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Datasheet for the decision of 7 July 2020

Case Number: T 1230/18 - 3.3.02

Application Number: 10171837.7

Publication Number: 2286901

IPC: B01D65/10, B01D69/02, G01N15/08

Language of the proceedings: EN

Title of invention:
Method for improved scaling of filters

Applicant:
EMD Millipore Corporation

Headword:

Relevant legal provisions:
EPC Art. 84

Keyword:
Claims - all requests - clarity (no)

Decisions cited:
T 0630/93

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1230/18 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 7 July 2020

Appellant: (Applicant)	EMD Millipore Corporation 400 Summit Drive Burlington, MA 01803 (US)
Representative:	Uexküll & Stolberg Partnerschaft von Patent- und Rechtsanwälten mbB Beselerstraße 4 22607 Hamburg (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 December 2017 refusing European patent application No. 10171837.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	M. Maremonti
	L. Bühler

Summary of Facts and Submissions

I. The appeal by the applicant (hereinafter "appellant") lies from the decision of the examining division to refuse European patent application No. 10 171 837.7.

II. The claim request refused by the examining division contained three claims, independent claim 1 of which reads as follows:

"*1. A method of reducing performance variability in a filtration scaling device used to estimate the requirements of a full scale filtration device, the method comprising:*

a. determining the performance distribution of a plurality of membranes or filtration media;

b. selecting a subset of said distribution, said subset having a known range of performance with said distribution;

c. inserting membrane or filtration media from said subset into said filtration scaling device;

d. assigning a scaling safety factor to said filtration scaling device, wherein said scaling safety factor is directly proportional to the product of the full scale device high end potential performance within said distribution and the scaling device high end potential performance within said subset of said distribution, and inversely proportional to the product of the scaling device low end potential performance within said subset of said distribution and the full scale device low end potential performance within said distribution; and

e. estimating membrane or filtration media area requirements of the full scale filtration device by applying said scaling safety factor."

III. Document US 2005/194317 (D2) was among the documents cited during the examination proceedings.

The examining division came to the following conclusion on the then pending claim request:

- The subject-matter of claim 1 did not involve an inventive step in view of either the background art cited in the application as filed or D2 taken as the closest prior art.

IV. In its statement of grounds of appeal, the appellant contested the reasoning of the examining division and submitted that the claimed subject-matter involved an inventive step. It filed a new main request and an auxiliary request, the latter corresponding to the request refused by the examining division. The appellant corroborated its arguments by filing the following new items of evidence (numeration inserted by the board):

A001: Statement of Salvatore Giglia, co-inventor of the present application, dated 11 April 2018

A002: US 8 387 256 B2

V. The appellant was summoned to oral proceedings. In preparation for these proceedings, the board issued a communication, in which it expressed, *inter alia*, the preliminary opinion that the subject-matter claimed in both the main request and the auxiliary request was not clear as required by Article 84 EPC.

VI. The appellant replied to the board's communication by letter dated 8 May 2020 (received on 8 June 2020). It contested the objections raised by the board and submitted, *inter alia*, that the claimed subject-matter was clear to a person skilled in the art. It filed a new main request and new auxiliary requests 1 to 4 to replace the previously filed requests, and corroborated its arguments by filing the following new documents (numeration inserted by the board):

A003: van Reis and Zydney, "*Bioprocess membrane technology*", J. Membrane Science, 297, 2007, pages 16 to 50

A004: Giglia and Sciola, "*Scaling Up Normal-Flow Microfiltration Processes*", BioProcess International, 9(9), October 2011, pages 58, 60 and 62

The appellant also referred to the following items of evidence (numeration inserted by the board):

A005: https://www.youtube.com/watch?v=lbPql35-Fng

A006: Z.F. Zui, H.S. Muralighara, "*Membrane Technology: A practical Guide to Membrane Technology and Applications in Food and Bioprocessing*", 1st edn., Elsevier, 2010, ISBN: 978-1-85617-632-3, pages 82 to 85

The appellant further requested that the oral proceedings be held as a video conference.

VII. By communication dated 15 June 2020, the appellant was informed that the oral proceedings would be held by video conference in accordance with its request.

VIII. The oral proceedings were held on 7 July 2020 by video conference, during which the appellant withdrew its previous auxiliary requests 1 to 4 and filed a new auxiliary request 1 containing claims 1 and 2.

IX. Final requests

The appellant requested that the decision under appeal be set aside and the case be remitted to the examining division with the order to grant a patent on the basis of the claims of the main request filed by letter dated 8 May 2020 or, alternatively, on the basis of the claims of auxiliary request 1 filed during the oral proceedings on 7 July 2020.

X. The arguments of the appellant, where relevant for the present decision, are summarised as follows.

Main request:

- The method defined in claim 1 by steps a) to e) made it possible to reduce the range of scaling device performance, so that the full scale requirements could be lowered and costs saved.

- The claimed method was addressed to a person skilled in the art. Therefore, it was clear to the skilled person that step a) was typically, though not necessarily, carried out by the manufacturer of the membranes intended to be used by a customer in a full scale process. The device used in step a) did not have to be defined in the claim. Any device could be used. Step a) was usually performed with a standard fluid, typically water, different from the working fluid of the customer.

- The manufacturer might not test all the membranes of a certain produced lot but, as defined in step

a), only a plurality of them. It would test the performance of these membranes, e.g. in terms of permeability or throughput capacity, and establish a performance distribution. The latter typically had the form of a Gaussian curve. This membrane rating was common in the art. The established distribution furnished the "*full scale device high end potential performance*" and the "*full scale device low end potential performance*" referred to in step d) of claim 1.

- Step b) was clear in that a subset of membranes tested in step a) and having a known range of performance was selected.

- In step c) a membrane from this subset was inserted into the filtration scaling device. Normally, a different device with respect to step a) was used. The membrane size was thus adapted to fit into the filtration scaling device.

- In step d) the scaling safety factor was determined according to the defined calculation. It was clear to the skilled person that the mentioned "*full scale device high end potential performance*" and "*full scale device low end potential performance*" pertained to the distribution established in step a). It was also clear that the mentioned "*scaling device high end potential performance*" and "*scaling device low end potential performance*" referred to the subset selected in step b).

- In step e) the scaling safety factor as determined in step d) was used for estimating the area requirements of the full scale device to be used by the customer in its actual filtration problem. It was clear to the skilled person that this step

implicitly implied that experiments with the filtration scaling device referred to in step c) had to be carried out with the working fluid which the customer was interested in. Typical experiments were those devoted to the determination of V_{max} and P_{max} of the membrane. For this, procedures pertaining to common general knowledge were followed, as demonstrated for example by document A003. The area was then estimated by applying the scaling safety factor within mathematical formulae well known to the skilled person, see for example documents A003 and A006.

- It was true that not all details had been included in step e), but this was not necessary, since the method was addressed to a skilled person, see decision T 0630/93. Only the borders of the claimed invention had to be specified, while details within these borders were not needed.

- It had to be concluded that the claimed subject-matter was clear.

Auxiliary request 1:

- The board's concerns regarding steps a) and d) had been addressed in that the method had been restricted to a microfiltration membrane and the performance distribution restricted to a water permeability distribution. Moreover, the way in which the permeability was measured had been included in step a).

- The numerical values of high and low end potential performance of the full scale filtration device had been specified. Also, the high and low end

potential performance of the filtration scaling device had been clarified in step b).

- Therefore, claim 1 of auxiliary request 1 met the requirements of Article 84 EPC.

Reasons for the Decision

Main request - claim 1 - compliance with Article 84 EPC

1. Claim 1 of the main request only differs from claim 1 of the request refused by the examining division (II, *supra*) in that step c) has been amended to recite (amendment highlighted by the board):

"*c. inserting* ***a*** *membrane or filtration media from said subset into said filtration scaling device;*".

2. The board comes to the conclusion that the subject-matter of claim 1 is not clear as required by Article 84 EPC for the following reasons.

2.1 Step a) of the claimed process reads as follows:

"*a. determining the performance distribution of a plurality of membranes or filtration media;*".

2.1.1 Contrary to the appellant's view (X, *supra*), step a) does not clarify to the skilled person which membranes should be tested for their performance. The appellant argued that a certain number of membranes of a same lot were intended. However, step a) does not mention any lot; it refers only to a *plurality of membranes*, without specifying the number or material of the membranes referred to. Therefore, the skilled person cannot understand the kind and quantity of membranes

required to determine the mentioned performance distribution.

2.1.2 Step a) also leaves open which device should be used for determining the mentioned performance distribution. The appellant argued that any device may be used. While this argument could be accepted, an ambiguity arises from the fact that claim 1, in its first three lines and in steps c) to e) (II, *supra*), refers to both a "*full scale filtration device*" and a "*filtration scaling device*". These terms unambiguously mean to the skilled person that different devices (especially devices of different sizes) should be used in the claimed method. It is thus unclear whether in step a) one of these two devices, or even a third unknown device, should be used. This ambiguity generates a further lack of clarity in step a).

2.2 Step b) of the claimed process reads as follows:

"*b. selecting a subset of said distribution, said subset having a known range of performance with said distribution;*".

Step b) of claim 1 thus requires a subset of the distribution determined in step a) to be selected. It is unclear how, i.e. under which criteria, this subset should be selected. Moreover, according to step c), one membrane ("*a membrane*") from this subset should be inserted into a filtration scaling device. Since only one membrane is taken from the subset selected in step b), the technical significance of selecting a subset is unclear. The skilled person might have been taught to simply select one membrane of known performance from the distribution as determined in step a). An ambiguity arises as to whether this would have been equivalent to carrying out steps b) and c) as claimed.

2.3 Step c) of the claimed process reads as follows:

"*c. inserting a membrane or filtration media from said subset into said filtration scaling device;*".

2.3.1 Step c) thus requires one membrane from the subset selected in step b) to be inserted into a filtration scaling device. It is unclear how such a membrane should be chosen. In particular, it is unclear whether any membrane from the selected subset should be indifferently chosen.

2.3.2 Furthermore, claim 1 is silent as to what the technical purpose of inserting such a membrane into the mentioned filtration scaling device should be. The appellant argued that step e) implicitly clarified that filtration experiments should be carried out with the mentioned filtration scaling device. The board disagrees. Step e) (see also below) merely requires the area requirements at full scale to be estimated. No reference whatsoever to step c) is included, let alone to experiments (what kind of experiments?) to be carried out with a (not further specified) filtration scaling device. Therefore, the technical significance of step c) is not derivable from step e) and remains obscure to the skilled person.

2.4 Step d) of the claimed process reads as follows:

"*d. assigning a scaling safety factor to said filtration scaling device, wherein said scaling safety factor is directly proportional to the product of the full scale device high end potential performance within said distribution and the scaling device high end potential performance within said subset of said distribution, and inversely proportional to the product of the scaling device low end potential performance within said subset of said distribution and the full*

scale device low end potential performance within said distribution;".

2.4.1 Step d) is thus directed to the calculation of a scaling safety factor, whereby a "*full scale device high end potential performance*", a "*full scale device low end potential performance*", a "*scaling device high end potential performance*" and a "*scaling device low end potential performance*" are required for the calculation. The terms "*high end potential performance*" and "*low end potential performance*" are obscure to the skilled person, so that it is not possible to understand without ambiguity which values should be intended.

2.4.2 The appellant argued that step d) was clear as it mentioned that the full scale device high and low end potential performances (F_h and F_l in the following) were said to be "*within said distribution*". The term *said* clarified that these values were determined in step a). They corresponded to the maximum and minimum performance of the plurality of membranes tested in step a) and were typically indicated by the membrane manufacturer according to known rating criteria. As regards the scaling device high and low end potential performances (S_h and S_l in the following), these were said to be "*within said subset of said distribution*". They thus corresponded to the maximum and minimum performance of the subset of membranes selected in step b) from the distribution obtained in step a).

2.4.3 The board disagrees. Even if one accepts (see however point 2.4.4 below) that the expressions "*within said distribution*" and "*within said subset of said distribution*" suggest that F_h, F_l, S_h and S_l should be derivable from the performance distribution as determined in step a), claim 1 is totally silent as to

how this should be done. No rating criteria generally adopted by membrane manufacturers for determining maximum and minimum performances are specified in claim 1.

2.4.4 Additionally, F_h, F_l and S_h and S_l are associated to the terms "*full scale device*" and "*scaling device*", respectively. Therefore, the skilled person unambiguously understands that these values pertain to performance distributions obtained by using different devices (especially devices of different sizes). However, the sole performance distribution mentioned in claim 1 is that determined in step a). Here neither the (not further specified) full scale filtration device nor the (not further specified) scaling device were used. It is thus totally unclear whether the mentioned values of F_h, F_l, S_h and S_l should be obtained from the distribution determined in step a) or from other, not further specified, performance distributions.

2.5 Step e) of the claimed process reads as follows:

"*e. estimating membrane or filtration media area requirements of the full scale filtration device by applying said scaling safety factor.*".

2.5.1 Step e) thus requires that once the scaling safety factor has been calculated in step d), this is *applied* to estimate the area requirements of the (not further specified) full scale filtration device. However, no information whatsoever is contained in step e) as to how this estimate should be done.

2.5.2 The appellant (X, *supra*) invoked the common general knowledge of the skilled person as represented, for example, by A003 and A006. According to A003, paragraph 3.1.3 on pages 22 and 23, flow filters were typically sized by applying the V_{max} or the P_{max} experimental

analyses. These were typically carried out by the customer with a scaling device and using the working fluid they were interested in. This was very important, since the performance distribution as determined in step a) of claim 1 was usually done by the membrane manufacturer by using water. The V_{max} model furnished the maximum volume of fluid that could be filtered before the membrane was completely clogged. In the P_{max} model, a similar approach was done, in which a constant filtrate flux was maintained and the transmembrane pressure was monitored as a function of the filtered volume per unit membrane area. According to A003 (*loc. cit.*), scale-up was then accomplished by assuming that the available capacity (usually between 50% and 80% of the V_{max}) scaled linearly with the membrane area. The scaling safety factor as calculated in step d) had then to be taken into account for calculating the area by using, for example, the formula reported in A006.

The appellant argued that in line with decision T 0630/93 only the borders of the claimed invention had to be specified, while details within these borders were not needed, since claim 1 was addressed to a person skilled in the art.

2.5.3 The board disagrees. As set out above, step e) is totally silent as to any experiments to be carried out in any scaling device, let alone to the V_{max} or the P_{max} analyses invoked by the appellant.

Even assuming that these analyses as described in A003 pertained to the common general knowledge of the skilled person, they do not involve any scaling safety factor, which is instead required by step e) of claim 1. In fact, paragraph 3.1.3 of A003 referred to by the appellant states that the results obtained by using a small-area test filter are "*extrapolated to larger*

production volumes assuming that the filter performance scales linearly with membrane area". A scaling safety factor, let alone the one referred to in step d) of claim 1, is not mentioned.

A006, also invoked by the appellant, is a book published in 2010, i.e. after the priority date claimed for the present application. As such, it does not represent prior art under Article 54 EPC and cannot be taken into account to demonstrate the common general knowledge of the skilled person at the priority date.

Therefore, the procedure necessary for estimating the area requirements of the full scale filtration device as required by step e) of claim 1 is completely obscure to the skilled person.

2.5.4 Decision T 0630/93 invoked by the appellant concerned a focus control apparatus for a video camera, i.e. a technical field extremely remote from that of the claimed method. The clarity of the claims was not the subject of that decision (reasons, 3.2.1); it was instead concerned with the requirement of Article 84 EPC that the claims must be supported by the description (reasons, 3.2 and 3.2.2). It was in this context that the statement (reasons, 3.2) was made that the borders of an invention should be defined rather than the details within the borders. This statement referred to the function of the essential features, i.e. those features that are essential to solve the technical problem as specified in the description. The board thus finds that decision T 0630/13 is of no relevance for the present case, in which the clarity of the claim is at issue.

3. For all the reasons set out above, the board concludes that the subject-matter of claim 1 is not clear and

does not meet the requirements of Article 84 EPC. The main request of the appellant is not allowable.

Auxiliary request 1 - claim 1 - compliance with Article 84 EPC

4. Claim 1 of auxiliary request 1 recites the following, with the amendments to claim 1 of the main request highlighted by the board:

"*1. A method* ***for estimating microfiltration membrane area requirements of a full scale filtration device by means of the calculation of a scaling safety factor*** ~~*the method of reducing performance variability in a filtration scaling device used to estimate the requirements of a full scale filtration device*~~*, the method comprising:*

a. determining the performance distribution of a plurality of membranes ~~*or filtration media*~~ ***to be used in said full scale filtration device, wherein the performance distribution is the distribution of water permeability of the plurality of the membranes, wherein an average of the performance distribution of the plurality of membranes is normalized to one, wherein water permeability is measured by supplying water to the membrane, maintaining a pressure difference across the membrane, and measuring the water flow rate, and, wherein an acceptable range of performance is defined as ± 30% of the average performance distribution, the distribution having a high end potential performance (F_h) of 1,3 and a low end potential performance (F_l) of 0,7 of said full scale filtration device;***

b. selecting a subset of said distribution, said subset having a known range of performance with said distribution, ***the distribution of the subset having a high end potential performance (S_h) and a low end***

potential performance (S_1) of said filtration scaling device;

c. inserting a membrane or filtration media from said subset into ***a*** ~~*said*~~ *filtration scaling device;*

d. ***determining*** ~~*assigning*~~ *a scaling safety factor* ~~*to said filtration scaling device*~~*, wherein said scaling safety factor is* ~~*directly proportional to*~~ *the product of the full scale device high end potential performance within said distribution and the scaling device high end potential performance within said subset of said distribution,* ~~*and inversely proportional to*~~ ***divided by*** *the product of the scaling device low end potential performance within said subset of said distribution and the full scale device low end potential performance within said distribution; and*

e. estimating membrane or filtration media area requirements of the full scale filtration device by applying said scaling safety factor."

4.1 The appellant argued that the amendments overcame the clarity objections raised especially to step a) of claim 1 of the main request.

4.2 However, the board notes that steps c) and e) are unchanged with respect to claim 1 of the main request. The amendments made do not address the clarity objections raised above under points 2.3 and 2.5, which still apply.

4.3 For this reason alone, the board concludes that the subject-matter of claim 1 of auxiliary request 1 is not clear and does not meet the requirements of Article 84 EPC. Auxiliary request 1 is not allowable.

Conclusion

5. None of the appellant's requests is allowable under Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin M. O. Müller

Decision electronically authenticated