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Language of the proceedings: EN

Title of invention:
SINGLE-USE MANIFOLD FOR AUTOMATED, ASEPTIC TRANSFER OF SOLUTIONS IN BIOPROCESSING APPLICATIONS

Patent Proprietor:
Parker-Hannifin Corporation

Opponent:
EMD Millipore Corporation

Headword:

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - added subject-matter in claim 1 of all requests (yes)

Decisions cited:

Catchword:

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Case Number: T 1463/12 - 3.2.07

D E C I S I O N
of Technical Board of Appeal 3.2.07
of 31 July 2015

Appellant I: (Opponent)	EMD Millipore Corporation 290 Concord Road Billerica MA 01821 (US)
Representative:	Garkisch, Marcus Henkel, Breuer & Partner Patentanwälte Maximiliansplatz 21 80333 München (DE)
Appellant II: (Patent Proprietor)	Parker-Hannifin Corporation 6035 Parkland Boulevard Cleveland, Ohio 44124-4141 (US)
Representative:	Calderbank, Thomas Roger Mewburn Ellis LLP City Tower 40 Basinghall Street London EC2V 5DE (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 20 April 2012 concerning maintenance of the European Patent No. 1525138 in amended form.**

Composition of the Board:

Chairman	H. Meinders
Members:	K. Poalas
	G. Weiss

Summary of Facts and Submissions

I. Appellants I and II (opponent and patent proprietor, respectively) lodged each an appeal against the interlocutory decision of the opposition division maintaining European patent No. 1 525 138 in amended form.

II. Opposition had been filed against the patent as a whole based on Article 100(a) EPC (lack of novelty and lack of inventive step) and Article 100(c) EPC (unallowable amendments).

III. The opposition division found that the subject-matter of claim 1 according to the fifth auxiliary request filed during the oral proceedings meets the requirements of the EPC.

IV. Oral proceedings took place before the Board on 31 July 2015.

a) Appellant I requested that the decision under appeal be set aside and that the patent be revoked.

b) Appellant II requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the set of claims filed as main request, or according to one of the sets of claims filed as first to seventh auxiliary requests, all filed with the letter dated 25 June 2015.

V. The **preamble** of claim 1 of all requests reads as follows:

"A method for automated aseptic biotechnology fluid preparative chromatography, comprising:
providing a manifold unit (48) which is pre-sterilized and disposable so as to be adapted for single-time usage, including:
(a) at least one length of tubing having at least one inlet end portion, at least one outlet end portion, an outside surface, and an inside surface which is sterilized for passage of a biotechnology fluid therethrough, wherein said tubing is in at least two sections including a chromatography feed section and a chromatography fluid section (64);
(b) a plurality of single-use bags including a first single-use bag (58) and a second single-use bag (62), each having a primary access port,
(c) an aseptic connector means for operatively connecting said length of tubing with said single-use bag primary access port,
(d) a chromatography column (56) positioned along the length of said tubing such that the biotechnology fluid flows through the chromatography column at a location upstream of said outlet end portion of the length of tubing,
(e) a pump unit (45) at a selected location along said length of tubing that is upstream of a discrete location therealong, said pump unit (45) moving the biotechnology fluid through said length of tubing and through said chromatography column (56),
(f) a plurality of pinch valves which are remotely operable in response to a signal remote from said pinch valves, each said pinch valve engages said outside surface of the length of tubing at said discrete location therealong, each said pinch valve independently selectively allowing or stopping flow of the biotechnology fluid through said inside surface of

the length of tubing at said discrete location for that pinch valve,
(g) wherein said chromatography feed section has an outlet and a plurality of serially arranged inlet passageways having one of said aseptic connector means (66) for operable connection with said single-use bag (54, 62, 63), wherein said chromatographed fluid section has an inlet and said outlet end portion of the tubing which has a plurality of serially arranged outlet passageways having one of said aseptic connector means for operable connection with said single-use bag (58, 61), wherein a first said pinch valve (51, 52, 53) controls passage of the biotechnology fluid from said single-use bags (54, 62, 63) to the chromatography feed section and wherein a second said pinch valve (49, 59) controls passage of the biotechnology-fluid from the tubing chromatographed fluid section (64) to the respective single-use bag (58, 61) of the chromatographed fluid section, and
(h) said pump unit (45) engages said outside surface of the length of tubing at said selected location upstream of said discrete location for the pinch valves".

VI. Appellant I's arguments, in so far as they are relevant for the present decision, may be summarised as follows:

Claims 1 according to all requests – amendments, Article 123(2) EPC

Originally filed claim 64 makes a clear distinction between the features (denominated (a) to (f)) of the manifold unit and the features not being parts of the manifold unit, namely the pinch valves, the chromatography column, the pump unit and the controller.

Also, according to paragraph [0027] of WO 03/106266 A1, which is the published originally filed application, the single-use, pre-sterilised components of the invention are only the manifold and transfer tubing assembly and a plurality of bags shown in figure 1. These components neither encompass the pump unit nor the pinch valves nor the chromatography column. There is no mention of pre-sterilizing the entire bodies of the chromatography column, the pump unit and the pinch valves, respectively.

There is no disclosure in the originally filed application that the chromatography column, the pump unit and the pinch valves are pre-sterilized so as to be adapted for single-time usage components of the manifold unit.

However, the present wording of claims 1 of all requests requires these components to be pre-sterilised.

VII. Appellant II's arguments, in so far as they are relevant for the present decision, may be summarised as follows:

Claims 1 according to all requests - amendments, Article 123(2) EPC

Claim 1 of all requests is directed to a method with the step of providing a manifold unit. Said manifold unit is provided with different components like a chromatography column, a pump unit and pinch valves. The step of providing said manifold unit can therefore be broken down in the provision of different components, of which some components are pre-sterilized and disposable and some are not.

The wording of claim 1 does not require that every single component of the manifold unit has to be pre-sterilized and disposable.

The skilled person would for example consider that only the inner surfaces of the chromatography column and the pump unit need to be pre-sterilized and not their outer surfaces.

Reasons for the Decision

1. *Claims 1 according to all requests – amendments, Article 123(2) EPC*

1.1 Claim 1 of all requests is directed to a method for automated aseptic biotechnology fluid preparative chromatography, said method comprising the step of providing of a **manifold unit** which is **pre-sterilized and disposable** so as to be adapted for single-time usage. According to the claim, said manifold unit **includes** the following components: at least one length of tubing, a plurality of single-use bags, an aseptic connector means, **a chromatography column**, **a pump unit and a plurality of pinch valves**.

1.2 The Board agrees with appellant II that the originally filed claim 64 makes a clear distinction between on the one hand the manifold unit **including** length(s) of tubing, a plurality of single-use bags and aseptic connector means, where the manifold unit is pre-sterilized and disposable so as to be adapted for single-time usage, and on the other hand the pinch valves, the chromatography column and the pump unit. These are all clearly **not** included in the manifold unit.

The same can be concluded from paragraph [0027] of WO 03/106266 A1, in that the chromatography column, the pump unit and the plurality of pinch valves are not mentioned as single-use pre-sterilized components of the invention, which originally was the manifold system. This applies to figure 1.

1.3 However, this is not what the claims 1 of all requests now claim. Due to the qualification of the manifold unit in claim 1 as being **"pre-sterilized"**, all parts included in said manifold unit, i.e. *inter alia* the chromatography column, the pump unit and the plurality of pinch valves have to be **pre-sterilized.**
If a single part of the manifold unit is not or only partly (i.e. having only its inner surfaces) pre-sterilized, then such a manifold unit including said part cannot be considered pre-sterilized.

1.4 Appellant II argues in this respect that the skilled person reading claim 1 of all requests and taking into consideration the general teaching of the originally filed application would immediately recognise that not every single part of the claimed manifold unit has to be completely pre-sterilized. He would know that only the inner surfaces of the chromatography column and the pump unit need to be pre-sterilized and that therefore these components would be seen as "pre-sterilized" in such a qualified sense.

1.5 There is no difference in opinion between appellant II and the Board as to what the original application discloses (see point 1.2 above) or what the person skilled in the art taking into consideration the general teaching of the originally filed application would consider to be the sterilisation requirement on the different components of the manifold unit. However,

the Board cannot agree with appellant II that the granted claim 1, or the present claims 1 of all requests, should be read in this sense. It is simply not what the claim states, and what it states has a technical meaning which makes sense. For instance, sterilizing these components completely may be easier or more feasible than making a distinction between those parts that come into contact with the liquid and those that do not. In particular, this plays a role at the respective connectors of the pump unit and chromatography column with the rest of the (pre-sterilized) tubing.

1.6 Finally, appellant II had the argument that the pre-sterilized manifold unit could easily be qualified as "pre-sterilized" and still include "not pre-sterilized" other components. This was illustrated by having (for argument's sake) a "pre-sterilized" bag into which a "not pre-sterilized" wallet was inserted, i.e. "included". This did not change anything to the "pre-sterilized" bag.

1.7 The Board cannot agree with this argument, since the manifold unit is not built up in this sense, but is composed of its components in a sequential order, according to the direction of flow. Being included in such a manifold unit has the consequence that the pre-sterilization of this unit applies also to the other components, such as the chromatography column and the pump unit.

1.8 For the above-mentioned reasons the Board finds that there is no basis in the originally filed application for the provision of a manifold unit **including** a chromatography column, a pump unit and pinch valves, whereby said three components are all **pre-sterilized** so

as to be adapted for single-time usage in the sense of claim 1 of all requests.

1.9 As a consequence, the claims 1 of all requests do not meet the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The appeal of the appellant II is dismissed.

2. The decision under appeal is set aside.

3. The patent is revoked.

The Registrar: The Chairman:

G. Nachtigall H. Meinders

Decision electronically authenticated