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**Datasheet for the decision
of 5 November 2019**

Case Number: T 0544/15 - 3.3.10

Application Number: 05758995.4

Publication Number: 1787024

IPC: F04B43/00

Language of the proceedings: EN

Title of invention:
PERISTALTIC PUMP TUBE

Patent Proprietor:
Gambro Lundia AB

Opponents:
RAUMEDIC AG
Fresenius Kabi Deutschland GmbH
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
RPBA Art. 12(2), 13(1), 13(3)
EPC Art. 56

Keyword:

Statement of grounds of appeal - party's complete case
Late-filed requests (main and first auxiliary request) -
change of subject-matter
Inventive step yes (second auxiliary request) - ex post facto
analysis

Decisions cited:

Catchword:



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Case Number: T 0544/15 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 5 November 2019

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 13 January 2015
revoking European patent No. 1787024 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: M. Kollmannsberger
 T. Bokor

Summary of Facts and Submissions

- I. The appeal lies from the decision of the opposition division to revoke European patent No. 1 787 024 under Article 101(3) (b) EPC.
- II. Three oppositions had been filed against the granted patent, invoking grounds of opposition under Articles 100(a), 100(b) and 100(c) EPC.
- III. Prior art documents cited during the opposition proceedings and still relevant in the present appeal proceedings are the following:
- D1: EP 1 393 759
D2: EP 1 402 885
D18: US 5,955,519
D19: Gächter/Müller: Kunststoffadditive, Karl-Hanser-Verlag, 3. Ausgabe, 1990, Seiten 382-407, 426
- IV. In the impugned decision the opposition division came to the conclusion that the independent claim of the then pending main request was not novel over D2, and that the independent claim of the then pending auxiliary request lacked an inventive step over D1 in combination with D18. The objections under Articles 83 and 123(2) EPC for insufficiency of disclosure and added subject-matter were rejected.
- V. In its statement of grounds of appeal the appellant no longer defended the main request pending before the opposition division. However, he argued that the auxiliary request pending before the opposition division should have been allowed because the subject-matter of the independent claim, contrary to the

opposition division's assessment, did involve an inventive step over D1 and D18.

This request is now on file as the second auxiliary request and forms the basis of the present decision. The wording of claim 1 of this request is as follows:

*"A tube for a peristaltic pump, comprising an elastically deformable tubular body (2), wherein the formulation of the material used for realising said tubular body is the following
100 phr of PVC resin;
From 40 to 100 phr of plasticizer;
From 0.05 to 1.0 phr of one or more lubricants;
From 0.3 to 15.0 phr of one or more stabilizers and co-stabilizers,
characterized in that said resin has a K value of not less than 85 measured according to standard ISO 1628-2 and said plasticizer is an alkyl ester of adipic acid."*

VI. Three months before the oral proceedings before the Board the appellant filed an amended claim set as new main request. During the oral proceedings he filed a further claim set as new first auxiliary request.

The independent claim of the main request is more limited with respect to the independent claim of the above second auxiliary request in that it, inter alia, requires the resin to have *"a K value comprised between 97 and 105"*.

The independent claim of the first auxiliary request requires the resin to have *"a K value of not less than 95"*.

The admission of both these requests was objected to by respondent 3 arguing that they were filed too late in the proceedings and raised new issues which had not been previously discussed. The appellant on the other hand, requested their admittance because they were narrower compared with the now second auxiliary request, easy to understand and thus beneficial for procedural economy.

VII. Oral proceedings were held on 5 November 2019 where the parties argued their case and stated their final requests. The decision was announced at the end of these proceedings.

VIII. The appellant (patent proprietor) requested:

That the decision under appeal be set aside, and the patent be maintained in an amended form on the basis of the main request or alternatively on the basis of any of the auxiliary requests 1 to 3, where the main request was filed with letter dated 5 August 2019, the first auxiliary request was filed during oral proceedings before the Board, and the second and third auxiliary requests were filed with the grounds of appeal dated 11 May 2015, at that time as main and auxiliary request.

IX. Respondent 3 (opponent 3) requested:

That the appeal be dismissed, including the request for the non-admission of the appellant's main and first auxiliary requests into the proceedings.

X. Respondent 1 (opponent 1) and respondent 2 (opponent 2) neither made substantive submissions nor filed requests during the appeal proceedings.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. Admission into the proceedings
 - 2.1 According to Article 12(2) RPBA 2007 the statement of grounds of appeal shall contain a party's complete case. Admission of amendments to a party's case at a later stage is governed by Articles 13 RPBA 2007. Article 13(1) RPBA 2007 states that it is at the discretion of the Board to admit such amendments, taking into account, inter alia, the complexity of the new subject-matter submitted, the current state of the proceedings and procedural economy.
 - 2.2 The claims of the main request were filed after oral proceedings had been arranged, so that, in addition, the provisions of Article 13(3) RPBA 2007 are also applicable.

These claims limit the K value of the resin to a narrower range than that specified in the requests previously on file. From the accompanying argumentation in the submission of 5 November 2019 it becomes clear that the appellant considers the K value of the resin to be the decisive feature for the discussion of inventive step over D1 and D18. In particular, this submission centres around applicable criteria for inventive selections from parameter ranges disclosed in the prior art.

- 2.3 On the other hand, the impugned decision deals with the question of whether, starting from D1, it was obvious to exchange the plasticizer used in the PVC composition for the one disclosed in D18 (see pages 6-9 of the decision). The K value of the resin was not considered a distinguishing feature and was thus not considered in the inventive step assessment. Also the appellant's statement of grounds for the appeal exclusively deals with the exchange of the plasticizer and does not mention the K value at all. The auxiliary request filed together with the statement of grounds for the appeal does not relate to variations in the K value either, but to the sterilisation of the tubes.
- 2.4 Thus, the appellant's amended main request shifts the discussion on inventive step to an issue which had neither been dealt with in the impugned decision nor in the appeal proceedings up to the filing of these amendments three months before the oral proceedings.
- 2.5 This amendment therefore opens up complex new issues at a late stage of the proceedings, e. g. a discussion on selection inventions, which neither the parties nor the Board can be reasonably expected to deal with. This is neither compatible with procedural economy nor with the purpose of the appeal proceedings to conduct a final review of the decision given in the previous instance. The appellant submitted that the amendments are easy to understand and lead to a narrower claim. However, the criteria to be used under Articles 13(3) RPBA 2007 relate to the complexity of the issues raised and not merely to the complexity of the claim language.
- 2.6 Thus, the Board exercises its discretion under Articles 13(1) and 13(3) RPBA 2007 and does not admit this request into the proceedings.

First auxiliary request

3. The claims of the first auxiliary request, like the claims of the main request, also contain amendments relating to the restriction of the K-value of the PVC resin. The issue to be discussed would thus be the relevance of the K value of the resin for inventive step. Thus, for the same reasons as the main request the first auxiliary request is also not admitted into the proceedings.

Second auxiliary request

4. This request was dealt with as the auxiliary request in the impugned decision. It is thus part of the proceedings. This was not disputed.
5. Amendments (Article 123(2) EPC)
 - 5.1 During oral proceedings respondent 3, for the first time, raised an objection under Article 123(2) EPC concerning the wording "the material used for realising said tubular body *is the following*". In the respondent's opinion, a basis for the wording can be found only in paragraph [0022] of the patent, corresponding to page 6 line 8 of the original disclosure since original claim 10, which discloses the claimed amounts, is also worded in an open way. It was not permissible to combine this closed wording with the open ended wording ("comprising") of granted claim 1.
 - 5.2 The appellant stated that this objection was filed late and should not be admitted. Furthermore, it stated that no originally undisclosed subject-matter was introduced by the amendment to the claim.

5.3 The Board notes that auxiliary request 2 in its present form was filed during oral proceedings in the opposition proceedings. No objection under Article 123(2) EPC was raised during the opposition proceedings. Neither was any such objection made in the respondent's reply to the statement of grounds of appeal, which according to Article 12(2) RPBA 2007 should contain the respondent's complete case. Making such an objection for the first time in oral proceedings before the Board is an amendment to the respondent's case and may be admitted only at the Board's discretion, see Article 13(1) RPBA 2007.

Moreover the Board *prima facie* cannot see that any originally undisclosed subject-matter is introduced by changing the wording of original claim 10 to the wording used in claim 1 of the second auxiliary request which is disclosed on page 6 of the original description.

This objection is thus not admitted into the proceedings.

6. Inventive step (Article 56 EPC)

Claim 1 of auxiliary request 2 is directed to a tube for a peristaltic pump.

6.1 Closest prior art

6.1.1 In the impugned decision D1 was chosen as the document representing the closest state of the art and this was undisputed up to the day of the oral proceedings. D1 discloses a tube for pumping in claim 5 (referring to claim 2) and in example 3.

6.1.2 During the oral proceedings respondent 3 submitted that D18 should rather be considered as closest prior art. D18 disclosed a composition corresponding to the one defined in the present claim (paragraphs bridging columns 3 and 4) differing only in the K value of the PVC.

6.1.3 However, D18 is silent on pumping tubes. D18 refers to blood lines (example 4). Blood lines are not the same as pumping tubes which are exposed to severe stress due to the continuous compression and decompression movements.

According to long-standing jurisprudence of the Boards of Appeal, the closest state of the art is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common (see Case Law, 9th edition 2019, I.D.3). D18 does not disclose tubes for peristaltic pumps and is thus not conceived for the same purpose. D18 does not therefore constitute a document representing the closest state of the art.

The closest state of the art is therefore D1.

6.2 Technical problem

Starting from the pumping tube disclosed in D1 the problem to be solved was the provision of an alternative tube suitable for being used in a peristaltic pump.

No advantages of the claimed tube with respect to the tubes disclosed in D1 have been substantiated. The

comparative data in the patent (fig. 4) do not provide a comparison with D1 since the plasticizer in the reference example is not the one used in D1. Effects of the K value have been put forward. However, this is not a distinguishing feature over D1 since D1 discloses K-values of up to 100, see claim 2. Thus, the formulation of the technical problem as the provision of an alternative is appropriate.

6.3 Solution

The technical problem is solved by the tube as defined in claim 1 which is characterised by the nature of the plasticizer, being an alkyl ester of adipic acid instead of the cyclohexyl-1,2-dicarboxylic acid derivative DINCH used in D1.

The problem has been solved. That the tubes obtained are suitable for peristaltic pumps has not been disputed and can, for example, be seen from the example of the patent or from the diagram in figure 4.

6.4 Obviousness

6.4.1 It remains to be decided whether the claimed solution was obvious, i.e. whether a skilled person, starting from the disclosure of D1, would have replaced the DINCH plasticizer by the claimed adipic acid esters when trying to find alternative tubes for peristaltic pumps.

The opposition division answered this question in the affirmative arguing that the plasticizer is known from D18 for use in other types of applications of PVC resins, e.g. blood bags or blood lines.

In the view of the Board however, such an assessment is based on an ex post facto analysis. In the Board's view, the replacement of the plasticizer was not obvious from the prior art for the reasons outlined below.

- 6.4.2 D1 deals with the application of a new plasticizer, DINCH, in the medical field, see paragraphs [0008] to [0010]. This plasticizer is said to be advantageous compared to previously used plasticizers, e.g. phthalates like DEHP or others, for reasons of toxicity and/or cost, see column 1. However, when using this new plasticizer, compositions and/or processing conditions have to be adapted in order to achieve suitable results (see paragraphs [0010] and [0011]). Thus, D1 deals with the question of how to successfully incorporate the advantageous plasticizer DINCH into medical articles; one example is a pump segment as shown in example 3.
- 6.4.3 When looking for an alternative pumping tube starting from D1, a skilled person would thus first have to decide to abandon the teaching of D1 and to replace the plasticizer with a different one. Then he would have to turn to D18 where the presently claimed plasticizers are disclosed. D18 deals with the question of improving the stability of PVC compositions upon sterilisation with gamma or beta irradiation (see column 2, first and second full paragraphs), a problem which is unrelated to the problems addressed both in D1 and in the disputed patent. D18 contains no information on the suitability of the compositions for pumping tubes or other applications where stress and wear due to repeated elastic deformation is an issue. The medical articles addressed in D18 (blood bags, blood lines) do not undergo such stress. There is some useful information a skilled person can draw from D18, e.g.

that the plasticizer is biocompatible (see column 3, lines 7-37, example 1) and that it can be incorporated into PVC compositions in suitable amounts (see the compositions disclosed in columns 3 and 4). However, there is no disclosure in D18 indicating suitability for the purpose the skilled person is looking for.

Starting from D1 and combining its teaching with D18, a skilled person would not have arrived at the subject-matter of the disputed claim without hindsight. Although the technical features of the claim are individually disclosed in these documents, a skilled person would not have combined them in the expectation of solving the technical problem defined above.

6.4.4 Respondent 3 has submitted further arguments which, however, cannot change the assessment made above.

He has referred to the mentioning of mechanical properties in D18 (see column 2, lines 26ff). However, this paragraph refers to mechanical properties of the products produced in D18, i. e. blood bags and blood lines. These properties are not the same as the ones necessary for pumping tubes, and thus a skilled person cannot obtain any useful information from this disclosure.

He has, furthermore, referred to D19 which is a general textbook on additives for polymers. On page 406 of this document it is stated that aliphatic dicarboxylic acids lead to less brittle products ("Versprödungseffekte") than phthalates. However, this passage does not give the skilled person any further information on the usability of dialkyl adipates in pumping tubes or similar applications. The applications mentioned in

this paragraph relate to semisolid foils or low temperature applications. Also the general part introducing esters of aliphatic dicarboxylic acids as plasticizers (chapter 5.9.4 on page 401) stresses their ability to provide low temperature flexibility and low viscosity compositions. This is unrelated to the purpose looked for.

Another argument brought up was that a skilled person would know that the nature of the plasticizer does not have any influence on the mechanical properties of the tube. However, this is not apparent from the cited documents and no documentary evidence has been provided. On the contrary, rather it appears from the respondent's own arguments concerning the properties of aliphatic ester derivatives outlined above (see D19, page 406, last paragraph), that the use of different plasticizers does indeed lead to different mechanical properties (e.g. brittleness) in the final product.

7. Thus, the claims of the second auxiliary request comply with the requirements of the EPC. The third auxiliary request does not need not to be dealt with.

8. The claims have been amended during opposition proceedings. For compliance with Article 84 EPC, and finally Article 103(a) EPC, the description needs to be adapted to the claims of the second auxiliary request. Thus, the Board, under Article 111 EPC, remits the case to the opposition division for the adaption of the description.

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 an amended form on the basis of Claims 1 to 14 of the 2nd auxiliary request, filed as main request with the grounds of appeal dated 11 May 2015 and a description to be adapted thereto.

The Registrar:

The Chairman:



B. ter Heijden

P. Gryczka

Decision electronically authenticated