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**Datasheet for the decision
of 5 July 2021**

Case Number: T 2128/15 - 3.2.02

Application Number: 05804031.2

Publication Number: 1809579

IPC: A61M5/34, C03B23/09

Language of the proceedings: EN

Title of invention:

METHOD FOR REDUCING OR ELIMINATING RESIDUE IN A GLASS MEDICAL
CONTAINER AND CONTAINER MADE IN ACCORDANCE THEREWITH

Patent Proprietor:

Becton Dickinson and Company

Opponents:

Schott AG
Gerresheimer Bünde GmbH

Headword:

Relevant legal provisions:

EPC Art. 56

Keyword:

Inventive step - (no)

Decisions cited:

Catchword:



Beschwerdekammern
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Chambres de recours

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Case Number: T 2128/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 5 July 2021

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 4 September
2015 rejecting the opposition filed against
European patent No. 1809579 pursuant to Article
101(2) EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: M. Stern
 C. Schmidt

Summary of Facts and Submissions

- I. Appeals were lodged by both opponents against the decision by the Opposition Division rejecting the oppositions filed against European Patent No. 1 809 579. In the appealed decision it was held that the claimed subject-matter was novel and inventive.
- II. The following documents are relevant for the present decision:
- E1: US-B1-6 216 493
E8: EP-A1-0 867 418
E9: EP-B1-1 133 452
E18: DE-A1-196 44 673
E19: DE-A1-43 26 143
- III. In a communication pursuant Article 15(1) RPBA 2020 dated 17 December 2020, the Board presented its preliminary opinion on the requirements of novelty and inventive step concerning the subject-matter claimed in the granted patent.
- IV. Oral proceedings before the Board were held on 5 July 2021.
- The appellants (opponents 1 and 2) requested that the decision under appeal be set aside and that the patent be revoked.
- The respondent (patent proprietor) requested that the appeals be dismissed.
- V. Claim 1 of the patent as granted reads as follows:

"A method of producing a glass medical container (10) comprising the steps of:
providing a glass blank (24);
providing a pin (20) at an opening (22) in said glass blank (24); and
forming said glass blank (24) to conformingly engage said pin (20) to form a channel (14),
characterized in that
said pin (20) is of a material that does not contain tungsten and which is selected from the group consisting of metals or alloys containing platinum or platinum group metals, metals or alloys containing nickel, silicides, and combinations thereof."

VI. The arguments of the appellants (opponents 1 and 2) relevant for the present decision are summarised as follows:

The combination of the closest prior-art document, E1, with document E9 rendered obvious the subject-matter of claim 1 of the granted patent. E1 did not disclose any specific pin material. Hence, based on the differentiating features of claim 1, the objective technical problem had to be formulated as avoiding tungsten residues on the glass material or finding alternatives to pin materials with tungsten. The patent stated in paragraphs [0003] and [0004] that in the prior art it was known to reduce or remove tungsten-containing residues from glass medical containers. Hence, the avoidance of tungsten from the pin material was a triviality. In particular, document E9 disclosed in paragraph [0049] that certain platinum-gold alloys which contained no tungsten were especially suited for forming softened glass.

VII. The arguments of the respondent (patent proprietor) relevant for the present decision are summarised as follows:

The closest prior art, E1, disclosed the features of the preamble of claim 1. The objective technical problem had to be formulated based on the characterising features of claim 1, i.e. the difference between the subject-matter claimed and E1. The objective technical problem had been correctly formulated by the Board in their communication as "finding a pin material that leaves no unwanted residues on the formed glass material" (letter dated 5 May 2021; page 2, paragraph 2). Deviating from this view at the oral proceedings, the respondent argued differently, stating that the correct objective technical problem was "how to avoid unwanted residues on the formed glass material". Linking the choice of the pin material with the avoidance of unwanted residues on the glass amounted to a non-permissible pointer towards the solution of the problem. Although the patent stated in paragraphs [0003] and [0004] that in the prior art it was known to reduce or remove tungsten-containing residues from glass medical containers, this "prior art" was merely internal knowledge of the patent proprietor. Residues might well originate from other sources, for example, from the tooling which contacts the glass during formation or from the glass raw material, as explained in the patent on column 7, lines 13 to 17.

It was not apparent why the skilled person would consider E9 for the solution of the technical problem. E9 was concerned with a method using a roller to create surface structures on a flat glass panel. Thus, it was not apparent why the skilled person would (not only

could) consider any of the elements disclosed in connection with the roller that was used for surface machining of glass to be used as a pin for creating a channel within a glass body (rather than on the surface). The problem defined in E9 was directed to the creation of precision structures on a surface of glass panels (paragraph [0004]), such enormously high specification requirements necessitating a high-precision process. That is, E9 disclosed methods with very different requirements compared to the ones known from E1 adapted for high speed production. That is, the goals and the respective requirements of the methods of E1 and E9 were completely different. The materials disclosed in E9 were meant to be used in high-precision processes and not for low-cost fabrication of glass syringes. Moreover, E9 did not consider avoiding any unwanted residues. The choice of the "correct" material was a complex task which largely depended on the respective process requirements, i.e. also the product requirements, which were very different for flat screens and glass syringes that carry medical liquids.

Thus, there was no motivation to consult E9. Moreover, even if the skilled person would have considered any of the materials mentioned in E9, it was not apparent why he/she would have used platinum, let alone used platinum without the addition of any tungsten as this was commonly used in such processes at the time (paragraph [0002] of the patent). It was questionable whether pure platinum was actually disclosed, since the German expression "bzw" used in paragraph [0049] ("Platin bzw. Platinlegierungen") was usually used to indicate "more specifically" and not "or". The alloys disclosed in the cited documents did not explicitly rule out the inclusion of tungsten. The skilled person could have also developed (just as likely) a platinum

pin with a low level of tungsten or with a platinum coating, as disclosed in E8, E18 or E19. All of the solutions were equally likely and there was no indication in any of the prior art documents, or from common general knowledge, that suggested that the skilled person would be pointed to any of those possible solutions, let alone to the solution provided by claim 1 of the patent, to solve the underlying problem.

Reasons for the Decision

1. The invention

The patent concerns a method of producing a glass medical container in which a glass blank is engaged by a pin to form a channel in the glass, where the pin is of a material that does not contain tungsten and which is selected from the group consisting of metals or alloys containing platinum or platinum group metals, metals or alloys containing nickel, silicides, and combinations thereof.

The patent explains that tungsten-containing pins have been commonly used for forming apertures or channels in a glass container (such as glass syringe barrels, glass vials or glass drug cartridge bodies) by thermally and mechanically manipulating the glass about the pin (paragraph [0002]; column 1, lines 8 to 20). However, tungsten-containing pins undesirably leave a tungsten-containing residue on the formed glass structure, particularly on portions that had been in contact with the pins, for example, the aperture or channel. The tungsten-containing residue may have detrimental effects on any substance contained or stored within the

glass medical container (paragraph [0003]; column 1, lines 35 to 41). It is explained that although water washing of glass medical containers is known in the prior art to reduce or remove tungsten-containing residue, such washing techniques have inherent limitations and cannot reliably and repeatedly remove all or substantially all tungsten from the glass medical container (paragraph [0004]). Therefore, the method of the invention as specified in claim 1 requires, inter alia, that **"said pin is of a material that does not contain tungsten"**.

2. *Inventive step*

2.1 Document E1 is considered as the closest prior art. It is undisputed that E1 discloses a method of producing a glass medical container as defined in the preamble of claim 1, that is, a method comprising the steps of providing a glass blank and a pin at an opening in said glass blank and forming said glass blank to conformingly engage said pin to form a channel (column 2, lines 15 to 33).

2.2 E1 is silent on the choice of pin materials. Therefore, the method of claim 1 differs from that of E1 in its characterising features, i.e., *"said pin is of a material that does not contain tungsten and which is selected from the group consisting of metals or alloys containing platinum or platinum group metals, metals or alloys containing nickel, silicides, and combinations thereof"*.

2.3 In order to formulate the objective technical problem, the technical effect resulting from these distinguishing features needs to be identified. As mentioned in the description of the patent

(paragraph [0003], column 1, lines 35 to 41), the distinguishing feature of the pin material not containing tungsten has the technical effect of avoiding unwanted residues on the formed glass medical container. Hence, the objective technical problem should be formulated as **finding a pin material that leaves no unwanted residues on the formed glass material.**

2.4 To formulate the objective technical problem along the lines of avoiding **tungsten** residues on the glass material or finding **alternatives** to pin materials with tungsten - as proposed by the opponents (statement of grounds of appeal of opponent 1, page 7, first paragraph; statement of grounds of appeal of opponent 2, page 9, paragraph 4) - would already be pointing towards the solution of the problem, i.e., a pin material with no tungsten. The objective technical problem cannot be formulated either as finding **alternatives** to pin materials with tungsten, since E1 does not disclose any material for which an alternative needs to be found. Therefore, any such formulation is not permissible.

2.5 The respondent considered (in their letter dated 5 May 2021; page 2, paragraph 2) that the objective technical problem had been correctly formulated by the Board as "finding a pin material that leaves no unwanted residues on the formed glass material". However, at the oral proceedings, the respondent argued differently, stating that the correct objective technical problem should be "how to avoid unwanted residues on the formed glass material". They explained that linking the choice of the pin material with the avoidance of unwanted residues on the glass amounted to a non-permissible pointer towards the solution of the

problem. Residues may well originate from other sources, for example, from the tooling which contacts (i.e. holds) the glass during formation or from the glass raw material, as explained in the patent on column 7, lines 13 to 17.

The Board is not convinced by these arguments, since the differentiating feature whose technical effect needs to be established ("*said pin is of a material that does not contain tungsten*") clearly concerns the pin material, and not, for example, the tooling holding the glass blank from the outside (for example, the glass tube support 23 in Figure 2 of E1), or the glass raw material.

2.6 Consequently, the skilled person departing from E1 is confronted with the objective technical problem of finding a pin material that leaves no unwanted residues on the formed glass material. That is, the skilled person will have to search for a pin material appropriate for the glass forming method disclosed in E1 ascertaining that it leaves no unwanted residues on the formed glass material.

2.7 The skilled person searching for a solution to the problem posed is a person (or group of persons) with knowledge in glass-forming techniques. The Board sees no convincing reason why this person would only consider processes of hot-forming softened glass for syringes as disclosed in E1 (column 3, line 66 to column 4, line 1), rather than processes of glass forming in general, in particular, processes of hot-forming softened glass.

2.8 The skilled person would thus consider document E9 which relates to a method of hot-forming softened glass

(paragraph [0001]). The respondent submitted that since E9 is directed to the forming of precision structures in channel plates for flat panel display screens (paragraph [0001]), the skilled person would not take E9 into consideration. E9 was concerned with a method using a roller to create precision surface structures on a flat glass panel. Thus, it was not apparent why the skilled person would (not only could) consider any of the elements disclosed in connection with the roller that was used for surface machining of glass to be used as a pin for creating a channel within a glass body in high speed production.

The Board considers, however, that the teaching of E9 is broader than just disclosing a method of forming a glass display, as it explicitly mentions that the method is based on a long-standing experience in the design of tools for hot-forming of glass (paragraphs [0047] and [0049]). E9 discloses that such long-standing experience showed positive results regarding stickiness of the tools to glass, corrosion or oxidation when tools were made of platinum or platinum alloys (paragraph [0049]). These requirements are certainly to be contemplated in the forming process of softened glass of E1 too. Hence, while the choice of an adequate tool material may depend on the specific requirements of the glass-forming process, the skilled person obtains from E9 information on materials suited for hot-forming of softened glass that is also relevant for choosing the appropriate material for the pins in the glass-forming process of E1.

2.9 In paragraph [0049], E9 discloses the use of tools made of platinum or platinum alloys ("Platin bzw. Platinlegierungen"). The respondent argued that here the German expression "bzw" may actually indicate "more

specifically", rather than "or". Although the interpretation suggested by the respondent may not be dismissed altogether, the Board considers it implausible: if E9 intended to only disclose "platinum alloys", there was no need to mention "platinum". The phrase at any rate suggests (pure) platinum in contradistinction to platinum alloys, a suggestion which the skilled person would certainly consider when searching for an appropriate pin material. Pure platinum inherently contains no tungsten.

Moreover, in paragraph [0049] a specific platinum alloy, a "pure PtAu5 alloy", is disclosed. Since this alloy material is explicitly stated to be a **pure** alloy material, it is implicit that it lacks tungsten. Hence, the respondent's argument that the alloys disclosed in the cited documents do not explicitly rule out the inclusion of tungsten does not apply to E9.

- 2.10 When searching for an appropriate material for the pins of E1, the skilled person would consider these teachings from E9 and readily devise the pin in E1 from pure platinum or from a pure PtAu5 alloy. These materials will be ascertained to leave no unwanted residues on the formed glass material, in particular no tungsten residues, since they inherently contain no tungsten. Contrary to the proprietor's view, there is no need for E9 to explicitly state this inherent property. The obviousness of choosing these materials is not refuted either by the respondent's pointing to other possible alternatives which the skilled person may choose, such as a platinum pin with a low level of tungsten or a pin with a platinum coating as purportedly disclosed in E8, E18 or E19.

2.11 Summarising, by taking into account the teaching of E9, the skilled person would readily devise the pin of E1 *"of a material that does not contain tungsten and which is selected from the group consisting of metals or alloys containing platinum"*, as defined in claim 1, without the exercise of an inventive step.

2.12 Hence, the subject-matter of claim 1 of the granted patent is rendered obvious to a person skilled in the art, contrary to the requirements of Articles 52(1) and 56 EPC. Since there are no further requests on file, the patent has to be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated