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Datasheet for the decision of 31 March 2015

Case Number: T 0335/14 - 3.2.02

Application Number: 02079213.1

Publication Number: 1277485

IPC: A61M1/28

Language of the proceedings: EN

Title of invention:
System for infusion of a plurality of solutions to a peritoneal cavity of a patient

Patent Proprietor:
Baxter International Inc.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 83, 84, 54(1), 54(2), 56

Keyword:
Clarity (yes)
Sufficiency of disclosure (yes)
Novelty (yes)
Inventive step (yes)

Decisions cited:
T 2350/09

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Case Number: T 0335/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 31 March 2015

Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Herrmann, Uwe Lorenz - Seidler - Gossel Widenmayerstrasse 23 80538 München (DE)
Respondent: (Patent Proprietor)	Baxter International Inc. One Baxter Parkway Deerfield, Illinois 60015 (US)
Representative:	Potter Clarkson LLP The Belgrave Centre Talbot Street Nottingham, NG1 5GG (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 10 December 2013 concerning maintenance of the European patent No. 1277485 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	M. Stern
	P. L. P. Weber

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision of the Opposition Division concerning maintenance of European patent No. 1 277 485 in amended form. In the decision under appeal it was held that the amended patent satisfied the requirements of Articles 84, 100(b), 54 and 56 EPC.

II. Notice of appeal was filed on 6 February 2014 and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 3 April 2014.

III. In an earlier decision concerning the present opposition, T 2350/09, the Board held that claim 1 (of the main request underlying the decision now under appeal) satisfied the requirement of Article 76(1) EPC.

IV. The following documents are relevant for the present decision:

D2: WO-A-94/20 158
D3: US-A-5 091 094
D10: US-A-5 141 492
D11: WO-A-92/18 048
D11a: German translation of D11.

V. Oral proceedings were held on 31 March 2015.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed or, in the alternative, that the

decision under appeal be set aside and that the patent be maintained on the basis of one of the first to fifth auxiliary requests filed with letter dated 21 August 2014.

VI. Claim 1 of the main request (the same as claim 1 underlying the decision under appeal) reads as follows:

"1. A system (1) for infusion of a plurality of solutions to a peritoneal cavity of a patient, the system comprising:

means for storing each of the plurality of solutions in a plurality of separate containers (10a, 10b, 10(n-1), 10n);

input means (52) for inputting an amount of each of the plurality of solutions required for delivery to the peritoneal cavity of the patient; and

pumping means for pumping each of the plurality of solutions directly to the peritoneal cavity of the patient including first and second pumps (12, 14), a first set of supply valves (16a to 16c) operatively connected to the first pump and a second set of supply valves (20a to 20c) operatively connected to the second pump, each pump being connected to each of the plurality of containers via its supply valves in such a manner that either pump may be used to pump solution from each of said containers."

Claims 2 to 11 of the main request are dependent claims.

The first to fifth auxiliary requests are not relevant for the present decision.

VII. The arguments of the appellant-opponent relevant for the present decision are summarised as follows:

(i) Clarity

In claim 1 the terms "first set of supply valves" and "second set of supply valves" did not clearly define that the first and second sets of supply valves were indeed different sets of supply valves, as the Board had established in T 2350/09 (points 4.2.1 and 4.2.2) when assessing compliance with Article 76(1) EPC. Since two sets of elements could overlap, thereby sharing some of their elements, the claim did not exclude the possibility that the two sets of supply valves partially overlapped. Moreover, claim 1 failed to explicitly define that the number of supply valves in each set was equal to the number of solution containers, a feature which the Board had considered in T 2350/09 (point 4.2.3) to be implicitly defined in the claim.

Paragraphs [0061] and [0078] of the description of the patent were not properly adapted to claim 1 of the main request. In paragraph [0061], two options were mentioned, one being direct infusion into the peritoneal cavity of a patient. This latter option contradicted claim 1 which explicitly defined the direct infusion. Paragraph [0078] (lines 29 to 33 on column 9) also contradicted claim 1 in that it explained that the fluids were mixed in a solution bag before being infused into the patient.

(ii) Sufficiency of disclosure

Dependent claim 5 defined an embodiment in which the solutions were received in storage means for mixing prior to delivery to the peritoneal cavity of the patient. It hence contradicted what claim 1 defined, namely the pumping of the solutions directly to the

patient. In all embodiments disclosed in the patent, only a single fluid exit line was provided, to which either the patient or the intermediate storage container could be connected.

The simultaneous pumping of more than two solutions to the peritoneal cavity of the patient according to dependent claim 2 had not been disclosed. It appeared in fact impossible to simultaneously pump more than two solutions with only two pumps.

(iii) Novelty

Claim 1 did not define the method of pumping solutions directly into the patient, but merely the suitability of the pumping means to do so. D2 anticipated the features of claim 1, in particular the contested features of "input means for inputting an amount of each of the plurality of solutions" and of "pumping means (which were suitable) for pumping each of the plurality of solutions directly to the peritoneal cavity of the patient". Although the system in D2 was disclosed with an intermediate heating bag from which the dialysis solutions were pumped to the patient, the system also enabled the patient to be connected directly to the connector for the heating bag, whereby solutions could be pumped directly from the fluid containers to the patient. This would not result in any severe risk for the patient. Moreover, the system according to claim 5 of the patent was no different since it also provided an intermediate fluid mixing container.

(iv) Inventive step

Document D2 was the closest prior art. The system of claim 1 differed from D2 in that it was a system for infusion of solutions directly to the peritoneal cavity of the patient comprising pumping means for pumping each of the plurality of solutions directly to the peritoneal cavity of the patient. The elimination of the heater bag of D2 did not have any technical effect, so that the objective technical problem was the search for an alternative means to heat the fluid solutions before infusion into the patient, without the need for a heater bag. The claimed system was therefore inferior to that of D2 and, as such, did not involve an inventive step. Documents D10 and D11 too disclosed similar alternative systems in which the heating of the peritoneal solutions was performed at or close to the solution containers. Alternatively, also D3 provided an inline heater in a hemodialysis system. It was hence obvious to incorporate any of the alternative heating means of D10, D11 or D3 into the system of D2, thereby obtaining a system with pumping means for pumping solutions directly (that is, without a heater bag) to the peritoneal cavity of the patient as claimed. It was also obvious to depart from any of the peritoneal dialysis systems of D10 and D11, and to provide these systems with the pumping system of D2.

VIII. The arguments of the respondent-proprietor relevant for the present decision are summarised as follows:

(i) Clarity

The Board had already given a decision on the clarity of claim 1 in its first decision concerning the present case (T 2350/09), since it had admitted claim 1 into the proceedings and found it compliant with Article 76(1) EPC. Clarity was therefore res judicata.

Moreover, the arguments by the appellant that certain essential limitations were missing from claim 1 was nothing more than a disguised added-matter objection which had already been decided by the Board.

Paragraphs [0061] and [0078] of the patent description did not contradict the definition of the system of claim 1. Paragraph [0061] mentioned two options for the infusion of fluids into the patient, direct infusion into the peritoneal cavity of a patient and the mixing of fluids in an intermediate container before administration to the patient. These two options were two different methods which the claimed system was capable of carrying out. Paragraph [0078] also referred to the specific option of mixing the fluids in a solution bag before being infused into the patient, which was compatible with the invention as claimed.

(ii) Sufficiency of disclosure

The Opponent had not presented any substantive arguments in support of its objection of insufficiency in its notice of opposition. Therefore, this ground should not be available now as a ground for opposition. In any case, the patent specification described at least one embodiment in which the features of dependent claims 2 and 5 were realised. For example, regarding claim 5, Figure 5 and paragraph [0078] explained the capability of the system to draw fluids from the containers and to either mix them intermediately in a solution bag 54 before infusion into the patient or to infuse them directly into the patient. Regarding claim 2, paragraph [0055] explained that in the embodiment of Figure 1 only two of the three containers could contain components required to be administered to

the patient. These two solutions constituted a plurality of solutions as claimed.

(iii) Novelty

Claim 1 defined a system having pumping means for infusing solutions directly to the peritoneal cavity of the patient. Therefore the entire claimed system had the capability of infusing solutions directly to the patient. This was not contradicted by the fact that, according to dependent claim 5, the system had the additional capability of pumping solutions through an intermediate mixing container. The system of D2 did not disclose connecting the patient directly to the connector 38 for attachment of the heating bag so as to pump solutions directly into the patient. Such a connection would in fact be an improper utilisation of the peritoneal dialysis system disclosed in D2. For example, outside the patient the liquid was circulated in a "high-relative pressure mode", but for the patient's safety and comfort the liquid was circulated in a "low-relative pressure mode" when circulated directly to the patient's indwelling catheter (page 37, line 34 to page 38, line 13). Moreover, D2 highlighted the need to isolate the patient's peritoneal cavity from the air that the pump chambers P1/P2 collected (page 22, lines 12 to 18). For this, the cassette 24 deliberately provided certain "critical" air-free paths to convey liquid directly into and from the patient's peritoneal cavity (page 22, lines 19 to 26; page 22, line 35 to page 23, line 5). A further differentiating feature over D2 was the "input means" of claim 1, since the user interface 367 in D2 did not allow inputting an amount of each of the solutions as claimed.

(iv) Inventive step

The system of claim 1 differed from the closest prior-art document D2 at least in that the system was suited for infusion of solutions directly to the peritoneal cavity of the patient since it comprised pumping means for pumping each of the plurality of solutions directly to the peritoneal cavity of the patient. The elimination of the heater bag of D2 had the technical effect of simplifying the system and allowing easier operation by the patient. However, the system of D2, in particular the controller and its programming, was devised to work in conjunction with the heater bag. Documents D10 and D11 concerned hydrostatic systems, in which fluids were transported under the effect of gravity rather than by the action of any fluid pumps. Therefore, it would not have been obvious for the skilled person attempting to simplify the system of D2 to just incorporate into D2 the heating system disclosed in D10 or D11 (thus dispensing with the heater bag of D2), without however dispensing with the pumps of D2 as well. D3 concerned a hemodialysis system, thus of an entirely different construction to that of a peritoneal dialysis system as in D2. Hence, for similar reasons, it was not obvious to incorporate the inline heater disclosed in D3 into the peritoneal system of D2. Moreover, departing from the more remote hydrostatic systems of D10 or D11, and combining any of these with the pump-driven system of D2 (which included a heater bag), the skilled person would not have arrived at the claimed subject-matter either.

Reasons for the Decision

1. The appeal is admissible.

2. The patent

2.1 The patent in suit concerns a peritoneal dialysis system comprising, in essence, a plurality of containers with solutions and pumping means having two pumps and two different sets of supply valves, each of said pumps being connected to each of the containers via its supply valves for pumping a solution from each of the containers into the peritoneal cavity of the patient.

2.2 As explained in paragraphs [0007] and [0009] of the patent specification, in peritoneal dialysis it is often desirable to obtain a mixture of solutions which is delivered to the patient either directly or after passing the solutions through an intermediate mixing container. These two options are presented in the embodiment of Figure 5, wherein item 54 is either a solution bag or the patient himself (column 9, lines 29 to 33), and in the embodiments of Figures 1 and 2, where, at the bottom of these figures, the fluid flow "to patient/container" is indicated. Moreover, according to Figure 3 (column 7, lines 3 to 14), the solutions are first pumped into an intermediate storage container (130, 130'), whereafter the mixed fluid is pumped into the patient (160).

3. Clarity - Article 84 EPC

3.1 Claim 1 of the main request is the same as claim 1 of the "First Auxiliary Request" filed in the first appeal proceedings concerning the present opposition, T 2350/09. In that decision, the Board held that the claim was admissible in spite of its late filing, during the oral proceedings, and that it complied with the requirements concerning added subject-matter of

Article 76(1) EPC (points 4.1 to 4.2.4). The case was then remitted to the department of first instance for further consideration of all further requirements of the EPC (points 5 to 5.4).

Consequently, and contrary to the view expressed by the respondent, no decision on clarity had been given in that first decision, so that the clarity objections raised by the appellant before the Opposition Division after remittal and in the present appeal proceedings are indeed for the Board now to decide upon.

3.2 The appellant objected that in claim 1 the terms "first set of supply valves" and "second set of supply valves" did not clearly define that the first and second sets of supply valves were indeed different sets of supply valves, as the Board established in T 2350/09 when assessing compliance with Article 76(1) EPC (points 4.2.1 and 4.2.2). The appellant argued that since two sets of elements could overlap, thereby sharing some of their elements, the claim did not exclude the possibility that the two sets of supply valves partially overlapped.

It is correct to say that in a general, mathematical sense, two sets of elements may well overlap and share some of their elements. However, for the presently claimed peritoneal dialysis system, an overlap of supply valves is to be excluded since the claim defines that the first set of supply valves is connected to the first pump and the second set of supply valves is connected to the second pump, and that each pump is connected to each of the plurality of containers via *its supply valves* in such a manner that either pump may be used to pump solution from each of said containers. It would hence be an improper claim interpretation to

consider that the two sets of valves share some or all of their valves. There is consequently no need for the claim to exclude such an improper interpretation.

3.3 The appellant saw a further clarity deficiency in that claim 1 failed to explicitly define that the number of supply valves in each set was equal to the number of containers, a feature which the Board considered in T 2350/09 to be implicitly defined (point 4.2.3). The Board therefore considers that the explicit recitation of something which is implicit is not required as it amounts to a mere tautology.

4. Sufficiency of disclosure - Article 83 EPC

4.1 The respondent requested the Board not to admit the objection of sufficiency of disclosure since it had not been substantiated in the notice of opposition.

However, the ground for opposition of Article 100(b) EPC had been admitted by the Opposition Division and even decided upon in the impugned decision (point 9). The Board therefore considers that the ground of sufficiency of disclosure is indeed part of the present appeal, albeit under Article 83 EPC since claim 1 of the main request contains amendments to claim 1 of the patent as granted.

4.2 Whilst claim 1 defines the suitability of the claimed *"pumping means for pumping each of the plurality of solutions directly to the peritoneal cavity of the patient"*, dependent claim 5 defines a preferred embodiment *"further comprising storage means receiving each of the plurality of solutions for mixing prior to delivery to the peritoneal cavity of the patient"*. Contrary to the appellant's view, the patent discloses

an embodiment, shown in Figure 5 and described in paragraph [0078], in which the fluids drawn from the containers may be mixed intermediately in a solution bag (54) before infusion into the patient, or may be infused directly into the patient. Hence, the Board considers that the skilled person finds sufficient information in the patent specification for carrying out the embodiment defined in dependent claim 5.

4.3 Dependent claim 2 defines a preferred embodiment of the system of claim 1, wherein "*the pumping means is adapted to simultaneously pump each of the solutions to the peritoneal cavity of the patient*".

The appellant appears to question the feasibility of simultaneously pumping *more* than two solutions to the peritoneal cavity of the patient using two pumps, without however raising doubts about the feasibility of simultaneously pumping two solutions to the patient. In view of the fact that two solutions constitute a "plurality of solutions" as defined in claims 1 and 2, the feasibility of at least one embodiment falling under the terms of claim 2 is not contested. In fact, in relation to the embodiment of Figure 1, the patent specification explains in paragraph [0055] that only two of the three containers may contain components required to be administered to the patient. The fact that further subject-matter encompassed by the wording of dependent claim 2 may not have been (sufficiently) disclosed is no valid reason for concluding that the subject-matter of claim 2 is insufficiently disclosed, as argued by the appellant.

4.4 The Board therefore finds that the subject-matter of dependent claims 2 and 5 satisfies the requirements of Article 83 EPC.

5. Novelty - Article 54(1) and (2) EPC

5.1 Document D2 (cited in paragraph [0008] of the patent in suit) discloses a peritoneal dialysis system (Figure 1) in which solutions from bags 20 are pumped into a heater bag 22 by pumping means (within cassette 24) comprising two pumps P1 and P2, and are then pumped from the heater bag 22 into the patient (page 15, lines 16 to 20; page 17, lines 3 to 9; page 17, line 27 to page 18, line 4; page 67, lines 18 to 20). The detailed architecture of the pumps P1 and P2 with their respective sets of supply valves is shown in Figure 24 and described mainly on page 42, line 26 to page 43, line 19; page 47, lines 11 to 21. The pumps pump either a normal dialysis solution from bags 20 (attached to supply port 33 in Figure 8A; page 70, lines 13 to 15) or a "last fill" solution from a "last fill" bag (attached to last-bag port 31 in Figure 8A; page 75, lines 32 to 35). This "last fill" bag contains a solution different from the normal dialysis solution in bags 20 (page 75, lines 26 to 31).

5.2 The system of D2 also has a user interface 367 (Figures 1 and 2) which allows the user to enter therapy parameters (page 55, lines 1 to 3), for example the volume to be infused during each fill phase and the "last fill volume" (page 56, lines 21 to 35). Specifying these individual volumes from each of the respective fluid bags (normal dialysis solution from bag 20 or "last fill" solution from "last fill" bag) amounts to *"inputting an amount of each of the plurality of solutions"* as defined in claim 1.

5.3 It is not disputed between the parties that in D2 the different dialysis solutions are pumped from the respective container bag into a heater bag 22, and from

there into the patient. That is, D2 does not disclose the pumping of the solutions **directly** to the peritoneal cavity of the patient, as defined in claim 1. More specifically, claim 1 defines *"pumping means for pumping each of the plurality of solutions* ***directly*** *to the peritoneal cavity of the patient"*.

Strictly speaking, this definition just refers to the suitability of the pumping means for infusing solutions directly into the patient. However, a dialysis system comprising these pumping means can only be reasonably interpreted as a system which as a whole has this suitability. This conclusion is in no way invalidated or contradicted by the fact that the system, in a preferred embodiment defined in dependent claim 5, has the additional capability of pumping solutions through an intermediate mixing container (points 2.2 and 4.2 above).

Hence, the Board finds that claim 1 is to be interpreted as defining a system for infusion of a plurality of solutions directly to the peritoneal cavity of the patient.

5.4 The appellant argued that the system of D2 would be suitable for connecting the patient directly to the connector for attachment of the heating bag, whereby solutions would be pumped directly from the fluid containers to the patient.

For the following reasons, the Board cannot accept this argument since such a connection would go against a proper utilisation of the peritoneal dialysis system as disclosed in D2.

It is firstly not disclosed in D2 (and indeed highly doubtful) whether the conventional connectors 38 for attachment with a bag port would also allow the attachment with a conventional connector 36 on the patient's indwelling catheter 18 (Figure 1; page 15, lines 21 to 25). Actually, the different schematic presentation of the connectors 38 for attachment of the bags on the one hand and the connector 36 for attachment of the patient catheter on the other hand casts serious doubts on the validity of the appellant's assertion. Moreover, for the following patient safety and comfort reasons it appears implausible that the system would allow an inadvertent wrong connection by the user.

Document D2 highlights several parameters which are different for the pumping of liquid to the heater bag and for the injection of liquid into the patient. For example, whilst for speedy processing the liquid is circulated outside the patient in a "high-relative pressure mode", for the patient's safety and comfort, however, the liquid is circulated in a "low-relative pressure mode" when circulated directly to the patient's indwelling catheter (page 37, line 34 to page 38, line 13). Moreover, D2 highlights the need to isolate the patient's peritoneal cavity from the air that the pump chambers P1/P2 collect (page 22, lines 12 to 18). For this, the cassette 24 deliberately provides certain "critical" air-free paths to convey liquid directly into and from the patient's peritoneal cavity (page 22, lines 19 to 26; page 22, line 35 to page 23, line 5).

5.5 The Board therefore concludes that the system of D2 is not suitable for infusion of solutions directly to the peritoneal cavity of the patient.

5.6 Consequently, claim 1 satisfies the requirement of novelty of Article 54(1) EPC.

6. Inventive step - Article 56 EPC

6.1 It is common ground that document D2 constitutes the closest prior art. As explained above, in the peritoneal dialysis system of D2 liquid solutions are pumped from the container bags into a heater bag 22, and from there into the patient. The system of claim 1 instead comprises pumping means for pumping each of the plurality of solutions **directly** to the peritoneal cavity of the patient, whereby the system is suitable for infusion of solutions **directly** to the peritoneal cavity of the patient (point 5.3 above).

6.2 In other words, the system of claim 1 does not rely on a heater bag as in D2. The appellant disputed that the elimination of a heater bag had any technical effect at all, and posited that the objective technical problem was the search for an alternative to heat the fluid solutions before infusion into the patient. However, the respondent seems correct to point out that the technical effect of such a measure would result in a simplified construction, and easier operation by the user.

6.3 The appellant pointed to two peritoneal dialysis systems disclosed in the prior art, D10 and D11, in which the heating of the solutions is performed at or close to the solution containers, without the need to pass the solutions through an additional heating bag. In D10, heating means 74 heat the dialysate containers 72 (column 5, line 65). Similarly, D11 provides a heating unit 11 for heating water container 1 (Figure 1; page 8, last paragraph of D11a).

However, both D10 and D11 concern hydrostatic systems in which fluids are transported under the effect of gravity rather than by the action of any fluid pumps (D10: column 1, lines 19 to 21; column 5, lines 33 to 34; D11a, page 11, third paragraph). Therefore, for the skilled person attempting to simplify the system of D2, it would not be obvious to just incorporate into D2 the heating system disclosed in either D10 or D11, thus dispensing with the heater bag of D2, without however also dispensing with the pumps of D2, since this is the basis for the functioning of the systems of D10 or D11. It seems that it would only be with the benefit of hindsight that the skilled person would pick one element from D10 or D11 (the heater of the container bags) and combine it with other elements of D2 (such as the pumping means including the pumps and their supply valves, as well as the correspondingly programmed controller) which in D10 and D11 are also replaced (by gravity-propelling means).

Hence, from the combination of D2 with either D10 or D11 the skilled person would not arrive in an obvious way at the claimed subject-matter.

6.4 Alternatively, the appellant argued that it would be obvious to replace the heater bag of D2 with the inline flow heater 31 in Figure 6 of D3. However, the system disclosed in D3 is a hemodialysis system rather than a peritoneal dialysis system as in D2, and as such its construction is even more remote than that of the peritoneal dialysis systems of D10 or D11.

Hence, also this combination of documents does not lead the skilled person in an obvious way to the claimed subject-matter.

6.5 In yet further alternative lines of attack, the appellant departed from either D10 or D11 and combined it with D2. However, as indicated above, D10 and D11 concern hydrostatic systems (operating without any active pumping means), whilst D2 relates to a pump-driven system. Therefore, D10 and D11 on the one hand and D2 on the other hand are different, alternative constructions of peritoneal dialysis systems. It is noted that, as explained above, the pumping means of D2 are particularly devised to work in conjunction with the heater bag, so that the provision of the pumping means of D2 in any of the systems of D10 and D11 would not result in a system in which the pumping means are suitable for pumping the solutions directly into the patient.

6.6 The Board therefore concludes that the subject-matter of claim 1 of the main request involves an inventive step in the sense of Article 56 EPC. This is a fortiori so for the preferred embodiments defined in dependent claims 2 to 11.

7. *Adaptation of the description*

7.1 At the end of the oral proceedings, the appellant objected that paragraphs [0061] and [0078] of the description of the patent had not been adequately adapted to claim 1 of the main request.

7.2 In paragraph [0061], two options for the infusion of fluids into the patient are mentioned: direct infusion into the peritoneal cavity of a patient and the mixing of fluids in an intermediate container before administration to the patient. The latter is again mentioned in paragraph [0078] (lines 29 to 33). As explained under points 2.2 and 4.2 above, these two

options merely reflect the two capabilities of the system according to claims 1 and 5.

7.3 Therefore, the Board considers that the passages objected to in the description of the patent do not contradict in any way the subject-matter of the claims of the main request.

8. Since none of the objections raised is an obstacle to allowing the main request, there is no need for the Board to consider the auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated