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Datasheet for the decision of 11 December 2024

Case Number: T 2564/22 - 3.2.02

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Language of the proceedings: EN

Title of invention:
INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE

Patent Proprietor:
Bracco Diagnostics Inc.

Opponent:
Jubilant DraxImage Inc.

Relevant legal provisions:
EPC Art. 83, 84, 111(1)
RPBA 2020 Art. 13(2), 11

Keyword:
Amendment after notification of Art. 15(1) RPBA communication - taken into account (yes)
Sufficiency of disclosure - (yes)
Claims - clarity (main request - no) (first auxiliary request - yes)
Remittal - (yes)

Decisions cited:
G 0003/14, T 0716/17, T 0830/19, T 1436/19

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Case Number: T 2564/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 December 2024

Appellant: (Patent Proprietor)	Bracco Diagnostics Inc. 259 Prospect Plains Road, Building H Monroe Township, NJ 08831 (US)
Representative:	Reddie & Grose LLP The White Chapel Building 10 Whitechapel High Street London E1 8QS (GB)
Appellant: (Opponent)	Jubilant DraxImage Inc. 16751 TransCanada Highway Kirkland, Montréal QC H9H 4J4 (CA)
Representative:	Piotrowicz, Pawel Jan Andrzej Venner Shipley LLP 406 Cambridge Science Park Milton Road Cambridge CB4 0WW (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 October 2022 concerning maintenance of the European Patent No. 2328634 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	N. Obrovski

Summary of Facts and Submissions

I. Both the patent proprietor and the opponent appealed against the interlocutory decision of the opposition division to maintain the contested patent as amended on the basis of auxiliary request 4 then on file.

In its decision, the opposition division held that the main request was unallowable because the invention as claimed in that request was insufficiently disclosed.

II. In their statements of grounds of appeal, the appellants made the following requests.

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the main request or one of the first to sixth auxiliary requests, the main request and the second to sixth auxiliary requests being those on which the decision under appeal was based, and the first auxiliary request being that filed with the patent proprietor's statement of grounds of appeal.

The opponent requested that the decision under appeal be set aside and that the contested patent be revoked.

III. In its communication under Article 15(1) RPBA, the Board expressed the preliminary opinion that the invention as claimed in the main request was sufficiently disclosed but that claim 1 of that request was not clear. In the Board's view, this clarity objection was overcome in the first auxiliary request, for which, moreover, the same considerations on sufficiency of disclosure applied. The Board was

therefore inclined to admit the first auxiliary request and to remit the case to the opposition division for further prosecution of the basis of that request.

IV. Referring to the Board's preliminary opinion, the patent proprietor reversed the order of the main request and the first auxiliary request with its submission of 3 December 2024.

V. Oral proceedings were held before the Board on 11 December 2024.

After an objection by the opponent and a discussion of whether the claim requests referred to as the main request and the first auxiliary request in the patent proprietor's submission of 3 December 2024 should be admitted into the appeal proceedings under Article 13(2) RPBA, the Chair informed the parties about the Board's preliminary opinion to admit the main request but not the first auxiliary request.

The patent proprietor then changed the order of these two claim requests back to the order which it had originally pursued in its statement of grounds of appeal. The opponent did not request that this further change in the order of requests not be admitted.

The patent proprietor's final first two claim requests on appeal are therefore, in this order of preference, the main request on which the decision under appeal was based and the first auxiliary request filed with the patent proprietor's statement of grounds of appeal. These requests are referred to as "the main request" and "the first auxiliary request" respectively.

VI. This decision refers to the following documents:

D4 US 2007/0213848 A1

D5 N. J. Epstein *et al.*, "*A ^{82}Rb infusion system for quantitative perfusion imaging with 3D PET*", Applied Radiation and Isotopes 60, 2004, 921-7

D8 R. Klein, "*Precise ^{82}Rb infusion system for cardiac perfusion measurement using 3D positron emission tomography*", MASc Thesis, 2005

VII. Claim 1 of the main request reads as follows:

"*An infusion system for the generation of, and infusion of, radiopharmaceuticals, the system comprising:*

an eluant reservoir (15), a pump (33) coupled to the reservoir (15), an infusion tubing circuit (300), a radioisotope generator (21), an activity detector (25), a waste bottle (23), a computer (17), a timer, and a computer interface (172),

wherein the infusion tubing circuit (300) includes an eluant line (302, 304) coupled to the pump (33) and to the generator (21), and an eluate line (305) coupled to the generator (21), to the activity detector (25), and to the waste bottle; and

wherein the computer (17) is coupled to the computer interface (172), to the pump (33) and to the activity detector (25), wherein the computer (17) is arranged to

activate the pump (33) to pump a volume of eluant from the reservoir (15), through the eluant line (302, 304) and through the generator (21), in order to generate a sample or a dose of eluate in the eluate

line (305), via elution within the generator (21), each sample being intended for a quality control measurement, and each dose being intended for diagnostic imaging,

the system being characterised in that the computer (17) is further arranged to:

provide an indication, via the computer interface (172), that the elution is completed, when the pump (33) has completed pumping each volume of eluant through the generator (21);

start a timer once the elution is completed;

display, via the computer interface (172), an indication of a time lapse (677, 777, 878, 977) since each elution was completed based on the timer;

receive an activity of a sample and the time lapse between that at which the activity of the sample was measured by a dose calibrator and that at which the elution of the sample was completed; and

calculate a calibration coefficient for the infusion system based on the received activity and the received time lapse."

VIII. Claim 1 of the first auxiliary request reads as follows (with the amendments to claim 1 of the main request highlighted by the Board):

"*An infusion system for the generation of, and infusion of, radiopharmaceuticals, the system comprising:*

an eluant reservoir (15), a pump (33) coupled to the reservoir (15), an infusion tubing circuit (300), a radioisotope generator (21), an activity detector (25), a waste bottle (23), a computer (17), a timer, and a computer interface (172),

wherein the infusion tubing circuit (300) includes an eluant line (302, 304) coupled to the pump (33) and to the generator (21), and an eluate line (305) coupled to the generator (21), to the activity detector (25), and to the waste bottle; and

wherein the computer (17) is coupled to the computer interface (172), to the pump (33) and to the activity detector (25), wherein the computer (17) is arranged to

activate the pump (33) to pump a volume of eluant from the reservoir (15), through the eluant line (302, 304) and through the generator (21), in order to generate a sample or a dose of eluate in the eluate line (305), via elution within the generator (21), each sample being intended for a quality control measurement, and each dose being intended for diagnostic imaging,

detect, via the activity detector (25), an activity of the sample during elution of the sample;

the system being characterised in that the computer (17) is further arranged to:

provide an indication, via the computer interface (172), that the elution is completed, when the pump (33) has completed pumping each volume of eluant through the generator (21);

start a timer once the elution is completed;

display, via the computer interface (172), an indication of a time lapse (677, 777, 878, 977) since each elution was completed based on the timer;

receive an activity of a sample and the time lapse between that at which the activity of the sample was measured by a dose calibrator and that at which the elution of the sample was completed; and

calculate a calibration coefficient for the infusion system based on the received activity, ~~and~~ the received time lapse, and the activity of the eluate detected during elution of the sample."

IX. The **patent proprietor's arguments** relevant to the present decision can be summarised as follows.

Admittance of the main request and the first auxiliary request

The main request and the first auxiliary request should be admitted by the Board. The first reordering of these requests made with the patent proprietor's submission of 3 December 2024 had been made only in the interest of procedural efficiency, taking into account the preliminary opinion of the Board set out in its communication under Article 15(1) RPBA. The second reordering made during the oral proceedings before the Board merely restored the hierarchy of the claim requests originally pursued by the patent proprietor in its statement of grounds and on which the Board's communication was based and did not raise any new issues. Moreover, the first auxiliary request differed

from that on which the decision under appeal was based only in that the calculation of the calibration coefficient was further based on the received time lapse, an amendment motivated by and addressing the objection to claim 1 under Article 83 EPC raised by the opposition division for the first time during the oral proceedings.

Main request

Claim 1 of the main request was clear. As the activity measurement with the dose calibrator and the subsequent calculation of the calibration coefficient were carried out after the elution of the sample had been completed, the person skilled in the art would implicitly understand that the entire activity profile detected by the activity detector during the elution of the sample was used to calculate the calibration coefficient and not a single value measured at a certain time.

First auxiliary request

Claim 1 of the first auxiliary request was clear, and the invention as claimed in that request was sufficiently disclosed. The person skilled in the art would have no difficulty or undue burden in calculating a calibration coefficient as claimed using common general knowledge. The steps involved in that calculation amounted to mathematical operations which were well known to the person skilled in the art, particularly since they would be knowledgeable of radioisotope delivery systems. Moreover, the person skilled in the art would find sufficient teaching in the patent to carry out the invention as defined by claim 13 of the first auxiliary request.

X. The **opponent's arguments** relevant to the present decision can be summarised as follows.

Admittance of the main request and the first auxiliary request

The first auxiliary request could have been submitted in the opposition proceedings, in particular because the feature added to claim 1 of the first auxiliary request was defined in claim 1 of the main request on which the decision under appeal was based. The first auxiliary request should therefore not be admitted on appeal.

In any event, the first reordering of the main request and the first auxiliary request made with the submission of 3 December 2024 should not be admitted since it might allow the patent proprietor to avoid a negative decision by the Board on the main request, which had not been considered allowable in its preliminary opinion, without withdrawing it. This was particularly problematic in view of the envisaged remittal of the case to the opposition division, before which the patent proprietor could then rely on the main request again.

The opponent did not request that the further reordering of the requests made during the oral proceedings before the Board not be admitted.

Main request

Claim 1 of the main request was unclear, as objected to by the Board in its communication under Article 15(1) RPBA. In addition, claim 1 failed to define various other features or parameters, such as the flow rate

used to elute the sample, which were essential for defining the calculation of the calibration coefficient.

First auxiliary request

Claim 1 of the first auxiliary request was unclear for the same reasons as claim 1 of the main request. The definition in claim 1 that the detector detected "an activity of the sample", i.e. possibly a single activity, could not overcome the ambiguity raised by the Board in the main request.

Furthermore, the invention as claimed in the first auxiliary request was insufficiently disclosed.

The patent failed to provide sufficient information on how to calculate a "calibration coefficient" as defined in claim 1. While the person skilled in the art attempting to perform this calculation would know that they needed to compare alike measurements, they would be faced with a number of different options. However, the patent gave no guidance as to which choice to make, nor how to carry out the steps to produce a meaningful coefficient. Indeed, the calculation of the calibration coefficient required various considerations on which the patent was completely silent, such as how to properly account for the decay of the eluate, how to convolve the integrated activity measurement with the decay rate, what flow rate to use to elute the sample (which, as shown for example in Figure 5 of D5, had a strong influence on the calculated activity) and what dose calibrator to use.

Moreover, the person skilled in the art would recognise that calibration could not be performed after a certain

period of time when the radioisotope had decayed to such an extent that no activity measurement could be made in practice with a dose calibrator. This was definitely the case, for example, for the long time from the end of elution shown in Figure 8B, which was more than six times the half-life of Rubidium-82 - the radioisotope used in the infusion system described. Since claim 1 did not contain such a time limitation, the claimed invention was not sufficiently disclosed over the whole scope of the claims.

In addition, as originally objected to by the opponent for claim 11 of the claim request found allowable by the opposition division, with which claim 13 of the first auxiliary request is identical, the patent also failed to provide sufficient information on how to calculate the flow rate profile and how to control the speed of the pump according to the calculated flow rate profile as defined in that claim.

Reasons for the Decision

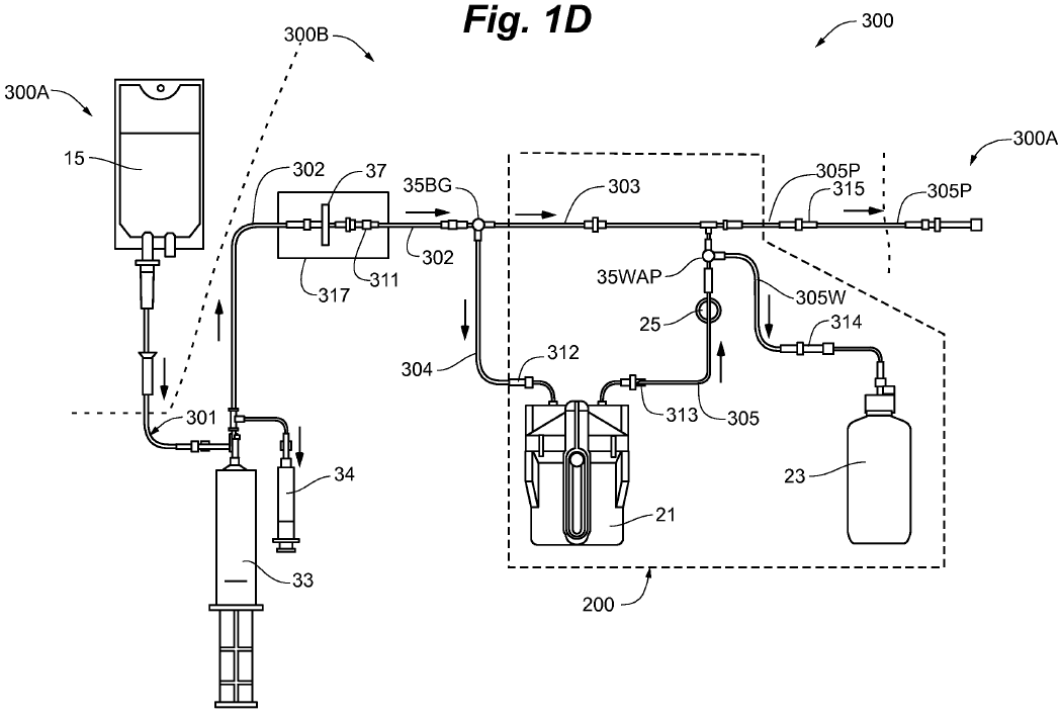
1. Subject-matter of the contested patent

1.1 The contested patent relates to a computer-facilitated system for preparing a dose or a sample of a solution containing a radiopharmaceutical, by elution within a radioisotope generator, for infusion into a patient for therapy and/or diagnostic imaging. An example of a radiopharmaceutical, which may be used for example in positron emission tomography, is Rubidium-82 (^{82}Rb) (paragraph [0002] of the patent specification).

1.2 An example of a system according to claim 1 of the main request is shown in Figure 1D, reproduced below. The system comprises a pump, such as a syringe pump (33),

for pumping eluant, such as saline solution, from a reservoir (15); a radioisotope generator (21), through which the eluant is pumped to produce a radioactive eluate; an activity detector (25) for measuring the activity of the eluate discharged from the generator (21); and a computer which, based on the feedback provided by the activity detector, controls the pump and several valves (35BG, 35WAP) to control the liquid flow within the tubing circuit (300) and to direct the eluate either to a waste bottle (23) or to a patient line (305P), for example to inject a dose of the radioactive eluate into a patient (paragraphs [0015] to [0018]).

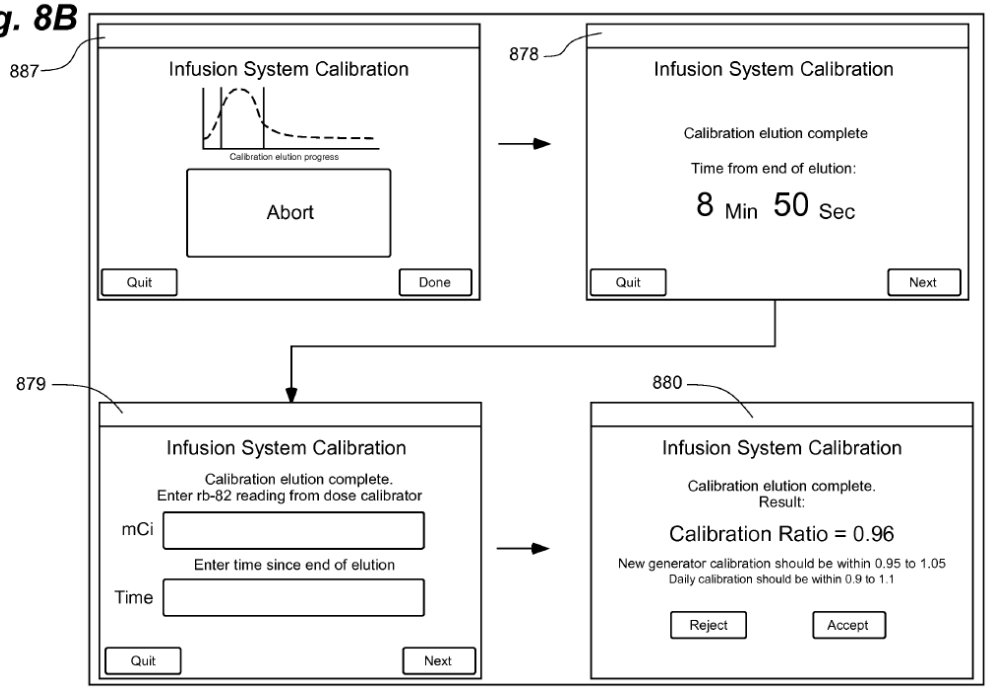
Fig. 1D



1.3 As described in paragraphs [0055] and [0056] with reference to Figure 8A and Figure 8B, reproduced below, the claimed system is configured to allow a user to perform a calibration. For this purpose, the user can start a calibration elution, during which a sample of the radioactive eluate is collected in a test vial attached to the patient line (see screen 887 in

Figure 8B). Upon completion of the elution process, the computer presents a screen 878 indicating the time lapse since completion of the elution, based on a timer. The user can then transfer the vial containing the sample to a dose calibrator to measure its activity, while noting the time lapse displayed on screen 878 at the time of the measurement. Once the user has received the activity measure from the dose calibrator, the user proceeds to a screen 879 which includes data entry fields for the measured activity and the noted time lapse, relative to the completion of elution, at which the dose calibrator measured the activity of the sample. Once the data has been entered by the user, the computer calculates a calibration coefficient, or ratio, and displays it on a screen 880.

Fig. 8B



2. Admittance of the main request and the first auxiliary request

2.1 Reordering claim requests in the appeal proceedings constitutes an amendment of the patent proprietor's appeal case (as to Article 13(2) RPBA, see T 1436/19, Reasons 1.2; T 716/17, Reasons 9 and T 830/19, Reasons 2.2.1). A reordering of claim requests can become particularly problematic if it leads to a situation, as in this case after the first reordering by the patent proprietor, where none of the claim requests on which the decision under appeal is based will likely be reviewed by the Board, contrary to the primary objective of the appeal proceedings pursuant to Article 12(2) RPBA. This can be exacerbated if the Board, again as in this case, issued a negative preliminary opinion on the claim request on which the decision under appeal is based and envisaged remitting the case to the opposition division for further prosecution on the basis of a lower-ranking request. In such a situation, a reordering of claim requests may disadvantage the opponent in that the reordering prevents the Board from issuing a negative decision on the claim request on which the decision under appeal is based although that claim request is not withdrawn, not even conditionally (for example, provided that the claim request put before it is admitted into the appeal proceedings), thus making it easier for this claim request to be relied on again in the continued opposition proceedings. For these reasons, the Board indicated that it intended not to admit the claim request which had been put, due to the first reordering by the patent proprietor, after the claim request on the basis of which the Board, as indicated in its communication under Article 15(1) RPBA, envisaged remitting the case to the opposition division for further prosecution.

2.2 The patent proprietor then changed the order of its claim requests a second time, thus restoring the original order of claim requests in its statement of grounds of appeal and allowing the Board to rule on the request on which the decision under appeal is based. This second reordering constitutes a further amendment of the patent proprietor's appeal case under Article 13(2) RPBA. In view of that amendment, the admittance of both claim requests affected by the reordering is subject to Article 13(2) RPBA. Having said this, the second reordering did not raise any issues other than those which had already been discussed in the parties' initial written submissions and in the Board's communication under Article 15(1) RPBA. The opponent did not raise an objection against the second reordering as such either. It confirmed, however, its request, initially made in its reply to the patent proprietor's statement of grounds of appeal, that the (then again) first auxiliary request not be admitted.

2.3 After the second reordering, the main request is again identical to the main request on which the decision under appeal was based. Although this was only (re)established after two amendments of the patent proprietor's appeal case, the Board saw in view of Article 12(2) RPBA no reason not to take the main request into account.

2.4 The first auxiliary request was filed for the first time on appeal but differs from the first auxiliary request on which the decision under appeal was based only on account of a minor amendment clarifying that the calculation of the calibration coefficient is also based on the received time lapse, as defined in claim 1 of the main request. As explained by the patent

proprietor, this amendment was prompted by the objection under Article 83 EPC which had been raised against claim 1 of the main request for the first time during the oral proceedings before the opposition division. As set out in point 3.2 of the Board's communication under Article 15(1) RPBA, the amendment merely brings claim 1 of the first-instance auxiliary request 1 in line with claim 1 of the main request and, contrary to the opponent's argument, does not raise any new issues. For the same considerations as discussed in the Board's communication for the main request, the invention as claimed in the first auxiliary request also appeared to be sufficiently disclosed. Moreover, as also indicated in point 3.1 of the Board's communication, the clarity objection that the Board had raised against claim 1 of the main request appeared to be resolved in the first auxiliary request.

2.5 For these reasons, there were exceptional circumstances under Article 13(2) RPBA which justified taking into account the main request and the first auxiliary request.

3. Main request - clarity

3.1 Claim 1 of the main request specifies that the "calibration coefficient for the infusion system" is calculated by the computer "based on the received activity and the received time lapse", i.e. based on the single activity value of the eluate sample measured by a dose calibrator and the time elapsed between this measurement and the completion of the elution of the sample.

3.2 It is common ground that the claimed calibration coefficient, in addition to being based on the received

activity measured by a dose calibrator, must also be based in some way on the output of the activity detector coupled to the eluate line which is defined earlier in the claim as part of the infusion system. In this way, the calibration coefficient can provide an indication of whether the infusion system is properly calibrated, namely whether the expected activity of a sample eluted by the system, as determined on the basis of the activity measurements of the activity detector, corresponds to the activity actually measured by a dose calibrator.

However, as the Board objected to in its communication under Article 15(1) RPBA, claim 1 does not define to what extent - and indeed whether at all - the output of the activity detector is used in the calculation. When discussing sufficiency of disclosure, the opposition division referred to "many" possible options. For example, the computer could use the whole series of measurements detected by the activity detector over the elution of the sample, i.e. an activity profile, or only a part of it, or even a single measurement at a certain time, for example, at the very end of the elution, as suggested by the opposition division. In the absence of any detail in claim 1, all these possibilities can be envisaged when reading claim 1. While this does not in itself lead to a lack of sufficiency of disclosure, it makes the scope of protection unclear.

Contrary to the patent proprietor's argument, the fact that the activity measurement with the dose calibrator and the subsequent calculation of the calibration coefficient are carried out after the elution of the sample has been completed does not shed any light, even implicitly, on the above question.

It follows that claim 1 of the main request is not clear.

3.3 This lack of clarity has been introduced by the amendments made to claim 1 as granted, which do not consist in the mere combination of granted claims. It is therefore open to an objection under Article 84 EPC, in accordance with G 3/14 (see catchword). For this reason, the main request is not allowable.

4. First auxiliary request

4.1 Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the computer is arranged to additionally "detect, via the activity detector (25), an activity of the sample during elution of the sample" and to calculate the calibration coefficient based not only on the received activity and the received time lapse, as defined in the main request, but also on "the activity of the eluate detected during elution of the sample".

4.2 Clarity

Contrary to the opponent's view, claim 1 of auxiliary request 1 is clear.

4.2.1 The opponent argued that by referring to "an activity" of the sample being detected by the detector, claim 1 of auxiliary request 1 suggested that the detector could, like the dose calibrator, detect a single activity of the sample. Hence, "the activity" of the eluate used to calculate the calibration coefficient as further claimed may not refer to an activity profile, as considered by the Board in its communication, but to

that single measurement. The ambiguity raised by the Board was thus not overcome.

The Board disagrees. In contrast to the single activity obtained from the dose calibrator, which is measured at a certain time - namely at a certain time lapse determined on the basis of a timer started by the computer - claim 1 specifies that the computer, via the activity detector, detects the activity of the sample "during elution of the sample", without any reference to a specific time or to a timer.

Similarly, whereas according to claim 1 the calculation of the calibration coefficient is explicitly based on both the activity measured with the dose calibrator and the time lapse at which this measurement was made, the computer calculates the calibration coefficient based on "the activity of the eluate detected during elution of the sample" again without relying on a specific time.

The person skilled in the art would therefore understand from the wording of claim 1 that, in the context of the claimed invention, "the activity of the eluate detected during elution of the sample" actually refers to the activity detected via the detector as the eluate flows past the detector to accumulate in the test vial and form the sample until completion of the elution process, i.e. an activity profile detected over the duration of the elution of the sample, and not to a single activity value.

The Board is thus satisfied that by excluding the other alternatives mentioned in point 3.2 above, the amendments made in the first auxiliary request resolve

the clarity objection raised by the Board against the main request.

4.2.2 The opponent also argued that claim 1 of the first auxiliary request was unclear because it did not define various other parameters or features which, according to the opponent, were also essential for defining the calculation of the calibration coefficient. The Board disagrees.

The opponent objected that claim 1 was silent on the flow rate used to elute the sample. This objection is not convincing. This flow rate, whether constant or varying over the duration of the elution, results from the activation of the pump by the computer as defined in claim 1. It is inherently included in the activity detected via the activity detector during the elution of the sample since the activity detected by the detector is the activity of the eluate, i.e. an extensive quantity which varies with the amount of radioactive material passing by the detector and thus with the flow rate used to elute the sample. Therefore, the fact that claim 1 does not explicitly state that the calculation of the calibration coefficient is also based on the flow rate used to elute the sample is not detrimental to clarity.

Furthermore, as discussed for sufficiency of disclosure (see point 4.3.5 below), the flow rate or flow rate profile used to elute the sample may have an influence on the quality of the calibration coefficient calculated by the system. However, this aspect relates to the meaningfulness of that calibration coefficient, but it does not *per se* render claim 1 unclear. Therefore, the fact that claim 1 does not specify a particular value or range of flow rate at which the

calibration coefficient is to be calculated is not detrimental to clarity either.

The opponent has not convincingly argued that other parameters or features essential to the definition of the calculation of the calibration coefficient have been omitted from claim 1, and the Board sees none.

4.3 Sufficiency of disclosure

4.3.1 Contrary to the opponent's view, the invention as claimed in the first auxiliary request is disclosed in the contested patent in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

4.3.2 Claim 1

4.3.3 The opponent objected that the very limited information provided in the contested patent on the calculation of the calibration coefficient would not enable a person skilled in the art to implement it in an infusion system as claimed in claim 1 without undue burden, even using common general knowledge. This is not convincing.

It is common ground that the person skilled in the art would recognise that the calibration coefficient defined in claim 1 - also referred to as a ratio in paragraph [0056] of the patent specification - should relate two quantities of the same nature.

Based on their understanding of the purpose of a calibration coefficient or ratio (see point 3.2 above) and their common general knowledge, the person skilled in the art seeking to implement the calculation of such a coefficient would consider it a straightforward

option to compare the single activity value of the collected sample actually measured with the dose calibrator (the "received activity") with the expected single activity value of that sample, namely that derived from the activity of the eluate detected via the activity detector as the eluate passes by the detector on its way to the test vial where it accumulates, i.e. the activity profile detected by the detector over the duration of the elution of the sample (see point 4.2.1 above). These two single activity values would be equal, i.e. their ratio would be equal to 1, if the infusion system, in particular the activity detector, were perfectly calibrated with respect to the dose calibrator.

Contrary to the opponent's argument, the person skilled in the art would be well aware of the need to take account of the exponential decay of the radioisotope with time, which implies, *inter alia*, that the two activity values of the sample to be compared must be appropriately decay corrected to be equivalent and comparable. Indeed, it is well known that the activity $A(t)$ of a sample of eluate containing a radioisotope decreases exponentially with time t according to the rule $A(t)= A_0.e^{-\lambda t}$, where A_0 is the activity of the sample at time $t=0$ and λ is the decay constant of the radioisotope. This was recognised by the opposition division (see the antepenultimate paragraph on page 13 of the decision under appeal), which itself used this rule to decay correct the activity of a volume of eluate (see the second paragraph on page 16).

As argued by the patent proprietor, the person skilled in the art would be aware that the expected single activity value of the sample could be calculated from the activity detector measurements by integration over

the duration of the elution of the sample, reflecting the fact that the sample is formed by the accumulation of eluate in the test vial. At the same time, they would be aware that the decay of the eluate from when it passes through the activity detector until the sample activity is measured by the dose calibrator (i.e. firstly, during the transport of the eluate to the test vial and its accumulation there until the completion of the elution of the sample and secondly, between this completion and the actual measurement by the dose calibrator, i.e. during the "received time lapse") would have to be taken into account to produce an expected activity value of the sample which is equivalent and comparable to that measured with the dose calibrator. The person skilled in the art would know that this could involve the convolution of the integrated activity measurement of the detector with an exponential decay factor.

The Board agrees with the patent proprietor that the steps outlined above amount to mathematical operations which would be well known to the person skilled in the art, particularly one skilled in radioisotope delivery systems. Thus, the person skilled in the art would be able to implement the calculation of a calibration coefficient as set out above without undue burden, using their common general knowledge.

The opponent's other arguments to the contrary are not convincing, as will be discussed below.

4.3.4 The fact that there might be other possible options for calculating the calibration coefficient, as suggested by the opponent and the opposition division in the decision under appeal, for example, with reference to D4 and D8, is in itself irrelevant since this would not

prevent the person skilled in the art from being able to implement the option discussed above.

In any event, when calculating the expected single activity value of the sample from the activity profile measured by the activity detector, the person skilled in the art would not take into account only those measurements detected at the very end of the elution, as suggested by the opposition division. This would lead to calibrating the detector in a range of activity which neglects the higher contribution of the bolus peak, which is normally the main contribution to the radioactive dose infused into the patient. The person skilled in the art would be aware of that and would therefore refrain from using such an approach to assess the calibration of the activity detector.

4.3.5 The opponent also objected that the person skilled in the art was completely left in the dark as to the flow rate at which the sample should be eluted. The opponent referred to Figure 5 of D5, which according to the opponent demonstrated that the flow rate used to elute a sample had a large influence on the calculated activity.

This argument is not convincing. As discussed in point 4.2.2 above, the flow rate used to elute the sample, whether constant or varying over the duration of the elution, is already taken into account implicitly in the calculation of the calibration coefficient via the activity of the eluate detected by the activity detector during the elution of the sample, which varies with the amount of radioactive material passing by the detector and thus with the flow rate used to elute the sample.

Figure 5 of D5 can at most indicate a possible discrepancy at lower flow rates between the calculated activity - when using the calculation scheme described in D5, on which the opponent has not commented - and the activity as measured by a dose calibrator. To the extent that this conclusion would also apply to the claimed calculation of the calibration coefficient, it would only show that the quality of the calibration coefficient, and thus its meaningfulness, may depend on the flow rate used to elute the sample. However, as shown in Figure 5 of D5, the person skilled in the art would be able to directly identify and exclude those flow rates for which the calculated calibration coefficient would not be meaningful. Therefore, this possible influence of the flow rate does not render the claimed invention insufficiently disclosed.

4.3.6 The opponent also objected that the contested patent did not provide any details on the dose calibrator mentioned in claim 1 and that, in any event, there was a physical time limit after which no calibration could be performed using a dose calibrator due to the exponential decay of the activity of the sample. Since claim 1 did not contain such a time limitation, it followed, according to the opponent, that the claimed invention was not sufficiently disclosed over the whole scope of claim 1.

This argument is also unconvincing. As argued by the patent proprietor, the person skilled in the art would have no undue burden in selecting a suitable dose calibrator with a working range and sensibility adapted to measure the activity of the sample, essentially depending on the half-life of the radiopharmaceutical used.

The person skilled in the art would be aware that measuring the activity of the sample with a dose calibrator a long time after the sample has been eluted would require the dose calibrator to be sufficiently sensitive since, as pointed out by the opponent, the activity of the sample will have decayed in the meantime, possibly significantly. The activity of the radioisotope of interest may even have become of the same order of magnitude as the breakthrough activity, making a meaningful calibration impossible. Conversely, the person skilled in the art would be aware that the range and sensitivity of a given dose calibrator will impose certain limits on the received time lapse, i.e. on the use of the system, to make the measurement of the sample activity, and hence the calculation of a calibration coefficient, feasible and meaningful.

However, the fact that an embodiment of the claimed system may not work in certain specific situations does not render the claimed invention insufficiently disclosed, provided that the person skilled in the art is able to identify and exclude those non-working setups upon consideration of the disclosure of the patent and, where appropriate, using common general knowledge. The Board considers that, as discussed above, this is the case here for the infusion system of claim 1.

4.3.7 Claim 13

The objection of insufficient disclosure raised by the opponent in points 89 to 93 of its statement of grounds of appeal against claim 11 of the first-instance auxiliary request 4 also applies to claim 13 of the first auxiliary request, which is identical.

However, as stated in the Board's communication under Article 15(1) RPBA (point 2.2), this objection is not convincing. As held by the opposition division in the decision under appeal (Reasons II.8.2), the specification of the contested patent provides the person skilled in the art with sufficient guidance to put into practice the subject-matter of this claim.

The opponent did not provide any further argument in its subsequent written submission or during the oral proceedings before the Board.

5. Remittal to the opposition division

Apart from a short note on inventive step which is marked as "not relevant to the present decision" (see Reasons 4.1.7), the decision under appeal does not contain any reasoning on novelty or inventive step for the main request and the then first auxiliary request on which the current first auxiliary request is based.

Moreover, the opposition division's findings on novelty and inventive step for the lower-ranking requests in the contested decision relate to other features which are not defined in claim 1 of the first auxiliary request. Those features, and the corresponding technical problems formulated in relation to them, do not relate to the calibration of the system as addressed by the current first auxiliary request but to the different problem of projecting a light signal to indicate that elution is taking place, which could be dangerous for people in the vicinity of the system.

In view of the primary object of the appeal proceedings, which is to review the decision under appeal in a judicial manner (Article 12(2) RPBA), the

Board therefore considers that there are special reasons under Article 11 RPBA for remitting the case to the opposition division for further prosecution under Article 111(1) EPC.

This conclusion is in line with the preliminary view of the Board expressed in its communication under Article 15(1) RPBA (point 4). At the oral proceedings before the Board, the parties did not contest the Board's intention to remit the case to the opposition division.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated