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Datasheet for the decision of 4 April 2014

Case Number: T 1306/11 - 3.3.06

Application Number: 01950382.0

Publication Number: 1292379

IPC: B01D61/22

Language of the proceedings: EN

Title of invention:
Enhancing filtration yields in tangential flow filtration

Applicant:
Parker-Hannifin Corporation

Headword:
Tangential flow concentration of cell suspensions/PARKER-HANNIFIN

Relevant legal provisions:
EPC Art. 52(1), 54(1), 54(2), 84, 111(1), 123(2)

Keyword:
Late-filed request - admitted (yes) new main request
Amendments - added subject-matter (no) - clarity (yes)
Novelty - (yes)
Remittal to the department of first instance - (yes)

Decisions cited:

Catchword:

Beschwerdekammern
Boards of Appeal
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Case Number: T 1306/11 - 3.3.06

D E C I S I O N
of Technical Board of Appeal 3.3.06
of 4 April 2014

Appellant: (Applicant)	Parker-Hannifin Corporation 6035 Parkland Boulevard Cleveland, Ohio 44124-4141 (US)
Representative:	Calderbank, Thomas Roger Mewburn Ellis LLP 33 Gutter Lane London EC2V 8AS (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 January 2011 refusing European patent application No. 01950382.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: B. Czech
Members: G. Santavicca
S. Fernández de Córdoba

Summary of Facts and Submissions

I. The appeal lies from the decision of the examination division to refuse European patent application n°01950382.0.

II. The application was refused on the grounds that the respective Claims 1 of each of the main, first and second auxiliary requests then on file lacked clarity (Article 84 EPC) and that the claimed process according to Claim 1 of the third auxiliary request then on file was obvious over document D3 (WO 98/35746 A1) taken as the closest prior art.

III. With its statement setting out the grounds of appeal, the appellant *inter alia* filed amended sets of claims as main request and auxiliary requests.

IV. In reaction to the summons to oral proceedings, with letter dated 10 March 2014, the appellant withdrew some of its previous requests and re-filed the accordingly renumbered remaining requests.

V. In preparation for oral proceedings, the board issued a communication indicating its provisional view regarding some of the salient issues of the case. Document D6 (US 5,947,689 A), acknowledged in the application as filed, was referred to.

VI. In response to the Board's communication, the appellant, with its letter dated 24 March 2014, filed further amended sets of claims as new first, second, third and fourth auxiliary requests.

VII. In a telephone conversation held on 2 April 2014, the rapporteur drew the attention of the applicant’s

representative to some of the points which might still need to be discussed at the oral proceedings and issued a fax communication summarising the issues addressed.

VIII. At the oral proceedings held on 4 April 2014 the issues mentioned in the Board's communications, in particular the clarity issues, were addressed exhaustively. The appellant submitted a new main request, replacing the main and first auxiliary requests previously on file. At the end of the oral proceedings the decision was announced.

IX. Claim 1 according to the main request filed at the oral proceedings reads as follows (amendments to Claim 29 as originally filed made apparent by the Board):

"1. A**n automated tangential flow filtration** method for ~~filtering liquids while maintaining a substantial trans-membrane pressure~~ **concentrating cell suspensions, for use in the pharmaceutical or biotechnology industries, the method** comprising:

providing, ~~with~~in a reservoir (**21**) ~~a liquid having a filterable material dissolved or suspended~~ **a supply (22) of a cell suspension** within a carrier liquid;

providing a **membrane** filtration unit (**24**) having an inlet (**28**), a ~~filtrate~~ **permeate** outlet (**29**) and a retentate outlet (**31**);

~~receiving~~ **passing** liquid to be filtered **by operation of a pump unit (25)** through the inlet of the filtration unit and separating at least some ~~filterable~~ material therefrom as ~~filtrate~~ **permeate** from the ~~filtrate~~ **permeate** outlet;

passing a retentate of the carrier liquid and residue ~~filterable~~ material from the retentate outlet;

directing the liquid from the retentate outlet and **recycling it** to the reservoir (**21**);

providing ~~at least one pressure~~ a **first** sensor (**S1**) **for sensing the pressure of the liquid passing through the inlet, to monitor an inlet pressure (P1);**
providing a second pressure sensor (S2) at the retentate outlet for monitoring the retentate pressure (P2) and a third pressure sensor (S3) at the permeate outlet for monitoring permeate pressure (P3) ~~and valve positioned along a location for monitoring and modifying pressure~~;

providing a processor (41) with control logic for adjusting the pump rate imparted to the liquid by the pump unit;

wherein

the method further includes:

providing a valve **(36,30)** ~~positioned along a location~~ for ~~monitoring and~~ modifying pressure **at the permeate outlet** (**29**)**, at the retentate outlet (31), or at each of the permeate outlet and retentate outlet, the control logic of the processor being also for adjusting the valve or valves, the adjustment of the pump rate and valve or valves being for modifying pressure at the outlet or outlets;**

passing the liquid through a flow meter (35) at a location upstream of the filtration unit;

determining an optimal feed rate and an optimal trans-membrane pressure across the membrane filtration unit for the particular filtration unit and for the particular process solution of the liquid for pharmaceutical or biotechnology use being filtered;

maintaining a substantially constant trans-membrane pressure **that substantially coincides with the optimal trans-membrane pressure across the membrane filtration unit while maintaining a substantially constant feed rate that substantially coincides with the optimal feed rate;**

said maintaining including controlling movement rate of the liquid through the filtration unit, including receiving data from the pressure sensor**s,** calculating **from the inlet pressure and the outlet pressures** the trans-membrane pressure across the filtration unit, comparing the thus calculated trans-membrane pressure with ~~a selected~~ **the optimal** trans-membrane pressure, and if a deviation between the calculated and ~~selected~~ **optimal** transmembrane pressure occurs, varying the pressure at **at least one of** the pressure sensor**s** so that the calculated trans-membrane pressure substantially coincides with the ~~selected~~ **optimal** trans-membrane pressure **across the membrane filtration unit;**

said maintaining further including receiving data from the flow meter and directing the pump unit to modify the flow rate detected by the flow meter in order to maintain a substantially constant feed rate into the membrane filtration unit which substantially coincides with the optimum ~~flow~~ feed rate; and

said determining of the optimal trans-membrane pressure

includes detecting the amount of filtrate which passes through the permeate outlet as filtrate amount data received by the control logic, whereby the transmembrane pressure value and the feed rate value are varied and the filtrate collection amount is monitored to detect an optimal trans-membrane pressure value and optimal feed rate achieving a maximum collection rate, and setting the optimal feed rate and optimal transmembrane pressure as thus determined for said maintaining step;

thereby achieving a maximum collection rate in the concentration of the cell suspension by tangential flow filtration without affecting the viability of the cells."

X. The appellant requested that the decision under appeal be set aside and that a European patent be granted on the basis of the main request submitted during oral proceedings, or, alternatively, according to one of the second, third or fourth auxiliary requests filed with letter dated 24 March 2014.

XI. The appellant's arguments concerning the main request can be summarised as follows:

a) The new main request should be admitted into the proceedings, for the following reasons:

i) Since the decision under appeal found that the claims of the third auxiliary request were clear and based on the application as filed, the appellant was not aware of any objections under Articles 84 or 123(2) EPC as raised by the Board for the first time in its communication, so that it was not

possible for the appellant to file earlier a claim request addressing these objections.

ii) The new claims addressed all the objections raised by the Board in its communications.

iii) The main request was thus clearly admissible.

b) As to the amended claims of the main request, they were based on the application as filed, and were also clear in all aspects of the claimed process, such as automation, tangential flow filtration, concentration of cell suspensions and recycling.

c) Document D6, referred to by the Board, and not one of documents D1 to D4 used by the Examining Division, was the most relevant starting point with respect to the claimed subject-matter, but inventive step arguments regarding D6 had not yet been considered. Hence, remittal to the first instance was appropriate.

Reasons for the Decision

1. The appeal is admissible.

Main request

Admissibility of the request

2. The main request submitted during oral proceedings before the Board addresses all the objections detailed in the Board's two communications. Since corresponding objections had not been raised previously, they could not possibly have been dealt with earlier by the appellant (applicant). Also, the claims according to

the new main request at issue are substantially restricted in breadth compared to the narrowest process claims (then pending third auxiliary request) dealt with in the decision under appeal, thereby providing a further convergence of the issues to be assessed.

The Board thus decided, pursuant to Article 114(2) EPC and Articles 12(4) and 13(1)(3) RPBA, to admit the new main request to the proceedings despite its late filing.

Amendments

3. Compared with Claim 29 of the application as originally filed (Point X., *supra*), Claim 1 according to the main request comprises a number of added features.

3.1 These added features find a basis in the application as filed, as follows:

(a) "*automated*": see page 1, line 8, and page 4, line 8; Figures 1 to 3 and description thereof;

(b) "*tangential flow filtration*": see page 1, line 21; page 2, lines 8-9; Figure 1 and page 7, lines 4-5 and 11-12;

(c) "*for concentrating cell suspensions*", "*for use in the pharmaceutical or biotechnology industries*", and "*supply of cell suspension*": see page 1, lines 1-4, 14-18 and 19-24; page 2, lines 15-16; page 4, lines 34-35; page 18, lines 15-16; Example 1;

(d) "*providing a membrane filtration unit*": see page 1, lines 5, 25-26; page 6, line 30-31; page 7, line 8;

(e) "*permeate*": see page 6, line 33; page 8, line 28;

(f) "*passing liquid to be filtered by operation of a pump unit (25) through the inlet of the filtration unit*": see page 6, lines 21-22 and 25-28;

(g) "*recycling*": see Figure 1; page 7, lines 1-3;

(h) "*first sensor for sensing the pressure of ... and a third pressure sensor (S3) at the permeate outlet for monitoring permeate pressure (P3)*": see page 8, lines 20-24;

(i) "*providing a processor (41) with control logic for adjusting the pump rate imparted to the liquid by the pump unit*": see page 11, lines 9-19, 27-28; page 15, lines 13-20, more particularly 17-19;

(j) "*providing a valve (36,30) ... for modifying pressure at the outlet or outlets*": see page 9, lines 14-24; page 15, lines 9-24;

(k) "*passing the liquid through a flow meter (35) at a location upstream of the filtration unit*": see Figure 1 and page 9, lines 20-22;

(l) "*determining an optimal feed rate and an optimal trans-membrane pressure ... being filtered*" and "*maintaining a substantially constant trans-membrane pressure ... substantially coincides with the optimal feed rate*": see paragraph bridging pages 9 and 10; page 15, lines 30-33; page 17, lines 22-33; page 19, line 27, to page 20, line 8;

(m) "*said maintaining including controlling movement rate ... optimal trans-membrane pressure across*

the membrane filtration unit": see page 9, lines 26-31, in combination with page 15, lines 9-23;

(n) "*said maintaining further including receiving data ... which substantially coincides with the optimal feed rate*": see page 16, lines 20-26;

(o) "*said determining of the optimal trans-membrane pressure ... for said maintaining step*": see Claim 10; page 13, lines 3-5; page 17, lines 10-33; and

(p) "*thereby achieving a maximum collection rate in the concentration of the cell suspension by tangential flow filtration without affecting the viability of the cells*": see page 17, lines 29-33; and Example 1, paragraph bridging pages 21-22.

3.2 Moreover, the combination of all of the features resulting from the incorporation of said features into Claim 1 at issue is fairly based on Claims 29, 30 and 10, Figures 1 to 3, and the general description of the application as filed, in particular page 5, lines 1-29, page 15, lines 9-23, page 16, line 5, to page 17, line 33, page 19, lines 27-30, and page 20, lines 15-29.

3.3 Dependent Claims 2 to 5 substantially correspond to, respectively, the process features derivable from original Claims 6, 9, 14 and 16, which concerned apparatuses.

3.4 The Board is thus satisfied that the amended claims comply with the requirements of Article 123(2) EPC.

Clarity

4. All of the objections raised in the Board's

communications have been addressed and overcome by the claims according to the present main request.

4.1 In particular:

(a) The "*filtering of pharmaceutical or biotechnology liquids containing cells*" has been clearly restricted to the automated concentration of liquids containing cells by tangential flow filtration, whereby Claim 1 also specifies that the viability of the cells in the concentrated cell suspension is maintained.

(b) The automated and recycling aspects of the method have been made apparent.

(c) The unclear feature "*filterable cell suspension*" has been made clear, *inter alia* by specifying, where necessary, that the filtrate is the permeate.

(d) "*Determining an optimal feed rate and an optimal trans-membrane pressure across the membrane unit for the particular filtration unit and for the particular process solution of*" is now a clear step of the claimed method.

4.2 Thus, in the board's judgement, Claim 1 as well as dependent Claims 2 to 5 according to the main request comply with the requirements of Article 84 EPC.

4.3 In the present case, the Board is also satisfied that a two-part form of independent claim 1 pursuant to Rule 43(1)b) EPC would not be appropriate considering the multitude of steps making up the claimed process and their complex interaction with each other.

Novelty

5. In the decision under appeal, the issue of novelty was not dealt with. The Board understands that novelty was tacitly acknowledged. Considering documents D1 to D4 cited by the Examining Division, the Board has no reason to take a different stance.

6. As regards document D6, the Board is satisfied that although it concerns an automated tangential flow filtration method for use in the pharmaceutical and biotechnology industries (see D6: claim 1 and column 1, lines 7 to 9), it does not disclose a method for the concentration of cell suspensions with all the features of Claim 1 at issue.

Remittal

7. The invention underlying the present application now relates to the enhancement of filtration yields in automated tangential flow concentration of cell suspensions.

7.1 In the decision under appeal, the Examining Division identified D3 as the closest prior art for assessing inventive step. However, the method of D3 is not applied to cell suspensions and comprises (see Claim 1, step D) the addition of water as an essential step. Hence, D3 does not apparently relate to the concentration of suspensions, but rather to the washing of impurities therefrom.

7.2 In fact, none of D1 to D4 appears to qualify as closest prior art, at least regarding the subject-matter of Claim 1 at issue. The reasoning given in the decision under appeal as regards inventive step (see point II

supra) can thus not apply to the process according to claim 1 at issue.

7.3 Arguments as to the issue of inventive step over the teaching of document D6, acknowledged as prior art and starting point for the invention in the description of the application as filed have, however, not yet been considered despite the apparent high relevance of the disclosure of this document.

8. Considering that the claims have been substantially amended in the appeal proceedings and that the issue of inventive step has not, up to now, been assessed taking into account document D6, the Board considers it appropriate to remit the case to the examining division pursuant to Article 111(1) EPC, as asked for by the appellant.

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:

D. Magliano B. Czech

Decision electronically authenticated