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Datasheet for the decision of 13 March 2023

Case Number: T 1235/21 - 3.2.04

Application Number: 10746644.3

Publication Number: 2401502

F04B13/02, F04B23/06, G01N1/38, IPC:

G01N1/40, G01N30/20

Language of the proceedings: ΕN

Title of invention:

AUTOMATED DILUTION FOR LIQUID CHROMATOGRAPHY

Patent Proprietor:

Waters Technologies Corporation

Opponent:

Agilent Technologies, Inc.

Headword:

Relevant legal provisions:

EPC Art. 123(2) RPBA 2020 Art. 13(2)

Keyword:

Amendments - allowable (no) Amendment after summons - exceptional circumstances (no)

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Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

Boards of Appeal of the European Patent Office Richard-Reitzner-Allee 8 85540 Haar GERMANY

Tel. +49 (0)89 2399-0 Fax +49 (0)89 2399-4465

Case Number: T 1235/21 - 3.2.04

DECISION
of Technical Board of Appeal 3.2.04
of 13 March 2023

Appellant: Waters Technologies Corporation

(Patent Proprietor) 34 Maple Street

Milford, MA 01757 (US)

Representative: Forresters IP LLP

Skygarden

Erika-Mann-Straße 11 80636 München (DE)

Respondent: Agilent Technologies, Inc.
(Opponent) 5301 Stevens Creek Boulevard
Santa Clara, CA 95051 (US)

Representative: Dilg, Haeusler, Schindelmann

Patentanwaltsgesellschaft mbH

Leonrodstraße 58 80636 München (DE)

Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 1 June 2021 revoking European patent No. 2401502 pursuant to

Article 101(3)(b) EPC.

Composition of the Board:

Chairman A. de Vries

Members: G. Martin Gonzalez

T. Bokor

- 1 - T 1235/21

Summary of Facts and Submissions

- I. The appeal was filed by the appellant (patent proprietor) against the decision of the opposition division to revoke the patent.
- II. The division held that the main request before it contained added subject-matter. They also did not admit auxiliary request 1, filed during oral proceedings, for introducing prima facie new objections under Article 123(2) EPC.
- III. In preparation for oral proceedings the Board issued a communication setting out its provisional opinion on the relevant issues. The oral proceedings were held before the Board on 13 March 2023.
- IV. The appellant requests that the impugned decision be set aside and the patent be maintained based on the main and auxiliary requests 1-3, filed with the grounds of appeal dated 29 September 2021, the main and auxiliary request 1 also underlying the appealed decision, while auxiliary requests 2 and 3 were filed on appeal. They further requests to maintain the patent on the basis of auxiliary requests 4 and 5, filed with letter dated 20 January 2023. They also request remittal for the not examined substantive issues if one of the requests should meet the formal requirements of the EPC.

The respondent opponent requests dismissal of the appeal, and also requests remittal for undecided issues if one of the requests is found to meet the formal requirements of the EPC.

- 2 - T 1235/21

- V. Claim 1 of the requests relevant to this appeal reads as follows:
 - (a) Main request (amendments vis-a-vis granted claim 1 emphasised by the Board)

"A method for injecting a diluted sample in a liquid chromatography system, the method comprising:

providing a sample syringe (22) coupled through a sample valve (26) and fluid channel/conduit (30) to a sample source;

providing a diluent syringe (38) coupled through a diluent valve (42) and fluid channel/conduit (46) to a diluent source;

combining (220) for a predetermined duration a sample flowing at a first flow rate <u>from the sample</u> <u>syringe (22)</u> and a diluent flowing at a second flow rate <u>from the diluent syringe (38)</u> to generate in a fluid channel (64) a volume of diluted sample having a dilution ratio responsive to the first and second flow rates;

loading (230) a portion of the volume of diluted sample in the fluid channel (64) into a sample loop (84) of an injection valve (68) using only one of the sample syringe (22) and diluent syringe (38); and

switching the injection valve (68) to insert the sample loop (84) into a channel for a mobile phase flowing to a chromatography column, wherein the portion of the volume of diluted sample is injected into the mobile phase."

(b) First auxiliary request

Claim 1 as in the same request where the term source has been substituted by the term reservoir as follows

- 3 - T 1235/21

(emphasis by the Board to indicate added or deleted text):

"...providing a sample syringe (22) coupled through a sample valve (26) and fluid channel/conduit (30) to a sample sourcereservoir (14);

providing a diluent syringe (38) coupled through a diluent valve (42) and fluid channel/conduit (46) to a diluent sourcereservoir (18);..."

(c) Second auxiliary request

Claim 1 as in the first auxiliary request.

(d) Third auxiliary request

Claim 1 as in the second auxiliary request with the following amendments (emphasis by the Board to indicate deleted text):

- "...loading (230) a portion of the volume of diluted sample in the fluid channel (64) into a sample loop (84) of an injection valve (68) using only one of the sample syringe (22) and diluent syringe (38); and..."
- (e) Fourth auxiliary request

Claim 1 as in the first auxiliary request with the following amendments (emphasis by the Board to indicate added or deleted text):

"A method for injecting a diluted sample in a liquid chromatography system, the method comprising:

providing a sample syringe (22) coupled through a $\underline{\text{sample}}$ valve (26) and sample fluid channel/conduit (30) to a sample reservoir (14);

- 4 - T 1235/21

providing a diluent syringe (38) coupled through a diluent valve (42) and diluent fluid channel/conduit (46) to a diluent reservoir (18);

providing a mixing component (60) having a first inlet port in communication with the sample valve (26), a second inlet port in communication with the diluent valve (42), and an outlet port;

providing an injection valve (68), which is in communication with the outlet port of the mixing component (60) through a fluid channel (64);

combining (220) for a predetermined duration at the mixing component (60) a sample flowing at a first flow rate from the sample syringe (22) and a diluent flowing at a second flow rate from the diluent syringe (38) to generate in a the fluid channel (64) a volume of diluted sample having a dilution ratio responsive to the first and second flow rates, the sample valve (26) being configured initially so that the sample is drawn into the sample fluid channel/conduit (30) by the sample syringe (22) and being configured subsequently so that the sample is pushed by the sample syringe (22) to flow at the first flow rate, and the diluent valve (42) being configured initially so that the diluent is drawn into the diluent syringe (38) and being configured subsequently so that the diluent is pushed by the diluent syringe (38) to flow at the second flow rate;

loading (230) a portion of the volume of diluted sample in the fluid channel (64) into a sample loop (84) of an—the injection valve (68) using only one of the sample syringe (22) and diluent syringe (38); and

switching the injection valve (68) to insert the sample loop (84) into a channel for a mobile phase flowing to a chromatography column, wherein the portion of the volume of diluted sample is injected into the mobile phase."

- 5 - T 1235/21

(f) Fifth auxiliary request

Claim 1 as in the fourth auxiliary request.

VI. The appellant's arguments can be summarised as follows:

Claim 1 corresponding to any of the requests on file does not contain added subject-matter. The auxiliary requests should be admitted.

VII. The respondent's arguments can be summarised as follows:

Claim 1 of all requests contain added subject-matter. Auxiliary request 1 was not admitted by the opposition division and therefore cannot be admitted in appeal, Article 12(6) RPBA. Auxiliary requests 2 and 3 are new in appeal, but ought have been submitted in opposition proceedings. They are not to be admitted under Article 12(6) RPBA. Auxiliary requests 4 and 5 are late filed and are not to be admitted under Article 13(2) RPBA.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Background

The patent is directed to liquid chromatography systems, in particular to a method for diluting a sample for injection into a mobile phase in a liquid chromatography system, see patent specification paragraph [0001]. A sample flowing at a first flow rate and a diluent flowing at a second flow rate are combined for a predetermined time. The diluted sample

- 6 - T 1235/21

has a dilution ratio responsive to the first and second flow rates. A portion of the volume is inserted into a channel for a mobile phase flowing to a chromatography column, see specification paragraph [0008]. The method eliminates the need to have a technician available to perform dilutions, see paragraphs [0004]-[0005].

- 3. Main request Added subject-matter.
- 3.1 Claim 1 of the main request has been amended vis-a-vis claim 1 as granted by the inclusion of various features. This decision is concerned with the following amendments (Board's emphasis):

 "providing a sample suringe (22) soupled through a

"providing a sample syringe (22) coupled through a sample valve (26) and fluid channel/conduit (30) to a sample source;

"providing a diluent syringe (38) coupled through a diluent valve (42) and fluid channel/conduit (46) to a diluent source";

combining (220) for a predetermined duration a sample flowing at a first flow rate <u>from the sample syringe</u>
(22) and a diluent flowing at a second flow rate <u>from the diluent syringe</u> (38).

3.2 As also held by the opposition division, the Board finds no basis for the amendment of "providing a diluent syringe coupled ... to a diluent source", where the diluent source can be of any kind, Article 123(2) EPC. In the original disclosure a basis can be found only for a diluent syringe coupled to a diluent reservoir.

Original claim 2 discloses drawing diluent from a "diluent source" in general, but not in specific combination with a syringe. In the original claims, the use of a syringe on the diluent side is only claimed in

- 7 - T 1235/21

the specific combination with a diluent reservoir, see original claims 15 and 16. In the original description the arrangement of a syringe for the diluent is described for the embodiments depicted in figures 1, 3-8. These consistently show the diluent syringe 38 drawing from a a diluent reservoir 18. The only relevant passage, paragraph 0021 of the published PCT application, states that "a diluent syringe 38 is coupled through a diluent valve 42 and tubing 46 to the diluent reservoir 18". Other passages of the published application (paragraphs 0023, 0024, 0029) which mention the diluent syringe always do so when describing operation of the arrangements that are shown in the figures. Consequently, there is no suggestion in the application as filed that the diluent syringe might draw diluent from anything other than from a reservoir.

In the case of the sample syringe 22 the published application as filed describes in paragraph 0028 in reference to figure 4 the alternative of drawing sample from a flowing stream in a conduit 100 via a sampling port, but it is clear that this relates only to the sampling side of the arrangement.

In order to determine the original content of the application, the Board applies the "gold standard", i.e. establishes what the skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the totality of the originally filed documents, see CLBA, 10th edition, 2022, II.E. 1.3.1 and the case law cited therein, in particular G 2/10, OJ 2012, 376. In the current case, claiming that the sampling syringe can be connected to an unspecific source, i.e. a source of any nature,

- 8 - T 1235/21

presents the skilled person with new technical information not present in the application as filed.

3.3 Contrary to the division's conclusions, the Board also sees no basis for the feature as now amended of "... a sample flowing at a first flow rate from the sample syringe (22)...".

This feature in a normal reading of the terms "flowing" and "from" (OED: 6.a.: "denoting removal, abstraction, separation, expulsion, exclusion, etc., from a concrete object") read in context will be understood as meaning that the sample liquid exits the sample syringe, the syringe being its source. Though this may have been the case for the diluent syringe, where diluent is first drawn into the syringe, see published application, paragraph 0023, 2nd sentence, the same paragraph makes clear that for the sample syringe 22 this does not apply: thus in the drawing step "the volume of drawn sample is not sufficient to reach the sample syringe 22". The sample syringe 22 merely acts to draw sample into the "holding loop" 30 (presumably thus named as it holds the drawn sample), paragraph 0023, 2nd sentence, from which it is expelled in the subsequent step, see the following paragraph 0024 of the published application. For the skilled person it is unambiguously clear when reading these two paragraphs together that sample liquid does not flow out of the sample syringe in the following injection step. This is so even if paragraph 0024 when describing the expelling step states that "sample and diluent are pushed ... from their syringes 22 and 38", where the skilled person understands from the context that the preposition "from" rather denotes the source of the pushing action. This does not mean, however, contrary to the division's argument in section 13.2 of their decision and taken up - 9 - T 1235/21

by the appellant, that this contextual reading of "from" in paragraph 0024 applies also to the new expression "flowing ... from" which first appears in this amendment (and only there).

In accordance with established jurisprudence, see CLBA (10th edition, 2022) II.A.6.3.1, in particular T 0197/10, headnote and reasons point 2.3, if the claims are worded so clearly and unambiguously as to be understood without difficulty by the person skilled in the art, there is no need to use the description to interpret the claims. In the event of a discrepancy between the claims and the description, the unambiguous claim wording must be interpreted as it would be understood by the person skilled in the art without the help of the description.

In the present case, the Board considers that the feature of "... a sample flowing... from the sample syringe (22)..." is completely clear, nor has the contrary been argued by the appellant. Therefore, the skilled person would not resort to the description to give it a narrower interpretation (only denoting direction and excluding any indication of origin). Therefore, the appellant's argument is moot.

3.4 The Board also finds an unallowable intermediate generalization in both added features of "providing a ... syringe coupled through a ... valve and fluid channel/conduit to a ... source", which (leaving aside the generalization to "source") adds some but not all features from the specific embodiment of figure 1, originally disclosed in paragraphs 0021 to 0027 (pages 4 to 6) of the published application.

- 10 - T 1235/21

- 3.4.1 According to established case law, cf. CLBA (10th edition) II.E.1.9.1, it will normally not be allowable to base an amended claim on the extraction of isolated features from a set of features originally disclosed only in combination, e.g. a specific embodiment in the description. Such an amendment results in an "intermediate generalisation". An intermediate generalisation is justified only in the absence of any clearly recognisable functional or structural relationship among the features of the specific combination or if the extracted feature is not inextricably linked with those features. Otherwise, it represents an unallowable intermediate generalisation.
- 3.4.2 Claim 1 is a method claim. The added features of providing a (diluent or sample) syringe coupled through a valve and fluid channel/conduit to a fluid source are taken from the embodiment of Figure 1, originally disclosed in pages 4 to 6 of the published application. Original pages 4 to 6 describe how the claimed sample syringe and valve are used in the method steps for transferring the sample fluid from the sample reservoir 14. Sample fluid is drawn and held in tubing 30 and subsequently transferred to injection port 50 connected to the mixing component 60 and configured to receive the sample needle, cf. original paragraph 0021. While the sample needle may be optional, the injection port is not. There is no alternative to the described injection port and therefore no alternative to the steps of uncoupling and coupling the sample side channel/conduit to injection port 50 for transferring the sample fluid.

On the sample side the syringe, sample valve, fluid channel and injection port interact in a particular manner and arrangement (distinct from the diluent - 11 - T 1235/21

side), in which sample is drawn and held in the holding loop 30 (and not in the syringe), from which it must then be transferred by physically moving the holding loop 30 from the reservoir 14, with or without the needle 34, to the injection port 50 where the sample is then injected in a precisely metered amount, paragraphs 0023 to 0025. In this, and indeed all other embodiments, all the above features, including the injection port 50 and holding loop 30, are inextricably linked by their arrangement and their function to allow drawing and injection of sample. By adding to claim 1 only some but not others of these features - the injection port and the holding loop -, its scope now covers embodiments without those features and thus more general than the original specific context. These include for example using the sample syringe, sample valve of figure 1 and channel/tubing in an arrangement similar to the diluent side, with a fixed connection to the fluid mixing component and a drawing and introduction of sample in the same manner as for the diluent. These combinations were not originally disclosed. They represent new technical subject-matter resulting in an unallowable intermediate generalisation.

3.4.3 The same applies to the features added to define the diluent side, as it is not specified in the amended claim how the diluent valve is connected to the mixing component 60 (tee 60) as disclosed in the specific embodiment. The claim scope thus now includes diluent arrangements that mirror the specific sample side arrangement with movable holding loop that is connectable to an injection port on the diluent side, and an associated method of injecting diluent fluid into the mixing component. As for the sample side the specific features of diluent syringe, diluent valve,

- 12 - T 1235/21

conduit fixedly connected to the mixing port are inextricably linked in function and structure to allow for diluent extraction and introduction as originally described. Consequently, adding only some but not all results in an unallowable intermediate generalization.

- 3.5 The Board thus concludes that amended claim 1 according to the main request contains added subject-matter,
 Article 123(2) EPC.
- 4. Auxiliary requests 1-3 Added subject-matter

Without prejudice to their admissibility, these requests are clearly not allowable. The amendments do not suffice to overcome all above identified added subject-matter deficiencies, Article 123(2) EPC.

Thus, where identical claim 1 of auxiliary requests 1 and 2 replaces "source" by "reservoir" it addresses only the first of the above points. Claim 1 of auxiliary request 3 includes a further amendment that limits the loading step to the sample syringe, but does not further address the remaining two points above.

- 5. Auxiliary requests 4-5 Admission
- 5.1 Auxiliary requests 4 and 5 were filed on 20 January 2023, after notification of the summons to oral proceedings dated 10 March 2022. These late filed requests, which add to claim 1 further features from the description, are amendments to the party's case in the sense of Article 13(2) RPBA, the admission of which is at the discretion of the Board.

- 13 - T 1235/21

5.2 Article 13(2) RPBA stipulates that such late amendments to a party's appeal case shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

The appellant proprietor submits that these requests were filed as a response to the negative preliminary opinion of the Board in its communication of 5 August 2022 in preparation to the oral proceedings. They further submit that waiting for the preliminary opinion of the Board is procedurally more efficient, what also justifies the late filing of the requests.

However, as variously stated in case law, where objections had already been raised by the first-instance division or by a party, the board taking up such objections, or where the board's objections merely mean a developing of the objections originally raised or stating them more precisely are normally seen as an ordinary development in the appeal proceedings which cannot justify the filing of new requests, cf. CLBA V.A.4.5.4.a). Even a change in the board's opinion (e.g. departing from an opinion as set out in a communication) normally does not justify new requests, if the underlying issue was otherwise known to the party.

In the present case, the Board's preliminary opinion for the main request and auxiliary requests 1-3 considered only such objections that were raised in the opponent's reply to the proprietor's appeal. That the Board's preliminary opinion differed from the conclusion of the opposition division is, if perhaps subjectively surprising, in fact an objectively

- 14 - T 1235/21

possible and as such foreseeable outcome. The Board is unable to see in these circumstances anything exceptional that might justify at such a late stage the introduction of further features from the description, as is the case for present auxiliary requests 4 and 5. Such late filed requests are moreover clearly contrary to the "convergent approach" underlying the RPBA 2020, that intends to ensure a just, speedy and efficient appeal procedure by encouraging parties to submit all relevant facts, evidence, arguments and requests as early as possible, see CLBA V.A.4.1.2.

- 5.4 In view of the above the Board decided not to admit auxiliary requests 4 and 5 into the proceedings, Article 13(2) RPBA.
- 6. In summary, the Board confirms the conclusions of the decision under appeal that the main request is not allowable. The appellant's further auxiliary requests are either not allowable or have not been admitted. Consequently, the appeal fails.

- 15 - T 1235/21

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



G. Magouliotis

A. de Vries

Decision electronically authenticated