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D E C I S I O N
of 12 October 2004

Case Number: T 0305/03 - 3.2.3

Application Number: 98906117.1

Publication Number: 0960311

IPC: F25D 31/00, F28D 7/12,
F28F 1/14

Language of the proceedings: EN

Title of invention:
Freezing and thawing vessel with thermal bridges

Applicant:
Integrated Biosystems

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty and inventive step - (yes) after amendment"

Decisions cited:
-

Catchword:
-



Case Number: T 0305/03 - 3.2.3

D E C I S I O N
of the Technical Board of Appeal 3.2.3
of 12 October 2004

Appellant: Integrated Biosystems
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CA 94510 (US)

Representative: Goddard, Frances Anna
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 11 September 2002
refusing European application No. 98906117.1
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: C. T. Wilson
Members: U. Krause
M. J. Vogel

Summary of Facts and Submissions

I. The appeal contests the decision of the examining division, dated 11 September 2002, to refuse European Patent application No. 98 906 117.1 for lack of novelty. The examining division held that all the constructional features of independent claim 1 were known from document GB-A-518 301 (D1).

II. The appeal was filed by the applicant (hereinafter denoted appellant) on 11 November 2002 and the appeal fee was paid the same day. The statement of the grounds of appeal was submitted on 10 January 2003.

III. In response to a communication issued by the Board on 27 November 2003, making reference to further document US-A-3 595 308 (D2), and to a further telephone conversation on 24 September 2004 the appellant submitted, with letters of 10 September 2004 and 28 September 2004, amended claims 1 to 52 and amended description pages 3 to 6 and 13. The claims include two independent claims 1 and 50 which are worded as follows:

"1. A biopharmaceutical product thermal transfer system, comprising:
a container (4; 34; 302) adapted to receive a medium comprising a biopharmaceutical product;
a heat exchange structure (6,8; 31,33; 37,39; 40,44,46; 50A,50B,50C,58A,54A,54B,54C; 60,62,64,66,68,70,72; 82,83; 87,89; 92,93; 102,120; 314; 412) positioned in the container such that the structure segments a cavity defined by the container into a plurality of compartments wherein the container and the structure are

arranged such that a distal end of the structure is in close proximity to an interior surface of the container (33; 41; 42; 84; 91; 94; 122; 316; 414) such that, in use, a frozen and/or liquid thermal transfer bridge is formed by said medium in a gap between the distal end of the structure and the interior surface of the container, wherein heat is transferred from said distal end of the structure through said thermal transfer bridge to said interior surface in response to said interior surface being actively cooled."

50. A method of cooling a biopharmaceutical product, the method comprising:
- providing a container with a heat exchange structure positioned therein such that the structure segments a cavity defined by the container into a plurality of compartments wherein the container and the structure are arranged such that a distal end of the structure is in close proximity to an interior surface of the container;
 - providing a medium comprising a biopharmaceutical product in the container and
 - actively cooling the interior surface such that a frozen and/or liquid thermal transfer bridge is formed by the medium in a gap between the distal end of the structure and the interior surface of the container wherein heat is transferred from the distal end of the structure through the thermal transfer bridge to the interior surface."

IV. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of amended claims 1 to 52, namely claims 1 to 24 (in part), 40(in part) to 47 and 52 (in part) on claim pages 22 to 25, 28 and 30 being submitted on 19 September 2004 and claims 24 (in part) to 40 (in part) and 48 to 52 (in part) on claim pages 26, 27 and 29 being submitted on 28 September 2004, description pages 3-6,13 submitted on 19 September 2004 and description pages 1,2,7-12,14-21 as well as figure sheets 1/18 to 18/18 as originally filed.

V. The essential arguments of the appellant can be summarized as follows:

The amended claims 1 and 50 are clearly restricted to a system and method, respectively, whereby the medium comprising a biopharmaceutical product is cooled through heat transfer bridges formed by frozen or liquid medium in a gap between the structure and the actively cooled interior surface of a container. Support for this limitation is to be found for example in page 5, lines 14 to 21, and page 6, lines 8 to 12 of the application as filed.

Document D1 discloses a perforated container rotating within a cooled cabinet. As cooled air is permitted to circulate through the perforations in the container, and on the outside of the container, there is no thermal transfer bridge formed in the gap between the interior wall of the cabinet and the container. Further, the container is divided into compartments adapted to receive foodstuff, rather than a biopharmaceutical medium.

The subject-matter defined in the amended claims is distinguished from document D2, disclosing the cooling of hot viscous liquids by heat exchange with actively cooled cooling units placed within a container, by cooling a medium comprising a biopharmaceutical product by heat transfer to the interior surface of the container which is actively cooled and to the heat exchange structure positioned in the container, heat being transferred from the structure through the thermal transfer bridges to the interior surface of the container. The invention as claimed is particularly beneficial for the treatment of biopharmaceutical media because it achieves controlled freezing rates for a biopharmaceutical product to promote dendritic ice growth to aid in cryopreservation, and, since the thermal transfer bridge is not present when the system is not in use, the structure can easily be removed from the container for cleaning, decontamination etc. when not in use.

Reasons for the Decision

1. The appeal complies with the provisions of Articles 106 to 108 EPC and of Rules 1(1) and 64 EPC and is, therefore, admissible.
2. *Amendments*

The amended independent claim 1 differs from original claim 1, which corresponds in substance to claim 1 on which the appealed decision was based, by limiting the claimed system to cooling of a medium comprising a

biopharmaceutical product by transferring heat from the distal end of the heat exchange structure to the interior surface of the container through a thermal transfer bridge formed, in use, by frozen and/or liquid medium in the gap between the distal end of the structure and the interior surface of the container. A basis for these amendments can be found especially on page 4, lines 16 to 20, and page 12, lines 5 to 12, of the application as filed for the cooling by heat removal through a thermal transfer bridge formed of frozen medium in the gap between the distal ends of the heat exchange structure and the interior surface, on page 5, lines 14 to 21, for forming the thermal transfer bridge out of frozen or liquid medium and on page 7, lines 3 to 8, for the medium comprising a biopharmaceutical product.

New independent claim 50 is a method claim corresponding in substance to system claim 1 and being, therefore, likewise supported by the application as filed.

The dependent claims 2 to 49 have been amended for consistency with claim 1, as far as the terminology and the restriction to cooling is concerned, and for compliance with Rule 35(12) EPC concerning the units for the gap width. The new claims 51 and 52 are dependent method claims corresponding to dependent system claims 5 and 14.

The description has been amended to bring it into conformity with the amended claims and, likewise, to comply with Rule 35(12) EPC.

The amendments are, therefore, not open to objection under Article 123(2) EPC.

3. *Novelty*

The amendments to claim 1 functionally define the claimed system, thereby establishing novelty with respect to document D1 which discloses a compartmented food storage container located within a cooled cabinet. In fact, cooling of frosted food items or commodities stored within the container is achieved, according to D1, by cooled air circulating between the cooled interior surface of the cabinet and the food within the storage container through the perforated wall of the container, which arrangement excludes any formation of frozen and/or liquid heat transfer bridges in any gaps between the compartment walls within the container and the interior surface of the cabinet or the outer wall of the container by cooling the cabinet.

Document D2 discloses the cooling of hot viscous liquids by heat exchange with radially oriented, actively cooled cooling units placed within a cylindrical container in heat exchange relationship with the medium which is circulated by a propeller along a path including a passage between the cooling units. Whilst a radial gap is shown in Figures 1 and 3 between the distal ends of the cooling units and the interior surface of the surrounding container, there is no disclosure of a heat transfer between the cooling units and the container through a frozen and/or liquid heat transfer bridge formed from the cooled medium in this gap. In fact, the arrows shown in the gap make clear that the medium is supposed to flow through this

gap, precluding any frozen and/or liquid medium therein which could act, by forming a stagnant medium layer, as a bridge enhancing heat transfer between the cooling units and the container.

Indeed, the system of claim 1 is distinguished from this prior art by actively cooling the container and additionally removing heat from the medium by the heat exchange structure positioned in the container through the frozen and/or liquid thermal transfer bridge to the container, whereby it is evident, as explained on page 5 of the application, that the frozen bridge is formed when cooling a liquid medium and the liquid bridge is formed when cooling a gas.

Since there is no other relevant document available and the method of claim 50 is defined by the same features as claim 1, the invention claimed in independent claims 1 and 50 is considered to be new. The claims, therefore, meet the requirements of Article 52(1) EPC in combination with Article 54 EPC.

4. *Inventive step*

The Board considers D2 to be the closest prior art since this document is also concerned with cooling of a fluid medium, as opposed to the cooling of frosted food items or like commodities in the system of D1.

As set out above, the subject-matter defined in the amended claims 1 and 50 is distinguished from the cooling system of D2 in that the medium comprising the biopharmaceutical product is cooled by actively cooling the container and additionally removing heat from the

medium via the heat exchange structure positioned in the container and the thermal transfer bridge formed, in use, of frozen medium when cooling a liquid medium or of liquid medium when cooling a gas, to the actively cooled interior surface of the container. Since heat is removed from the structure only via the thermal transfer bridge in the narrow gap between a distal end of the structure and the interior surface of the container, rather than through a coolant flowing through channels within the structure, and the thermal transfer bridge is formed only by cooling the system, the bridge being absent when the system is not in use, the area available for heat exchange is enlarged, in use, by the heat exchange structure which can easily be removed from the container for cleaning, decontamination etc. when not in use. This is a clear advantage over the system of D2 where the heat exchange area includes only the cooling structure which is actively cooled and, therefore, must be connected to inlet and outlet pipes for the coolant, precluding any easy removal for cleaning etc.

There is no pointer to such a solution in the available prior art. In D1 only the interior surface of the actively cooled cabinet exchanges heat with the gaseous medium circulating towards the food items within the perforated container, and due to the absence of any heat transfer path between this surface and the various parts of the container, such as the frozen and/or liquid thermal transfer bridge defined in the claims, the container and the radial partitions therein cannot make any relevant contribution in cooling either the gaseous medium or the food items. Thus, whilst the container may be removable for cleaning etc., it does

not form an enlarged heat exchange area comparable to the heat exchange structure defined in claims 1 and 50. A suggestion for enlarging the heat exchange area by forming, in use, a frozen and/or liquid thermal transfer bridge cannot be derived from the remaining documents cited in the Search report either.

The Board is, therefore, satisfied that the subject-matter of independent claims 1 and 50 meets the requirement of inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent on the basis of the following documents:

Claims:

1 to 24 (in part), 40(in part) to 47 and 52 (in part) on claim pages 22 to 25, 28 and 30 submitted on 19 September 2004;

24 (in part) to 40 (in part) and 48 to 52 (in part) on claim pages 26, 27 and 29 submitted on 28 September 2004;

Description:

pages 3-6,13 submitted on 19 September 2004;

pages 1,2,7-12,14-21 as originally filed;

Drawings:

sheets 1/18 to 18/18 as originally filed.

The Registrar:

The Chairman:

A. Counillon

C. T. Wilson



Case Number: T 0305/03 - 3.2.3

D E C I S I O N
of 10 November 2004
correcting errors in the decision
of the Technical Board of Appeal 3.2.3
of 12 October 2004

Appellant: Integrated Biosystems
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Composition of the Board:

Chairman: C. T. Wilson
Members: U. Krause
M. J. Vogel

In application of Rule 89 EPC the decision given on 12 October 2004 is hereby corrected as follows:

In paragraph 2 of the order on page 10, and in paragraph IV, page 3, the claims 1 to 24 (in part), 40 (in part) to 47 and 52 (in part) on claim pages 22 to 25, 28 and 30 are those submitted on "10 September 2004" rather than on "19 September 2004", and the description pages 3 to 6, 13 are those submitted on "10 September 2004" rather than on "19 September 2004".

The Registrar:

The Chairman:

A. Counillon

C. T. Wilson