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**Datasheet for the decision of 18 May 2020**

**Case Number:** T 2640/18 - 3.3.06

**Application Number:** 11763151.5

**Publication Number:** 2552584

**IPC:** B01J47/14, B01D15/18, G01N30/28, G01N30/46

**Language of the proceedings:** EN

**Title of invention:**
A PARALLEL SEPARATION SYSTEM

**Applicant:**
Cytiva BioProcess R&D AB

**Headword:**
Parallel chromatography

**Relevant legal provisions:**
RPBA Art. 12(4)
EPC Art. 56

**Keyword:**
Late-filed request - admitted (no) - request identical to request not admitted in first instance proceedings - request clearly allowable (no)
Inventive step - (no)

**Decisions cited:**
G 0007/93

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**

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**Case Number: T 2640/18 - 3.3.06**

# D E C I S I O N
# of Technical Board of Appeal 3.3.06
# of 18 May 2020

| | |
|---|---|
| **Appellant:** (Applicant) | Cytiva BioProcess R&D AB<br>Björkgatan 30<br>751 84 Uppsala (SE) |
| **Representative:** | Bedford, Grant Richard<br>Global Life Sciences Solutions Operations UK Ltd<br>Amersham Place<br>Little Chalfont, Buckinghamshire HP7 9NA (GB) |
| **Decision under appeal:** | **Decision of the Examining Division of the European Patent Office posted on 24 May 2018 refusing European patent application No. 11763151.5 pursuant to Article 97(2) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | J.-M. Schwaller |
| **Members:** | S. Arrojo |
| | C. Brandt |

## Summary of Facts and Submissions

I. This appeal lies from the decision of the examining division to **refuse European patent application No. 11763151.5** for non-compliance with the requirements of Articles 84, 54 and 56 EPC.

II. In the summons to oral proceedings, the examining division cited documents D15, D16 (Colleen K. Van Pelt et al: "*A Four-Column Parallel Chromatography System for Isocratic or Gradient LC/MS Analyses*", Analytical Chemistry, vol. 73, no. 3, February 2001) and D17 in support of the patentability objections against the then main request as filed on 9 February 2017.

III. With letter dated 12 March 2018, in response to the above summons and within the time limit set out under Rule 116 EPC, the appellant requested to maintain the patent on the basis of said main request or, alternatively, on the basis of one of auxiliary requests 1 and 2 filed with this letter.

IV. According to point 12 of the "Summary of Facts and Submissions" of the appealed decision, a telephone consultation was held on 5 April 2018. There is no information on file reflecting the content of this consultation.

V. With letter dated 11 April 2018 (one day before the oral proceedings), the appellant filed auxiliary requests 3-6 and announced that he would not be attending the oral proceedings. The main request and auxiliary requests 1-2 were maintained but the applicant indicated that they would be withdrawn if the

newly filed requests were admitted into the proceedings.

VI. At the oral proceedings, held in the absence of the appellant, the examining division decided that the main request and auxiliary requests 1 and 2 were not allowable under Articles 84, 54 and that they were not inventive under Article 56 EPC in view of document D16. The examining division also came to the conclusion that auxiliary requests 3-6 should not be admitted into the proceedings under Rule 137 EPC because they were late filed, *prima facie* not allowable and based on subject-matter which diverged from the invention defined in the higher ranking requests.

VII. With its statement of grounds of appeal, the appellant requested to grant a patent on the basis of the main request as filed on 9 February 2018 (it is assumed that it intended to refer to 9 February 2017), or alternatively, on the basis of one of auxiliary requests 1-6 attached to the grounds, all requests corresponding to those which had been filed during first instance proceedings. The appellant also requested that the appeal fee be reimbursed, arguing that the non-admission of auxiliary requests 3-6 into the proceedings amounted to a substantial procedural violation.

VIII. **Claim 1 of the main request** reads as follows:

*"A method in a separation system (1; 31) comprising parallel fluid paths (F1,F2 ... Fn; Fl',F2', .... Fn') each comprising a separation module (Ml,M2, ... Mn; Ml',M2', ... Mn'), said method comprising the steps of:*

*- providing an adjustable flow restrictor (R1,R2, ... Rn; R1',R2', ... Rn') in each fluid path; the method being characterised by the steps of:*
*- identifying the fluid path with highest hydraulic resistance by measuring the hydraulic resistance of each fluid path sequentially and separately while stopping the fluid flow through all other fluid paths or alternatively by measuring sequentially the hydraulic resistance of all fluid paths except one fluid path and additionally measuring the hydraulic resistance of the whole system and using said hydraulic resistance measurements for obtaining also the hydraulic resistance of said one fluid path; adjusting the hydraulic resistance of each of the parallel fluid paths to be substantially the same, by adjusting the adjustable flow restrictors in the fluid paths sequentially and separately while stopping the fluid flow through all other fluid paths, such that the hydraulic resistance of each fluid path is equal or higher than the hydraulic resistance of the fluid path identified to have the highest hydraulic resistance."*

**Claim 1 of auxiliary request 1** corresponds to that of the main request, with the last step being amended as follows (the added features are underlined):

*"..., adjusting the hydraulic resistance of each of the parallel fluid paths to be substantially the same, by adjusting the adjustable flow restrictors in the fluid paths sequentially and separately while stopping the fluid flow through all other fluid paths, such that the hydraulic resistance of each fluid path is equal or higher than the hydraulic resistance of the fluid path identified to have the highest hydraulic resistance, and*

*then operating the separation modules in parallel and at the same time with synchronised hydraulic resistance to provide the same residence times for each module".*

**Claim 1 of auxiliary request 2** corresponds to that of auxiliary request 1, with the second step being defined as follows (the added features are underlined):

*"- identifying the fluid path with highest hydraulic resistance by measuring the hydraulic resistance of each fluid path sequentially and separately using same constant level fluid flow rate for each path while stopping the fluid flow through all other fluid paths or alternatively by measuring sequentially the hydraulic resistance of all fluid paths except one fluid path and additionally measuring the hydraulic resistance of the whole system and using said hydraulic resistance measurements for obtaining also the hydraulic resistance of said one fluid path; ..."*

IX. Since the appellant did not request oral proceedings under Article 116 EPC, the board is in a position to issue a written decision.

## Reasons for the Decision

1. (Non-)admittance of auxiliary requests 3-6 and alleged substantial procedural violation

1.1 The appellant argued that by not admitting auxiliary requests 3-6, the examining division deprived the applicant from its right to fully address the prior art documents D15, D16 and D17, which had been cited by the examining division for the first time in the summons to oral proceedings, and which were relied upon in the decision to refuse the application.

1.2 The board cannot follow this argumentation for the following reasons:

- The applicant was given an opportunity to react to the preliminary opinion in the summons within the time limit set by Rule 116 EPC;

- It reacted thereto on the last possible day (12 March 2018) of the period to file new submissions by filing a letter containing observations and auxiliary requests 1 and 2;

- It then filed auxiliary requests 3-6 with a letter dated 11 April 2018 (i.e. one day before the oral proceedings). These were however late filed under Rule 116(2) EPC;

- A telephone consultation took place on 5 April 2018, but since no minutes were taken and neither the appellant nor the examining division has indicated what the content of the discussion was, it cannot be concluded whether it was this conversation which triggered the late filing of these requests;

- For the board, the examining division was therefore right in concluding that auxiliary requests 3-6 were late filed and that, consequently, their admissibility was at its discretion pursuant to Rules 116(2) and 137(3) EPC;

- The examining division also applied the right criteria when exercising its discretion, in particular by assessing whether the newly filed requests were clearly allowable and whether they constituted a convergent development of the subject-matter which had hitherto been the subject of examination;

- In view of the fact that claim 1 in each one of auxiliary requests 3-6 had been amended *i.a.* by deleting the requirement to perform the pressure measuring and adjusting steps "sequentially", the conclusions of the examining division that these requests were not convergent developments of the invention discussed thus far, and that they appeared to give rise to new issues under Article 123(2) EPC are considered to be reasonable;

- While the non-attendance of the applicant to the oral proceedings deprived it of an opportunity to contest the arguments of the examining division concerning admissibility and allowability of the different requests, this absence was voluntary and effectively implied that the examining division was entitled to decide on the allowability and admissibility of the requests on file in the absence of the applicant.The principle of the right to be heard pursuant to Article 113(1) EPC is observed since that provision only affords the opportunity to be heard.

1.3 The board therefore considers that:

- the examining division was right in concluding that auxiliary requests 3-6 were late filed and that, therefore, their admissibility was at the discretion of the examining division;

- the discretion to not admit these requests into the proceedings was exercised following the right criteria in a reasonable way; and
- the applicant's right to be heard pursuant to Article 113(1) EPC was respected.

1.4 The board therefore concludes that the examining division did not commit any substantial procedural violation and that, consequently, the appellant's request that the appeal fee be reimbursed cannot be granted.

2. Auxiliary requests 3-6 - Admittance

2.1 Auxiliary requests 3-6 are identical to those which were not admitted by the examining division.

2.2 As indicated above, the board considers that the exercise of the discretion by the examining division concluding that auxiliary requests 3-6 were not admitted into the proceedings was performed correctly, in particular by applying the right criteria in a reasonable manner.

2.3 The board sees therefore no reason to overrule the way in which the first instance exercised this discretion (see point 2.6 of G 7/93).

2.4 The board therefore exercises its own discretion under Article 12(4) RPBA-2007 (applicable under the transitional provisions, Article 25(2) RPBA 2020) not to admit these auxiliary requests into the proceedings.

3. Main request - Inventive Step

3.1 The board has concluded that this request is not allowable under Article 56 EPC for the following reasons.

3.2 Closest prior art

3.2.1 In its grounds of appeal, the appellant started from document D2 (EP 1 850 129 A1) as the closest prior art and referred to D16 only as a document to be potentially combined with the disclosure of D2.

3.2.2 While any one of documents D2 and D16 could be considered as a suitable starting point, the board has decided to assess the inventive step of the claimed subject-matter starting from document D16 as closest prior art for the following reasons:

- the contested decision (see point 18) relied solely on document D16;

- the board considers D16 as a more promising springboard because, unlike D2, it discloses a method which is very similar to the one defined in claim 1, in particular because it includes a step of equalisation of the back pressure of the parallel lines;

- the appellant itself explicitly indicated (page 2, 2nd. par. and page 3, 6th par. of the grounds of appeal) that the method in D16 was closer to the one defined in claim 1 than that described in any other cited prior art, including D2.

3.2.3 In fact, D16 discloses (figure 1) a chromatographic system including parallel lines connected to a single binary pump, each line comprising a chromatography column and a pressure regulation valve downstream of the column.

On its page 582 (final lines of the right column) it indicates that assays having long run times generally involve an extended "idle" elution period (i.e. elution of the compounds of interest) and a comparatively short

"window of interest" (i.e. peak of the measured compounds). To solve this problem, D16 proposes (page 583, beginning of left column) "to use the idle time by staggering injections onto separate columns such that the chromatographic window of interest is always eluting from one of the columns". In other words, the method of D16 comprises operating the columns simultaneously, sequentially injecting analytes into each line and sequentially connecting the outlet of each line to the MS detector (i.e. once the analytes of interest have eluted), thereby reducing the idle time of the system (i.e. the time in which the analytes are eluting and not being detected) and increasing its overall efficiency.

In order to obtain reproducible and consistent results in the different lines, D16 proposes (page 584, left column, 2nd. par.) to equalise the back pressure at each line following the next steps: i) blocking the flow through all the lines but one, ii) adjusting the pump to ensure that the flow-rate through the single open line is the same as it would be if all the lines were open, and iii) adjusting the pressure regulation valves to equalise the hydraulic resistance or back-pressure of all lines. These steps are performed for each individual line, and the whole process is repeated to ensure that the back pressures of all the lines are matched.

3.2.4 According to the appellant, the subject-matter of claim 1 differed from the content of D16 in that:

- the system worked with the lowest hydraulic pressure,
- the back pressure equalisation did not require an iterative process and

- the step of pressure balancing or flow control was performed with the objective to synchronise the concentration peaks in the parallel lines.

3.2.5 The board considers that:

- Claim 1 explicitly defines that the hydraulic resistance is adjusted to be *"equal or higher"* than the path having the highest hydraulic resistance, wherein the option *"higher"* implies that the invention encompasses methods in which the hydraulic pressure is higher than the lowest possible hydraulic pressure (the lowest pressure corresponding to the maximum back pressure measured in the different lines). It follows that claim 1 cannot be distinguished from D16 in that the system works with the lowest hydraulic pressure.

- While D16 proposes equalising the pressure in a first step and repeating the process to ensure the lines have the same hydraulic resistance, this does not necessarily imply that the method of D16 is an iterative method (i.e. trial and error). The method of D16 simply indicates that the valve is adjusted until the "appropriate back pressure" is reached, without specifying how this value should be estimated. Thus, the actual difference between claim 1 and the content of D16 is the step of estimating the (minimum) appropriate back pressure by identifying the line having the highest hydraulic resistance.

- It is also noted that the objective associated with the pressure/flow balancing step is not part of the invention and can therefore not be regarded as a differentiating feature.

3.2.6 The board therefore agrees with the examining division in that the only feature differentiating the subject-matter of claim 1 from D16 is the step of "*identifying the fluid path with highest hydraulic resistance*".

3.3 Problem solved

3.3.1 According to the appellant, the invention addressed the problem of providing equal residence time in each of the parallel fluidic separation paths in order to obtain uniform concentration peaks which could be readily combined. In its opinion, the key technical effect of the invention was to ensure peak synchronisation among the parallel lines as shown in figures 3 and 5 of the application and the corresponding disclosures.

3.3.2 It is not apparent for the board how the so-called effect of peak synchronisation can be of any relevance for the inventive step discussion. This effect is essentially what would happen if, on top of the pressure and residence time equalisation, the following steps were defined: i) all the lines are operated at the same time, ii) analytes are simultaneously injected in each line, iii) the analytes are separated in chromatographic columns and iv) the eluted analytes reach a detector and form peaks as those shown in the chromatogram of figures 3 or 5 of the application.

By contrast, claim 1 neither defines any of the steps i) to iv) (auxiliary requests 1 and 2 define step i) but not steps ii) to iv)) nor that the different lines have the same residence time. In fact, the claim does not even define the use of chromatographic columns (reference is simply made to "separation modules") or of a detector. It is thus clear that the invention in

claim 1 cannot be plausibly linked to the technical effect of peak synchronisation.

3.3.3 The only difference between claim 1 and D16 is the step of identifying the fluid path with the highest hydraulic resistance. This step is used to estimate the minimum back pressure value to which the different lines have to be adjusted in the back pressure equalisation step.

Thus, the only problem plausibly solved by the claimed subject-matter is that of proposing an alternative process to equalise the back-pressure or hydraulic resistance in the parallel lines.

3.4 Obviousness

3.4.1 The appellant argued that the inventive contribution of the method defined in claim 1 at issue was based on the realisation that by working with the highest hydraulic resistance, there was no need for real time flow control in each line. The flow could then be kept constant during separation, which would lead to equal residence times in all lines, with the benefit that peak concentrations would be less disturbed. In its opinion neither D2 nor D16 recognised that pressure equalisation could be used to provide equal residence times, that is, to synchronise the concentration peaks in the different lines. By contrast the pressure balancing in D16 was only done with the objective of "sequential consistency, e.g. for Good Manufacturing Practice (GMP)" (see 6th par. of page 3 of the statement of grounds of appeal).

3.4.2 The board is not convinced by this argumentation, because claim 1 does not define that the residence time

in all lines should be the same or that the peaks should be synchronised (see also point 3.3.2 above). These aspects are therefore not relevant for the discussion on obviousness.

3.4.3 Instead, as indicated above, the problem solved is to find an alternative process to equalise the back-pressure, so the relevant question is whether the skilled person would consider the step of identifying the line with the highest back pressure as an obvious alternative when starting from document D16.

3.4.4 In this respect, D16 proposes (page 584, left column, 2nd par.) adjusting each line to an "appropriate back pressure", without specifying how this pressure value should be determined. Since the back pressure in the lines can only be adjusted upwards (i.e. there is no mechanism to reduce the hydraulic resistance or back pressure of the lines), it is self-evident (as argued by the examining division) that to equalise all lines, the back-pressure will have to be increased at least to the value of the line having the highest back pressure.

From this starting point, it is immediately apparent for a person skilled in the art that the adjustment to the "appropriate back pressure" in D16 should be performed in one of the following two ways: either by bringing the back-pressure up to at least the highest back pressure identified so far in the lines and readjusting if a higher back pressure is subsequently found, or else by first measuring the back-pressures in all lines and then selecting a value which is equal or higher than the highest value to adjust all the lines. While the first alternative might require back pressure readjustments (what the appellant calls "iterative method"), this is not excluded in claim 1, which merely

requires an identification of the highest hydraulic resistance and an adjustment of all the lines to that value or above. In other words, there is no requirement in claim 1 that the steps of identifying and adjusting the hydraulic resistance be performed separately and/or that no readjustments should be performed. Thus, both of the above alternatives are considered to fall within the scope of protection of claim 1 (i.e. both include steps of identifying the highest hydraulic resistance and adjusting the back pressure of all the lines accordingly).

While there is a third alternative that would not require an identification of the highest hydraulic resistance in the different lines, such option would involve "blindly" increasing the back pressures to a very high value in all the lines in order to avoid the need to readjust the back pressure of some lines, which appears to be technically unreasonable and to go directly against the objective of D16 to reduce the idle elution time of the system.

The board therefore agrees with the examining division, in that, when starting from document D16, there would be no alternative, or at least no technically reasonable alternative, to the solution proposed in claim 1. Consequently, when implementing the method proposed in D16, the skilled person would arrive at the subject-matter of claim 1 in a nearly one-way street situation and without requiring any inventive skills.

Claim 1 is therefore considered to be obvious in view of document D16 alone.

4. Auxiliary request 1 - Inventive step

4.1 The board has concluded that this request is not allowable under Article 56 EPC.

4.2 Its claim 1 differs from that of the main request in that *"the separation modules are operated in parallel and at the same time with synchronised hydraulic resistance to provide the same residence times for each module"*.

4.3 Since the method in document D16 intends (par. bridging pages 582 and 583) to reduce the idle time resulting from long elution periods of some analytes by staggering injections into the different columns, it is implicit that (at least during some periods) all the modules (i.e. the chromatographic columns) will be operated in parallel and at the same time. D16 also proposes (page 583, right column, last par. and page 584, left column, 2nd par.) working with identical columns or modules in all lines, and to equalise the back-pressures using the same flow-rate for each line, which implies that the columns will have substantially the same residence time. In fact, the goal of sequential consistency in D16 (i.e. to obtain comparable results for all the sequentially measured peaks) can only be attained if residence times in the different lines are substantially equal, since it is the residence time (and not the back-pressure as such) which determines the elution time, form and height of the chromatographic peaks. The equalisation of back-pressure in D16 is therefore merely a means for equalising the residence times in the different columns.

4.4 Thus, the board agrees with the examining division in that this request does not provide any additional differentiating feature, and that, consequently, the

same arguments and conclusions as presented for the main request also apply for this case.

4.5 The subject-matter of claim 1 at issue is thus considered to be obvious in view of document D16 alone.

5. Auxiliary request 2 - Inventive step

5.1 The board has concluded that this request is not allowable under Article 56 EPC.

5.2 Its claim 1 differs from that of auxiliary request 1 in that the step of measuring the hydraulic resistance in each fluid line uses "*the same constant level fluid flow rate for each path*".

5.3 In document D16 the process of equalising back-pressure line by line is performed (see page 584, left column, 2nd par.) by blocking three of the four lines and "changing the pump flow rate from 748 to 187 µL/min, which was the flow rate in a single line". In other words, since only one of the four lines is kept open during back-pressure adjustment, the flow-rate of the pump is reduced to one fourth of its usual value to ensure that the flow-rate through each single open line is the same and corresponds to the value when all four lines are open.

5.4 It is therefore apparent that in D16 the step of measuring and adjusting back-pressure is performed at the same constant fluid flow rate for each line as defined in claim 1.

5.5 The board therefore agrees with the examining division in that this request does not provide any additional differentiating feature, and that, consequently, the

same arguments and conclusions as presented for the main request also apply for this case.

5.6 The subject-matter of claim 1 of this request is thus considered to be obvious in view of D16 alone.

6. As this decision is essentially based on the evidence, facts and arguments brought forward in the appealed decision, and since the appellant did not request oral proceedings as an auxiliary measure, its right to be heard under Article 113(1) EPC has been respected and the decision can be issued in writing.

7. The board therefore concludes that the main request and auxiliary requests 1 and 2 are not allowable under Article 56 EPC, auxiliary requests 3, 4, 5 and 6 are not admitted into the proceedings under Article 12(4) RPBA-2007, and the request for reimbursement of the appeal fee cannot be granted.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed

The Registrar: The Chairman:

A. Pinna J.-M. Schwaller

Decision electronically authenticated