the main request.

Moreover, even if a difference in this respect were to be acknowledged, it could not involve an inventive step. In this case, starting from E2 as closest prior art, two different independent partial problems were to be considered: reduction of milking and improved lubrication of the inner surface. The problem of reducing milking was solved in an obvious way by providing an enhanced umbrella as taught by E1 or E3. As to the problem of improving the lubrication of the inner surface of the liner, E2 itself disclosed that a Parylene coating could be used to improve lubrication, albeit for the outer surface. Hence, it was obvious to provide the same Parylene coating over the whole surface, arriving at the liner of claim 1. Therefore, the subject-matter of claim 1 did not involve an inventive step.

The subject-matter of claim 4 did not involve an inventive step either, because the claimed method was essentially an obvious modification of the production method for obtaining the liner disclosed in E1.

## **Reasons for the Decision**

### 1. Main request - Sufficiency of disclosure

According to claim 1, "the" prosthetic comprises a coating containing Parylene. The respondent was of the view that this feature stipulates that the Parylene layer is applied not on the liner but on the element to be connected to the liner. However, the claim does not mention any element to be connected to the liner but only the prosthetic liner and the prosthetic medical device which comprises it. Hence, this feature defines that the coating is applied to said device, for instance to the liner. This is the case in Figure 3, which shows an embodiment exhibiting this layer on the prosthetic liner and thus discloses where the coating can be applied.

It is true that Figure 3 does not show the cloth reinforcement layer, to which the side walls of the enhanced umbrella extend in order to reduce the pistoning (see paragraph [0022]). However, the determination of the position of this layer to provide this effect is a task that the person skilled in the art can carry out on the basis of his common general knowledge without undue burden, especially since the

claim does not specify which maximum level of pistoning would be acceptable.

Therefore, the patent in suit discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

2. Main request - Inventive step

2.1 The closest prior art for assessing inventive step is normally a document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant features in common.

E3 deals with the problem of reducing pistoning in a prosthetic liner (see column 3, lines 62 to 63). It discloses a prosthetic medical device, comprising a prosthetic liner (11) with an umbrella attachment (13), which is an enhanced umbrella attachment that reduces pistoning between the bottom of the liner and re-inforced sections adjacent to and above the same.

The appellant submitted that E3 could not represent the closest prior art, which was rather to be seen in E2 dealing with the problem of easing donning of a prosthetic liner.

However, the patent in suit is concerned with a liner that not only can be easily donned and doffed but also exhibits reduced pistoning. Hence, there is no reason to regard E3 as less relevant to the claimed invention than E2. Accordingly, the attack of lack of inventive step starting from E3 has to be considered.

- 2.2 Starting from this prior art, the object underlying the claimed invention is the provision of a liner which can be easily donned and doffed (see paragraph [0006]).

This object is achieved by a prosthetic device in accordance with claim 1 that comprises a liner with a lubricious coating on its "periphery".

- 2.3 E2 relates to the problem of making it easier to don a prosthetic liner (see page 2, lines 8 to 11). To solve this problem E2 proposes coating the exterior of the liner with a friction-reducing polymer film, preferably a Parylene film (see claims 1 and 2 and abstract).

This teaching could be applied also to the liner of E3, rendering it obvious to provide the liner disclosed in E3 with a lubricious coating of Parylene on its exterior surface to facilitate donning and doffing.

In the appellant's opinion, such a liner would not fall within the scope of claim 1 since the term "periphery" stipulates that the coating is applied to all the outside and inside area surface of the liner. However, the term "periphery" merely defines the external surface of an object. Indeed the disclosure of the rest of the patent (see claim 3 and paragraph [0017]) makes clear that also embodiments exhibiting a coating which is not applied to the whole surface area of the liner are to be seen as exhibiting a coating on the "periphery" of the liner. Hence, the liner rendered obvious by applying the teachings of E2 to the device of E3 exhibits a Parylene coating on its periphery.

Therefore, the subject-matter of claim 1 does not involve an inventive step in view of the combination of E3 and E2.

3. Admission of the first auxiliary request into the appeal proceedings

The first auxiliary request was filed during the oral proceedings before the opposition division, which did not admit it into the proceedings.

The appellant did not demand to have this request re-considered by the opposition division but re-submitted it in appeal, for consideration by the Board. Therefore, the Board is not limited to a review of the discretionary decision of the opposition division, which declined to admit this request, but can exercise its own discretion, as provided by Article 12(4) RPBA, over whether to admit the request in appeal proceedings (see also T 1253/09 of 25 April 2012, points 6 and 7 of the Reasons).

Auxiliary request 1 was submitted to address, by incorporating into claim 1 the features of claim 3 as granted, the issue of the interpretation of the term "periphery", which played a crucial role in the decision of the opposition division (point 5.4). Hence, this request does not alter the legal and factual framework of the case significantly and does not result in a "fresh case".

Moreover, since the importance of the interpretation of the term "periphery" became apparent during the oral proceedings before the opposition division and from its written decision, the belated submission of auxiliary request 1 is to be seen as a reaction to the course of said oral proceedings and said written decision.

Finally, as auxiliary request 1 has been re-submitted at the earliest possible stage of the appeal



proceedings (with the statement of grounds of appeal), the respondent had sufficient time to prepare its reaction to it.

Under these circumstances, the Board decided to admit this request into the proceedings.

4. Auxiliary request 1 - Clarity

The objection of lack of clarity in respect of auxiliary request 1, in particular in connection with the feature according to which the prosthetic liner is coated over substantially all of its surface area, raised by the respondent in the first oral proceedings, was not maintained at the second oral proceedings. As a matter of fact, claim 1 of auxiliary request 1 essentially corresponds to the combination of granted claims 1 and 3. In particular, the feature above was comprised in the latter claim. Hence, compliance of claim 1 with the requirements of Article 84 EPC cannot be examined (see decision G 3/14).

5. Auxiliary request 1 - Article 123(2) EPC

5.1 According to claim 1 of auxiliary request 1, the prosthetic "further comprises at least one layer of coating (47) containing Parylene whereby the prosthetic liner (38) is coated over substantially all of its surface area". In view of the use of the term "whereby", without any comma preceding it, the claim stipulates that the coating over substantially all of the surface area of the liner is the result of the Parylene coating. In other words, substantially all of the surface area of the liner is coated with Parylene. The parties also understood the claim in this way.

- 5.2 The feature according to which the prosthetic liner is coated over substantially all of its surface area was literally disclosed in claim 3 as originally filed. However, it remains to be established if the application as originally filed discloses also that said coating extends over substantially all of the surface area contains Parylene.
- 5.3 In the claims as originally filed Parylene is mentioned in dependent claim 2, on which claim 3 depends. According to claim 2, the improved prosthetic liner of claim 1 further comprises "at least one layer of coating containing Parylene". Originally filed claim 3 reads: "The improved prosthetic of claims 1 or 2, whereby the prosthetic liner is coated over substantially all of its surface area". It is true that it comprises a comma before the word "whereby", which is not present in claim 1 of auxiliary request 1, and that it may also depend on original claim 1, which does not specify that the lubricious coating contains Parylene. However, when original claim 3 is considered as being dependent on claim 2, the straightforward interpretation of the claim is that the coating over substantially all of the surface area of the liner is the only one mentioned in the claim, namely the Parylene coating.

Moreover, even if the person skilled in the art had some doubts as to the correctness of this interpretation, these doubts would be dispelled by the rest of the patent application. Both the description (in particular page 4, line 21 to page 5, line 3) and the drawings (Figure 2) disclose Parylene as a preferred coating. The Parylene coating is not described in combination with other coatings and preferably covers the entire liner, with the possible

exception of the gripping zones. Hence, there is no doubt that, when a Parylene coating is present and the prosthetic liner is coated over substantially all of its surface area, it is indeed said Parylene coating that covers substantially all said surface area.

5.4 Accordingly, claim 1 of auxiliary request 1 has not been amended in a way which extends beyond the content of the application as filed.

6. Auxiliary request 1 - Inventive step of claim 1

6.1 It is true, as submitted by the respondent, that the exact meaning of a coating covering "substantially all" of the surface area of the liner is a matter of interpretation which could vary from one person to another. However, this feature is not completely without technical meaning, since the person skilled in the art is able to identify some arrangements that, irrespective of the particular interpretation which is chosen, do not satisfy this requirement. Indeed none of the prior-art documents discloses a liner with this feature.

In particular, E2 discloses a coating of Parylene only on the exterior of the liner (see for instance claims 1 and 2). Since the whole inner surface does not have the coating, it cannot be said that "substantially all" of the surface area of the liner is coated as required by claim 1, and this requirement constitutes an additional distinguishing feature. Therefore, the findings in respect of claim 1 of the main request cannot, contrary to the view of the respondent, be transposed to claim 1 of auxiliary request 1.

6.2 The respondent submitted that, if this additional distinguishing feature were acknowledged, E2 represents the closest prior art for claim 1 and that starting from the device known from E2 the problems to be solved were the reduction of milking and the improvement of lubrication of the inner surface. Solving both these problems by providing (a) an enhanced umbrella and (b) a Parylene coating on the inside of the liner was obvious in view of the teaching of E1 or E3 and of E2 itself respectively.

6.3 The subject-matter of claim 1 of auxiliary request 1 does indeed differ from the device of E2 by said features (a) and (b).

However, since the method of wearing the liner disclosed in E2 is rolling (see page 4, lines 29 to 30), the person skilled in the art had no reason to improve the lubrication of the inner surface in order to ease the wearing of the liner. On the contrary, he would keep the inner surface tacky, to reduce movement and, as a consequence, milking. Hence, E2 does not render the provision of feature (b) obvious.

Nor is such a teaching to be found in E1 or E3, since neither of them discloses a lubricious coating on the inner surface of the liner.

Therefore, starting from E2 the person skilled in the art had no reason to provide the Parylene coating on substantially all the surface of the liner, as required by claim 1.

Accordingly, the subject-matter of claim 1 of auxiliary request 1 involves an inventive step.

7. Auxiliary request 1 - Inventive step of claim 4

The same conclusion applies to the subject-matter of claim 4, because the claimed method also involves the coating with Parylene of substantially all the surface of the liner, rendering it non-obvious over the prior art.

## 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 in the following version:
  - claims 1 to 6 of auxiliary request 1 filed at the oral proceedings before the Board,
  - description: columns 1 to 5 as filed at the oral proceedings,
  - drawings: figures 1 to 3 as granted.

The Registrar:

The Chairman:



V. Commare

P. Acton

Decision electronically authenticated