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**Datasheet for the decision
of 9 July 2021**

Case Number: T 0401/19 - 3.3.05

Application Number: 14715577.4

Publication Number: 2925419

IPC: B01D15/18, G01N30/42,
G01N30/46, G01N30/86

Language of the proceedings: EN

Title of invention:

CHROMATOGRAPHIC PURIFICATION METHOD

Patent Proprietor:

ChromaCon AG

Opponent:

Cytiva Sweden AB

Headword:

Chromatographic purification/ChromaCon

Relevant legal provisions:

RPBA 2020 Art. 13(2)

EPC Art. 123(2), 87(1), 54, 56, 112(1)

EPC R. 106

Keyword:

Amendment after summons - taken into account (no)
Amendments - added subject-matter (no)
Priority - partial priority (yes)
Novelty - (yes)
Inventive step - (yes)
Referral to the Enlarged Board of Appeal - (no)
Obligation to raise objections - objection dismissed

Decisions cited:

G 0009/91, G 0001/15, R 0005/14, J 0014/19, T 0131/01,
T 0635/06, T 0597/07, T 0329/16, T 0764/16, T 0844/18,
T 0995/18

Catchword:



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Case Number: T 0401/19 - 3.3.05

D E C I S I O N
of Technical Board of Appeal 3.3.05
of 9 July 2021

Appellant:
(Patent Proprietor)

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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
10 December 2018 concerning maintenance of the
European Patent No. 2925419 in amended form.**

Composition of the Board:

Chairman E. Bendl
Members: G. Glod
R. Winkelhofer

Summary of Facts and Submissions

- I. The appeals of the patent proprietor (appellant 1) and the opponent (appellant 2) lie from the opposition division's decision finding that the then auxiliary request 1 met the requirements of the EPC.
- II. The following documents cited in the decision are of relevance here:
- E2: Snapshots of ChromaCon AG website <http://www.chromacon.ch/technology/capturesmb/>, "Capture SMB process", dated 25.01.2013
- E3/E3a: Contichrom Capture SMB figures and animation.pps
- E11: BioPharm International, vol. 26, issue 10: "Increasing Capacity Utilization in Protein A Chromatography", published on 01.10.2013
- E12: US 2013/0046080 A1
- E13: WO 2012/074481 A1
- III. In its communication under Article 15(1) RPBA 2020 dated 8 March 2021, the board was of the preliminary opinion that the main request appeared to be allowable.
- IV. On 8 June 2021 appellant 2 filed submissions relating to extension of subject-matter, priority, novelty and inventive step.
- V. Oral proceedings took place on 9 July 2021.

Independent claim 1 of the main request is as follows:

"1. Chromatographic purification method for the isolation of a desired product fraction from a mixture

using 2 chromatographic columns (1,2) by sequential loading, wherein the method comprises, within one cycle to be carried out at least once, the following steps: a first batch step (B1), wherein during a batch timespan (t_B) said columns are disconnected and a first column (1) is loaded with feed via its inlet using a first flow rate ($Q_{feed,B}$) and its outlet is directed to waste, and from a second column (2) thereof desired product is recovered via its outlet and subsequently the second column (2) is regenerated, with the proviso that if this first batch step (B1) is carried out for the first time, said second column is either idle or preceding the first batch step (B1) an interconnected startup step is carried out, in which the second column (2) is loaded with feed; a first interconnected step (IC1), wherein the outlet of the first column (1) is connected to the inlet of the second column (2) during an interconnected timespan (t_{IC}), the first column (1) is loaded beyond its dynamic breakthrough capacity with feed via its inlet using a second flow rate ($Q_{feed,IC}$) which is larger than the first flow rate ($Q_{feed,B}$), and the outlet of the second column (2) is directed to waste, and wherein during a subsequent washing timespan ($t_{wash,IC}$) which is larger than 0 s the outlet of the first column (1) is connected to the inlet of the second column (2), the first column (1) is loaded with solvent and/or buffer which is free from feed material, and the outlet of the second column (2) is directed to waste, a second batch step (B2) analogous to the first batch step (B1) but with exchanged column positions, such

that the first column (1) of the first batch step (B1) performs the tasks of the second column (2) of the first batch step (B1), and the second column (2) of the first batch step (B1) performs the tasks of the first column (1) of the first batch step (B1); a second interconnected step (IC2), analogous to the first interconnected step (IC1) but with exchanged column positions, such that the upstream column (1) of the first interconnected step (IC1) is the downstream column of the second interconnected step (IC2), and the downstream column (2) of the first interconnected step (B1) is the upstream column of the second interconnected step (IC2)."

Claims 2 to 15 directly or indirectly relate to claim 1.

VI. The following features of claim 1 are pertinent for the present decision (designation of features as used in the decision under appeal):

- Feature 1.2.4: "idle"
- Feature 1.2.5: "or preceding the first batch step (B1) an interconnected startup step is carried out, in which the second column (2) is loaded with feed;"
- Feature 1.3.1: "the first column (1) is loaded beyond its dynamic breakthrough capacity with feed via its inlet using a second flow rate ($Q_{\text{feed, IC}}$) which is larger than the first flow rate ($Q_{\text{feed, B}}$)".

VII. Appellant 2's arguments can be summarised as follows.

Article 13(2) RPBA 2020

The feature according to which column (2) was loaded with an unspecified amount of feed during the interconnected startup lacked a basis in the application as originally filed. This aspect had not been brought up in the board's preliminary opinion even though it had been part of the opponent's appeal brief. It had therefore been re-emphasised in the submission of 8 June 2021 and did not constitute an amendment to the opponent-appellant's appeal case. Article 13(2) RPBA 2020 did not apply.

The priority document did not describe anywhere that the second column was idle when the first batch step was carried out for the first time. The patent proprietor had addressed this feature in their grounds of appeal. There had been no need for the opponent to deal with this point in their appeal. Since it had not been dealt with in the preliminary opinion, it had been recalled in the submission of 8 June 2021. It was immediately evident that this feature was not present in the priority document. The discussion relating to it was not a change of case. The patent proprietor had been aware of this objection, as it was part of the proceedings. It was the board's duty anyway to check whether the priority had been validly claimed, as set out in T 844/18.

E11 had to be taken into consideration for the question of inventive step for the part of claim 1 not enjoying priority. The inventive-step objection based on E11 had already been raised in the grounds of appeal. There had been no need to bring up the objection at an earlier

stage, since E11 had been found to anticipate the novelty of the subject-matter of claim 1 by the opposition division. In partial priority scenarios where it turned out that novelty was acknowledged, inventive step had to be discussed even if it was not raised as a ground of opposition (T 597/07, T 131/01), and even if it was not separately substantiated in the opposition brief for an allegedly novelty-destroying prior-art document (such as E11 in the present case) (T 635/06 and Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, IV.C.3.4.2). In spite of the case law cited above, an evaluation of inventive step for the part not enjoying priority when starting from E11 as the closest prior art had not been performed in the board's preliminary opinion. Therefore, it had only been after the preliminary opinion that it was necessary to address the inventive-step objection based on E11 in more detail.

Article 123(2) EPC

The expression "sequential loading" in claim 1 was an extension beyond the content of the application as originally filed.

Articles 83 and 84 EPC

The feature of sequential loading was unclear and insufficiently disclosed.

Article 87 EPC

Feature 1.2.5 had no counterpart in the priority document. There was no doubt that the priority was only valid for an interconnected startup step wherein "a larger amount of feed solution is loaded onto the

upstream column in comparison with an interconnected step IC". The amount of feed loaded onto the second column was not limited at all numerically, but by a relative term "larger". Since this feature was unclear, claim 1 could not be divided into two distinguishable parts. The ruling of G 1/15 was not applicable to the present situation in which the conceptual division of the feature in dispute resulted in two parts which were both unclear and not clearly distinguishable. Therefore, a referral to the Enlarged Board was necessary to resolve this question.

Article 54 EPC

E3a anticipated the novelty of the subject-matter of claim 1. The skilled person who noted that the front runs more slowly in the batch step than in the IC step would conclude that this was due to a slower flow rate. No other variables were visible in the charts of E3a to which this could be attributed.

E11 anticipated novelty for the part of claim 1 not enjoying priority. Selecting a "smaller or equal amount of feed solution than in an IC step" did not constitute a novel selection from a generic disclosure encompassing any amount of feed.

E12 and E13 were novelty-destroying for the reasons set out in the notice of opposition.

Article 56 EPC

Starting from E3a as the closest prior art, the distinguishing feature was either (i) that the second flow rate of the first interconnected step ($Q_{\text{feed, IC}}$) was larger than the first flow rate used in the first

batch step ($Q_{\text{feed},B}$) or, formulated differently, (ii) that the first flow rate of the first batch step ($Q_{\text{feed},B}$) was smaller than or equal to the second flow rate of the first interconnected step ($Q_{\text{feed},IC}$).

In case (i) the problem was to provide a purification method with improved productivity. The solution was obvious in view of E2.

In case (ii) the problem was to provide a purification method that reduced the loss of yield during the batch step. The solution was straightforward and obvious to the skilled person.

Rule 106 EPC

Since E11 was not being taken into consideration for the question of inventive step, an objection under Rule 106 EPC had to be raised, reading as follows:

"Opponent objects under Rule 106 EPC that its right to be heard has been violated since it was not allowed to advance inventive step objections for a document forming part of the case after the Board in its preliminary opinion deviated from the Opposition Division's decision, in which the document was considered to anticipate the claimed subject-matter and Opponent (only) relied on said novelty attack in the appeal proceedings before issuance of the Board's preliminary opinion."

Article 112(1) (a) EPC

The following questions should be referred to the Enlarged Board of Appeal, to enable a decision on partial priority:

"1. If partial priority is at issue, can a partial priority be acknowledged under G1/15 if the resulting subject matter not enjoying partial priority is delimited from the subject-matter enjoying partial priority by an unclear relative term only?

2. If the answer to question 1 is in the negative, would this answer differ if the subject-matter enjoying partial priority is not open to a clarity objection (Art. 84 EPC) in opposition proceedings, because such clarity objection against said subject matter is not allowable in view of G3/14."

VIII. Appellant 1's arguments are reflected in the reasoning below.

IX. Appellant 1 requests that the impugned decision be set aside and the patent be maintained on the basis of the main request of 26 September 2017, or one of the first to third auxiliary requests submitted on 16 June 2021.

In addition to the request that the questions above be referred to the Enlarged Board of Appeal, appellant 2 requests that the impugned decision be set aside and the patent be revoked.

Reasons for the Decision

1. Article 13(2) RPBA 2020

According to Article 13(2) RPBA 2020, which applies in the present case, any amendment to a party's appeal case after notification of a summons to oral proceedings is, in principle, not to be taken into account unless there are exceptional circumstances,

which have been justified with cogent reasons by the party concerned.

In the case in hand several such amendments to appellant 2's appeal case were submitted on 8 June 2021.

- 1.1 The objection under Article 123(2) EPC relating to the feature according to which column (2) is loaded with an unspecified amount of feed during the interconnected startup was not part of appellant 2's appeal and/or reply to appellant 1's appeal, which form the basis for evaluating whether the appeal case has been amended (J 14/19, Reasons, 1.4). The general reference made to the notice of opposition (page 2, last paragraph, of the statement of grounds of appeal) is not generally considered to be sufficient substantiation on appeal (Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, V.A.2.6.4.a)). In addition, in the present case the grounds of appeal do not make it possible to understand why the opposition division's decision including the reference to page 8, lines 28 to 31 (point B.1. of the decision) is allegedly wrong. At the latest, this objection should have been raised in appellant 2's reply to appellant 1's appeal. Therefore, submitting this objection only after the summons and the communication under Article 15(1) RPBA were issued constitutes a change of appeal case. This change would require a new factual analysis and does not relate only to questions of law. Appellant 2 has not provided any cogent reasons that would justify the admission of the objection, nor can the board identify any. Therefore, this objection is not taken into consideration.
- 1.2 The objection that the feature "idle" is not part of the priority document was likewise not raised in

appellant 2's appeal and/or reply. The fact that appellant 1 mentioned it in their appeal (statement of grounds, page 3) does not imply that appellant 2's late submission in this respect is not a change of case. Rather, appellant 2 should have reacted to appellant 1's position in their reply to appellant 1's appeal. Since this objection was not part of appellant 2's appeal case, there was no need to discuss it in the preliminary opinion. Again, this change would require a new factual analysis and does not relate only to questions of law. Contrary to appellant 2's view, it is not the board's duty to check the priority in each case *ex officio*.

T 844/18 is not relevant to the case in hand, since it did not concern the question of whether the priority document related to the same invention. Rather, it concerned the transfer of priority rights and the entitlement to priority. It was questioned whether the board was empowered to analyse this or to instead leave any challenge to be decided in entitlement actions before national courts.

Again, appellant 2 has not provided any cogent reasons that would justify the admission of the objection, nor can the board identify any. Therefore, this objection is not taken into consideration either.

- 1.3 In their statement of grounds of appeal, appellant 2 argued that the main request lacked an inventive step starting from E11 in combination with common general knowledge, E3a, E12 and/or E13, without providing any further substantiation of this objection. There was consequently no need to deal with this unsubstantiated objection in the board's communication pursuant to Article 15(1) RPBA. In the submission of 8 June 2021,

appellant 2 substantiated the inventive-step objection based on E11 for the first time and relied on T 131/01, T 635/06 and T 597/07. This is a new case, since appellant 2 argued a disadvantageous modification for part of claim 1 for the first time.

Appellant 2's argument, using the cited decisions, that they had been relying only on the novelty attack based on E11 and that inventive step had to be considered if novelty was recognised is, at least for the case in hand, not convincing. Appellant 1 argued partial priority in their appeal, and so the inventive-step objection could and should have been raised in the reply to appellant 1's appeal.

The board's preliminary opinion was based only on the appellants' appeals and replies. It does not justify the filing of a new inventive-step attack, since it is the very nature of appeal proceedings that the board may not agree with the opposition division's decision (T 764/16, Reasons, 3.3.2). The communication pursuant to Article 15(1) RPBA 2020 is not an invitation to the parties to make further changes to their case (T 995/18, Reasons, 1.4, and Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, III.C.6.4.1).

The case law cited by appellant 2 is not relevant to the case in hand, since it relates to the question of whether inventive step is admissible as a ground of opposition. It does not deal with the question of whether a new inventive-step objection after the communication pursuant to Article 15(1) RPBA 2020 is to be considered part of the proceedings. Moreover, it concerns only the RPBA 2007, or even older versions of the RPBA that were in force when the decisions were taken, and is not comparable for this reason alone.

Therefore, the board's different view on partial priority in the communication pursuant to Article 15(1) RPBA 2020 compared to the impugned decision is not, in the case in hand, a cogent reason that would justify the submission of a new inventive-step attack. Consequently, the inventive-step objection based on E11 is not taken into consideration either.

1.4 The question of whether the inventive-step objection based on E3a can be taken into consideration does not need to be answered, since it fails on substantive grounds (see point 6 below).

2. Article 123(2) EPC

Appellant 2 objects that the wording "by sequential loading" present in lines 2 and 3 of claim 1 is a generalisation of the wording "sequential countercurrent loading" disclosed on page 4, line 20, of the application as filed.

This objection was not raised in the opposition proceedings, and the opposition division, which has a duty to check the amendments for compliance with Article 123(2) EPC (G 9/91, OJ 1993, 408, Reasons, 19), apparently did not find any problem with this amendment.

The objection is without merit, since the process steps of claim 1 imply that claim 1 relates to countercurrent chromatography.

The requirements of Article 123(2) EPC are fulfilled.

3. Articles 83 and 84 EPC

These objections raised by appellant 2 on page 2 of the grounds of appeal are not substantiated and therefore cannot be given any substantive consideration in the appeal proceedings.

4. Article 87(1) EPC

4.1 The opposition division found that the priority of claim 1 had not been validly claimed. It considered "*that for the subject-matter not including that if the first batch step (B1) is carried out for the first time then a [sic] interconnected startup step is also carried out in which the second column is loaded with a larger amount of feed, the priority would be invalid*" (impugned decision, paragraph bridging pages 16 and 17).

4.2 This conclusion is not in line with G 1/15, OJ 2017, A82 (Reasons, 6.4), which indicates that the claim can be *de facto* conceptually divided into two parts, the first corresponding to the invention disclosed directly and unambiguously in the priority document, and the second being the remaining part of the subsequent generic "OR"-claim not enjoying this priority. There is not a restriction to a specific type of claim in this respect. Although such division may be a demanding intellectual exercise (Reasons, 6.6), it is possible in the present case, and this conclusion is not altered by the presence of the term "larger". The skilled person is perfectly able to determine whether the amount of feed solution in one step is larger, smaller or equal to that of a second step, and so they can easily determine whether the startup step falls within the priority claimed or not.

4.3 Therefore, the subject-matter that includes a startup step in which the columns are interconnected and wherein a larger amount of feed solution is loaded into the upstream column in comparison with an interconnected step (IC) of a cycle of the method - a step that is disclosed in claim 7 of the parent application - validly claims the priority, and so claim 1 enjoys partial priority as set out in G 1/15 (Catchword and Reasons, 6.4).

5. Article 54 EPC

Appellant 2 contests the novelty of claim 1 in view of E3a, E11, E12 and E13.

The requirements of Article 54 EPC are met, for the following reasons.

5.1 The opposition division admitted E3a into the proceedings. There is no scope to disregard on appeal evidence admitted by the opposition division in exercise of its discretion (Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, V.A.3.5.4).

The opposition division found that E3a did not disclose feature 1.3.1 of claim 1.

The board concurs that it is at least not directly and unambiguously derivable from E3 whether the second flow rate ($Q_{\text{feed, IC}}$) is larger than the first flow rate ($Q_{\text{feed, B}}$). E3a is only a schematic illustration (animation) of the CaptureSMB[®] process principle. The front lines are also shown schematically and do not exactly reflect the real flow rate. The animation and the figures do not provide any details on flow rates and/or on the quantity of material entering or exiting

the columns. The skilled person would also read the animation and the figures as a schematic illustration of the different process steps without any further details. Consequently, they would not directly and unambiguously link the speed of the red colour to the flow rate. The interpretation given by appellant 2 is based instead on knowledge of the patent.

- 5.2 If appellant 2's line of argument were to be accepted, E11 would, at most, disclose that the amount of feed solution loaded into the upstream column is larger than in the IC step. In view of the valid partial priority for the subject-matter of claim 1, E11 is not prior art for this part of the claim.

E11 does not anticipate the novelty of the remaining subject-matter either, since the criteria of selection inventions are not applicable to the case in hand. E11 does not disclose a numerical range for the amount of feed solution. The selection of a sub-range relates to numerical values (Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, I.C.6.3.1), which does not apply in the current case.

Therefore, E11 does not anticipate the novelty of claim 1.

- 5.3 E12 and E13 were also cited as novelty-destroying with reference to the notice of opposition, but no further substantiation was provided, in particular with respect to claim 1 as amended in the current request. As stated above, a general reference to the notice of opposition is not generally considered to be sufficient substantiation on appeal (Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, V.A.2.6.4.a)).

Therefore, there is no reason to consider E12 and E13 as anticipating the novelty of claim 1.

5.4 The same conclusion applies to claims 2 to 15, which directly or indirectly relate to claim 1.

6. Article 56 EPC

6.1 The invention concerns capture chromatography.

6.2 E3a is the closest prior art. It discloses a method as claimed except that, at the least, it is not directly and unambiguously derivable from E3a whether the second flow rate ($Q_{\text{feed},\text{IC}}$) is larger than the first flow rate ($Q_{\text{feed},\text{B}}$) (point 5.1).

6.3 The problem to be solved is to increase the productivity of the process (see paragraphs [0016] and [0098]).

6.4 The problem is solved by a method according to claim 1, characterised in that the second flow rate ($Q_{\text{feed},\text{IC}}$) is larger than the first flow rate ($Q_{\text{feed},\text{B}}$).

Appellant 2's argument that the problem has to be formulated differently depending on the way the differentiating feature is expressed (second flow rate larger than first flow rate vs first flow rate smaller than or equal to second flow rate) cannot be accepted. The difference between E3a and claim 1 is the same, but just differently expressed, and the overall goal is also the same, namely to increase productivity.

6.5 The problem is regarded as successfully solved in view of the data present in the patent.

6.6 The proposed solution is not obvious for the following reasons.

E3a is silent on the flow rates and does not provide any details about them (see point 5.1). E2 discloses that another significant advantage of the process of E3a (CaptureSMB[®] process) is the possibility to use significantly higher loading flow velocities. The skilled person reading E2 learns that the process of E3a can be conducted with high loading flow velocities, but E2 does not differentiate between different process phases. Thus, it points to increased flow rates in all parts of the process. There is no pointer towards the solution of the present invention.

Appellant 2's argument that the skilled person would know that $Q_{\text{feed},B}$ should be lower to avoid breakthrough and that $Q_{\text{feed},IC}$ should be maximised as indicated in paragraphs [0044] and [0045] of the patent is not corroborated by evidence, but is instead based on hindsight.

6.7 The subject-matter of claim 1 involves an inventive step. The same conclusion applies to claims 2 to 15, which directly or indirectly relate to claim 1.

Therefore, the requirements of Article 56 EPC are fulfilled.

7. Rule 106 EPC

Appellant 2 considered their right to be heard to be compromised since the inventive-step objection based on E11 was not taken into consideration.

The admission of this objection was extensively discussed during the oral proceedings and both appellants were given time to present their cases in this respect.

The right to be heard does not mean that the board must agree with an argument; the board must merely consider it (R 5/14, Reasons, 3). It is evident from point 1.3 above that the board has considered appellant 2's argument but did not agree with their position. If an objection is not taken into consideration, there is no scope to give the party the possibility to present the substance of the objection (T 329/16, Reasons, 8.2).

Therefore, the objection under Rule 106 EPC is to be dismissed.

8. Article 112(1)(a) EPC

It is established case law that a question for which referral is requested must be relevant for deciding the case in question (Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, V.B.2.3.3). This clearly does not apply here; the board has been able to reach a conclusion without the need for a referral (see point 4 above). In addition, the board is not aware of any conflicting case law on the subject of partial priority after the issuance of G 1/15, nor has appellant 2 cited any.

Therefore, there is no need to refer the questions relating to partial priority to the Enlarged Board of Appeal.

Order

For these reasons it is decided that:

1. The request for referral to the Enlarged Board of Appeal is refused.
2. The decision under appeal is set aside.
3. The case is remitted to the opposition division with the order to maintain the patent on the basis of the main request, filed on 26 September 2017, and a description to be adapted, if necessary.

The Registrar:

The Chairman:



C. Vodz

E. Bendl

Decision electronically authenticated