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**Datasheet for the decision
of 22 February 2018**

Case Number: T 0078/15 - 3.3.10

Application Number: 08154718.4

Publication Number: 2110147

IPC: A61L29/14, A61L29/08, A61L31/00

Language of the proceedings: EN

Title of invention:
Improved medical device with hydrophilic coating

Patent Proprietor:
Dentsply IH AB

Opponent:
Hollister Incorporated

Headword:
Improved medical device / Dentsply

Relevant legal provisions:
EPC Art. 100(b)

Keyword:
Grounds for opposition - insufficiency of disclosure (no)

Decisions cited:

T 0409/91, T 0435/91

Catchword:



Beschwerdekammern
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Chambres de recours

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Case Number: T 0078/15 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 22 February 2018

Appellant: Dentsply IH AB
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Representative: Awapatent AB
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Respondent: Hollister Incorporated
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Representative: Høiberg P/S
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 10 November
2014 revoking European patent No. 2110147
pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: J.-C. Schmid
T. Bokor

Summary of Facts and Submissions

- I. The appellant (Proprietor of the patent) lodged an appeal against the decision of the Opposition Division revoking European patent No. 2 110 147, independent claims 1 and 10 reading as follows:

"1. A medical device comprising a substrate and a hydrophilic surface coating arranged on said substrate, wherein the substrate has, on its surface underlying said hydrophilic surface coating, a surface texture with an arithmetical mean deviation of the surface profile (Ra) according to ISO 4287:1997 of at least 3 μm and/or a profile section height difference (Rdc (1-99%)) according to ISO 4287:1997 of at least 18 μm ."

"10. A method of producing a medical device with a hydrophilic surface coating, comprising the steps of:
providing a substrate material having a surface texture with an arithmetical mean deviation of the surface profile (Ra) according to ISO 4287:1797 of at least 3 μm and/or a profile section height difference (Rdc (1-99%)) according to ISO 4287:1997 of at least 18 μm . [sic]

coating said substrate material with a hydrophilic surface coating."

- II. Notice of opposition had been filed by the respondent requesting revocation of the patent-in-suit in its entirety on the grounds of inter alia insufficient disclosure of the invention (Article 100(b) EPC).

According to the Opposition Division, the parameters used to define the surface roughness of the substrate were usual in the art and could be easily measured using a profilometer. The patent specification taught

to lower the extrusion temperature in order to increase roughness. However, the claims required a surface roughness with an arithmetical mean deviation of the surface profile (Ra) according to ISO 4287:1997 of at least 3 μm and/or a profile section height difference (Rdc (1-99%)) according to ISO 4287:1997 of at least 18 μm , which could only be achieved by trial and error. Therefore, it would require undue experimentation for a skilled person to determine the parameters required in an extrusion process or in a surface treatment process after extrusion in order to produce a substrate with a surface texture as required by claims 1 and 10. Hence the Opposition Division came to the conclusion that the invention was not sufficiently disclosed.

III. With the statement of the grounds for appeal, the appellant filed solemn declarations of two experts in the field of polymer extrusion stating that producing substrates having varying degrees of surface roughness was not a challenge for the person skilled in the art. It also filed in this context extracts of the text book "Polymer Extrusion" by Chris Rauwendaal, Hanser Publishers, Munich, Hanser Publications, Cincinnati, 5th Edition, henceforth referred to as document (11).

According to the appellant, the invention was not about how to obtain a roughened surface, but was based on the finding that by using substrates having a pronounced surface roughness the water retention of the hydrophilic surface coating was greatly improved, and a better adherence of the coating was achieved as well. How to produce a roughened surface was well known in the art. Examples of such methods were given in the patent and included controlling the extrusion process during manufacture of the substrate or performing surface treatment such as mechanical roughening of the

surface, chemical etching, plasma surface treatment or etching. The substrates having the desired roughness which were used in the examples were ordered from a provider of such substrates; they were commercially available. The parameters used to define the pronounced surface roughness were also well known and easy to measure. Hence, there was no undue burden for the skilled person to obtain the substrates used in the preparation of the claimed medical devices.

- IV. The respondent requested that the declarations of the two experts filed by the appellant should not be admitted into the appeal proceedings, because they could have been filed before the Opposition Division. It filed further extracts of document (11).

According to the respondent, it was common general knowledge to obtain more or less surface roughness, either during an extrusion process, or by surface treatment after extrusion. However, the claimed medical device required a substrate with a pronounced surface roughness. The patent specification did not indicate any reliable and repeatable way for preparing the substrate as claimed. The skilled person could only determine the correct process parameters for obtaining such a substrate by trial and error. The lack of information how to achieve such pronounced surface roughness could not be filled by the general common knowledge of the skilled person, at least not without trial and error to an extent which would represent an undue burden. Furthermore, there was no evidence that the substrates were commercially available. The patent taught that the substrates having the claimed rough surface could be obtained by an overall lowering of the extrusion temperature. However, this instruction went against the teaching of document (11), where it was

stated that an overall lowering of the extrusion temperature could reduce the surface roughness (shark skin problem). Furthermore document (11) revealed that extrusion of tubes for medical devices was a complex task. It was often difficult to predict the effect of a change in process conditions. Achieving a surface texture with Ra of at least 3 microns and/or Rdc (1-99%) of at least 18 microns as claimed in the opposed patent therefore involved a substantial amount of trial and error. Hence, the information given in the opposed patent and common general knowledge were not sufficient for preparing substrates with the claimed surface roughness. The requirements of Article 83 EPC were therefore not met, so that the opposition ground under Article 100(b) EPC was well founded.

- V. The appellant requested that the decision under appeal be set aside and that the case be remitted to the Opposition Division for further prosecution.

The respondent requested that the appeal be dismissed or subsidiarily that the case be remitted to the Opposition Division for further prosecution

- VI. At the end of the oral proceedings held on 22 February 2018, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request: claims of the patent as granted

Sufficiency of disclosure

2. The appellant contested the finding of the Opposition Division that the only possibility to produce a substrate having the required surface texture was by trial and error, which required an undue amount of experimentation. The production of the substrates having a surface roughness as required by claims 1 and 10 was not part of the invention, since it was well known in the art how to produce such substrates. The substrates which were used in the examples of the patent were ordered from a provider. However, they were also easily obtainable by adjusting the extrusion parameters following the teaching of paragraph [0013] of the patent-in-suit.

3. It is the established jurisprudence of the Boards of Appeal that the requirements of sufficiency of disclosure are only met if the invention as defined in the claim can be performed by a person skilled in the art without undue burden, using common general knowledge and having regard to further information given in the patent in suit (see decisions T 409/91, OJ EPO 1994, 653, point 3.5 of the reasons; T 435/91, OJ EPO 1995, 188, point 2.2.1 of the reasons).

4. The experimental part of the patent-in-suit starting from paragraph [0043] on page 5, relates to several materials which were used for the preparation of catheters, namely Pebax (examples A and A'), PVC (examples B, B', D and D') and Meliflex (example C and C'). Substrates A', B', C' and D' reflect substrates used in the prior art for the production of catheters which have a surface roughness below the claimed thresholds, while the roughness of the surfaces of substrates A, B, C and D is above, and therefore meet the requirement set in claims 1 and 10 (see tables 1 and 2 on pages 6 and 7).

According to paragraph [0044] of the parent specification, the only difference between substrates A and A' is that substrate A is extruded in such a way that it has an increased surface roughness compared to substrate A'. The other pairs of substrates B;B, C;C' and D;D' are made in the same manner. However, the experimental part of the patent specification does not disclose the parameters of the extrusion process.

5. It is acknowledged by the parties that it is general knowledge to obtain more or less surface roughness, either during an extrusion process as disclosed in the patent-in-suit, or by surface treatment after extrusion as mentioned in the patent-in-suit.

The respondent based its objection of insufficiency of disclosure on the fact that the skilled person was only aware of how to obtain more or less surface roughness, but did not have the necessary knowledge to achieve the specific and pronounced surface roughness on a substrate, as claimed

6. However, there is a clear indication in the patent specification how to increase surface roughness, namely in paragraph [0031] of the patent specification where it is taught that in extrusion equipment having various temperature zones, it is often possible to increase the surface roughness by increasing the temperature in the early stages of the extrusion process, and by lowering the temperature at the later stages, or by making an overall lowering of the temperatures.

In the decision under appeal, while the Opposition Division apparently took note of the instructions to increase roughness of an extruded substrate given in

paragraph [0031] of the patent specification, it seems to have disregarded the genuine scope of the claim when it stated in the decision that "the claims require not any type of roughness but a surface roughness *with an arithmetical mean deviation of the surface profile (Ra) of at least 3 μm and/or a profile section height difference (Rdc (1-99%)) of at least 18 μm* ". From this formulation the Board concludes that the Opposition Division considered these parameters as requiring some particular type of roughness. The Opposition Division also stated that "the patent is silent as to the different conditions which are used in order to produce a substrate with a higher roughness", while recognising that "the only practical information provided by the patent is that to lower the extrusion temperature for increasing the roughness", see page 3, last two paragraphs in the decision under appeal.

However, the claimed thresholds for the roughness parameters Ra and Rdc, as defined in the international standard ISO 4287:1997, do not characterise some highly particular type of roughness, as apparently assumed by the Opposition Division, but serve to set a minimum degree of roughness of the surface, i.e. in the present case they require a more pronounced surface roughness than that of substrates used in the manufacture of prior art medical devices. In addition, the two claimed roughness values are not simultaneously, but only alternatively required. There is no requirement that the roughness of the substrate should be in some narrow range or that the roughness may be anything between broad values but should generally be uniform over the whole substrate. In short, no further technical constraint is apparent that would make it plausible that the claimed roughness may not be easily achievable for the skilled person. While it appears to

be common ground that this may represent a "pronounced" roughness, there is no evidence on file that this roughness would represent such an extreme value which in itself would be impossible or technically difficult to achieve, beyond the argument that the patent itself does not provide much information.

Respondent argued that an upper limit of the roughness is in fact implied by the technical purpose of the medical device, and that this presents an additional difficulty in the manufacturing process, but did not submit any specific roughness values for this upper limit. The Board accepts that such an upper limit may be inherent in the purpose and/or dimensions of the claimed device, but the Board sees no evidence that this (undefined) upper limit would prevent the skilled person in achieving the roughness values as claimed, or that such an implied upper value would in fact result in a very narrow roughness range. Given that respondent has consistently argued that the skilled person would inevitably start from lower roughness values, it is not apparent why he would have any problem in going back towards these lower values, should it be established that an experimentally achieved roughness is indeed too high.

In this light, the Board cannot follow the conclusion of the Opposition Division according to which the instruction to increase the surface roughness of a substrate given in paragraph [0031] of the patent specification cannot be considered as sufficient for obtaining the substrates of claims 1 and 10 of the patent-in-suit.

7. According to the respondent, these instructions went against the teaching of text book document (11), which

reported that a reduction of the temperature in the extrusion process could reduce the surface roughness.

Notwithstanding the fact that the filed parts of document (11) are from the fifth edition, which has been published after the filing date of the patent-in-suit, it is taught therein that the "shark skin" problem can **generally** (emphasis added by the Board) be reduced by reducing the extrusion velocity and increasing the die temperature. Thus, document (11) rather corroborates the instructions given in paragraph [0013] of the patent specification, and the fact that these measures will indeed increase the roughness of the substrate. As pointed out by the respondent, document (11) also reports that there was "some evidence" that running at very low temperatures can also reduce the "shark skin" problem (see page 432). This comment is made referring to the citation [151], and thus rather appears to be an unusual event, which moreover is not in contradiction with the instructions of paragraph [0031] of the patent-in-suit. Moreover, citation [151] has not been identified in the filed extracts of document (11) and said "some evidence" has not been further described by the respondent.

Under these circumstances, the Respondent's argument based on document (11), that the instructions of paragraph [0031] of the patent-in-suit contradict the general knowledge of the skilled person, does not convince the Board.

8. According to the respondent, the patent specification does not contain adequate instructions which would lead the skilled person directly towards the claimed surface texture, and trial and error is therefore necessary in

order to obtain the claimed surface roughness during the extrusion process.

However, the patent specification provides clear instructions in paragraph [0031] on how to increase the surface roughness during the extrusion processing, namely by increasing the temperature in the early stages of the extrusion process, and by lowering the temperature at the later stages, or by making an overall lowering of the temperatures.

Accordingly, in the absence of any evidence to the contrary, the Board does not see any reasons to doubt that substrates A, B, C and D having the claimed surface roughness as shown in tables 1 and 2 of the patent-in-suit are obtainable by following instructions given in the patent-in-suit, with an amount of experimentation which is within those limits which can be expected from a skilled person working with extrusion technology.

Since the Board is convinced that substrates having the claimed roughness can directly be obtained by extrusion following the instructions given in patent specification, there is no need to consider whether the substrate having the claimed surface roughness were commercially available.

9. The Board comes therefore to the conclusion that the invention as defined in claims 1 and 10 can be performed by a person skilled in the art without undue burden, using common general knowledge and having regard to further information given in the patent in suit, such that the opposition ground pursuant to Article 100(b) EPC fails.

10. *Other issues*

The respondent requested that document (12) and (13) are not admitted into the appeal proceedings. However, as these documents are not needed by the Board to arrive at its conclusion that the invention is sufficiently disclosed, their admission into the proceedings need not be decided by the Board. If necessary, their admission may be decided by the department of first instance following the remittal (see below).

11. *Remittal*

As the Opposition Division has not yet ruled on the other grounds of opposition, the Board considers it appropriate to remit the case to the Opposition Division for further prosecution. This was also requested by both parties.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated