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Datasheet for the decision of 12 May 2026

Case Number: T 0082/23 - 3.2.02

Application Number: 16761807.3

Publication Number: 3269408

IPC: A61M1/36, A61M1/16

Language of the proceedings: EN

Title of invention:
BLOOD PURIFICATION DEVICE

Patent Proprietor:
Nikkiso Company Limited

Opponent:
Fresenius Medical Care AG

Headword:

Relevant legal provisions:
EPC Art. 56, 123(2)
RPBA 2020 Art. 13(2)

Keyword:
Inventive step - (no)
Amendments - allowable (no)
Amendment after summons - exceptional circumstances (no) - taken into account (no)

Decisions cited:

Catchword:

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Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0082/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 May 2026

Appellant: (Patent Proprietor)	Nikkiso Company Limited 20-3, Ebisu 4-chome Shibuya-ku Tokyo 150-6022 (JP)
Representative:	von Hirschhausen, Helge Grosse - Schumacher - Knauer - von Hirschhausen Patent- und Rechtsanwälte Nymphenburger Straße 14 80335 München (DE)
Appellant: (Opponent)	Fresenius Medical Care AG Else-Kröner-Str. 1 61352 Bad Homburg (DE)
Representative:	Bobbert & Partner Patentanwälte PartmbB Postfach 1252 85422 Erding (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted/ electronically transmitted on 7 November 2022 concerning maintenance of the European Patent No. 3269408 in amended fo rm.**

Composition of the Board:

Chair	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	N. Obrovski

Summary of Facts and Submissions

I. The patent proprietor and the opponent filed appeals against the opposition division's interlocutory decision finding that auxiliary request 1 met the requirements of the EPC.

II. Oral proceedings before the board took place on 12 May 2026.

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

The appellant-proprietor (proprietor) requested that:
- the decision under appeal be set aside and the patent be maintained as granted (main request);
- the opponent's appeal be dismissed and the patent be maintained as upheld by the opposition division (auxiliary request 1);
- the patent be maintained on the basis of one of auxiliary requests 2 to 7 filed with the proprietor's reply to the appeal; or
- the patent be maintained on the basis of one of auxiliary requests 8 to 11 filed by letter of 20 March 2026.

III. Claim 1 of the main request (patent as granted) reads as follows (with feature numbering added in bold by the board):

1.0 "A blood purification apparatus comprising:

1.1 a blood circuit (1) including an arterial blood circuit (1a) to a distal end of which an arterial puncture needle (a) is connectable, and a venous blood circuit (1b) to a distal end of which a venous puncture needle (b) is connectable, the blood circuit (1) being capable of extracorporeally circulating blood of a patient;

1.2 a blood purification device (2) provided between the arterial blood circuit (1a) and the venous blood circuit (1b) of the blood circuit (1) and being capable of purifying the blood flowing through the blood circuit (1);

1.3 a blood pump (3) provided to the arterial blood circuit (1a) and being capable of delivering liquid when activated; and

1.4 a control device (10) that executes

1.4.1 a connected step in which the blood pump (3) is activated with the arterial puncture needle (a) and the venous puncture needle (b) being stuck in the patient, and

1.4.2 an unconnected step in which the blood pump (3) is activated with neither the arterial puncture needle (a) nor the venous puncture needle (b) being stuck in the patient,

1.5 wherein the control device (10) is capable of executing, in the unconnected step, a checking step in which whether the arterial puncture needle (a) and/or the venous puncture needle (b) is not stuck in the patient is checked,j [sic] characterized in that,

1.6 in the unconnected step, the control device (10) makes a determination in the checking step by causing the liquid to be delivered from the distal end of the arterial blood circuit (1a) or the distal end of the venous blood circuit (1b) toward the blood purification device (2)."

IV. Compared with claim 1 of the main request, claim 1 of auxiliary request 1 (i.e. the version deemed allowable in the contested decision) further includes the following features, which have been added to the end of the claim:

", and that
the blood purification apparatus further comprises a dialysate introduction line (L1) through which dialysate is introduced into the blood purification device (2); and a dialysate drain line (L2) through which drain liquid is discharged from the blood purification device (2), wherein the unconnected step is a draining step in which the liquid in the blood circuit (1) is discharged into the dialysate drain line (L2) after a blood purification treatment performed by the blood purification device (2) or a returning step."

V. Claim 1 of auxiliary request 2 includes the following amendments compared with claim 1 of auxiliary request 1:

"... toward the blood purification device (2), that the control device (10) executes the checking step only at the activation of the blood pump (3) after transition from the connected step to the unconnected step, and that the blood purification apparatus further comprises ..."

VI. Claim 1 of auxiliary request 3 includes the following amendments compared with claim 1 of the main request:

"... an unconnected step in which the blood pump (3) is activated such that the flow rate of the liquid becomes a predetermined level with neither ...

toward the blood purification device (2), and that, during the checking step, the blood pump is operated such that the flow rate of the liquid is lower than the predetermined level."

VII. Compared with claim 1 of the main request and of each of auxiliary requests 1 to 3, respectively, claim 1 of each of auxiliary requests 4 to 7 further includes the following features, which have been added to the end of the claim:

", and in that the blood purification apparatus further comprises a blood-checking device (K1, K2) that is capable of checking presence of blood flowing in at least one of the arterial blood circuit (1a) and the venous blood circuit (1b), wherein the determination in the checking step is made on the basis of a result of checking of the presence of blood that is performed by the blood-checking device (K1, K2)."

VIII. The claims of auxiliary requests 8 to 11 are not discussed in this decision.

IX. The following documents are relevant to the present decision.

D6 US 7,959,593 B2
D8 EP 2 583 701 A1
D20 WO 2011/080186 A1

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

Main request – inventive step starting from D8

D8 in combination with the teaching of D6 rendered the subject-matter of claim 1 of the main request obvious.

D8 disclosed a blood purification apparatus having all the features of claim 1 except features 1.5 and 1.6. In D8, the operator had to manually confirm that all lines had been removed from the patient (see paragraph [0044]). The problem solved starting from D8 was to automate the manual checking step of D8.

D6 (column 7, line 43 to column 8, line 6) taught how to evaluate the state of the connection to the patient. In particular, it taught how to determine, for each of the arterial blood circuit and the venous blood circuit, if there was a good connection, a bad connection or a missed connection. This determination was done by causing liquid to be delivered from the distal end of each of the arterial blood circuit and the venous blood circuit towards the blood purification device, before the start of the dialysis step. D8 did not teach away from this since paragraph [0044] stated that the draining should not start until it was confirmed that all lines had been removed; it did not indicate that the blood pump could not be activated. A person skilled in the art wanting to automate the checking step of D8 would have implemented the checking step taught by D6 and would have arrived at the claimed solution.

Auxiliary requests 1, 2 and 4 to 6 – inventive step starting from D8

The features added to claim 1 of each of auxiliary requests 1, 2 and 4 to 6 were disclosed in D8 or in D6. Therefore, the subject-matter of claim 1 of each of

these requests was not inventive in view of the combination of D8 and D6.

Auxiliary requests 3 and 7 – added matter

Auxiliary requests 3 and 7 comprised added matter.

Claim 1 of each of auxiliary requests 3 and 7 defined the flow rate during the checking step as being lower than the flow rate of the unconnected step. This was not disclosed in the application as filed. The "low speed" in two embodiments of the application as filed was defined as being a flow rate lower than the flow rate of the ultrafiltration pump. However, the claimed flow rate could be higher than the flow rate of the ultrafiltration pump. In relation to a third embodiment, only an example for an extremely low speed was disclosed.

Auxiliary requests 8 to 11 – admittance

These requests were filed at a very late stage and should not be admitted. The appellant-opponent had relied on D6 throughout the proceedings and there were no exceptional circumstances justifying the admittance of the new requests.

XI. The proprietor's arguments, where relevant to the present decision, can be summarised as follows.

Main request – inventive step starting from D8

The subject-matter of claim 1 as granted was inventive when starting from D8.

D8 did not disclose features 1.5 and 1.6. D8 described a confirmation step prior to a draining step but did not require an actual checking step as claimed. Therefore, the distinguishing features made the draining step safer. The technical problem solved was how to increase the safety of the draining step.

D8 would not have been combined with D6. D8 dealt with an unconnected step (draining) and aimed to confirm that the patient had been disconnected. In contrast, D6 aimed to ensure proper needle connection for the dialysis treatment, i.e. for a connected step. Furthermore, a "missed connection" in D6 did not mean that the patient was disconnected; rather, it meant that the needle had been misplaced and was not in an artery or vein. Lastly, D8 emphasised that disconnection should be confirmed before starting the pump. This was important because if the patient were connected, it would pose a serious health risk. Therefore, D8 taught away from the approach of D6, which involved using a running blood pump to ensure that the connection had been properly established.

Auxiliary requests 3 and 7 – added matter

Auxiliary requests 3 and 7 complied with Article 123(2) EPC. In all three embodiments of Figures 2 to 4 of the application as filed, the blood pump was activated at a low speed during the checking step. After the checking step, the flow rate became the predetermined level. A flow rate lower than the flow rate of the ultrafiltration pump was only disclosed in two of the embodiments, so it was not necessary to include this additional limitation. In order to be clear, the term "low speed" required a reference. The only possible reference for the term "low speed" was the

predetermined level. A person skilled in the art would unambiguously interpret "low speed" in the application as filed as a speed lower than the predetermined level, as specified in claim 1 of each of auxiliary requests 3 and 7.

Auxiliary requests 8 to 11 – admittance

Auxiliary requests 8 to 11 should be admitted into the appeal proceedings. D6 had not played any relevant role in the first-instance proceedings. The opponent had not mentioned D6 in the numerous inventive-step attacks, nor had D6 been discussed in the contested decision. The objections based on D6 could thus be assumed to be unimportant. The proprietor was therefore surprised that the board considered these objections to be relevant in its preliminary opinion. Moreover, in auxiliary requests 8 to 11, claim 1 had only been amended to include the additional features of claim 3 as granted. Admitting these requests would not cause any inappropriate delay to the proceedings. Furthermore, the opponent had relied on new passages of a prior-art document in its statement of grounds of appeal, and the board's preliminary opinion had also cited new passages of the same document.

Reasons for the Decision

1. Patent

1.1 The patent relates to a blood purification apparatus. Such apparatuses typically comprise a blood circuit (with arterial and venous blood circuits), a blood purification device, a blood pump and a control device.

1.2 When operating a blood purification apparatus, some steps are performed with the arterial and venous puncture needles stuck in the patient ("connected steps"), while others are performed on the premise that neither the arterial nor the venous puncture needle is stuck in the patient ("unconnected steps").

1.3 An example of an unconnected step is the draining step. This step involves activating the blood pump after the needles have been removed in order to discharge any liquid remaining in the blood circuit into the dialysate drain line for easy disposal.

1.4 There is a risk of the arterial and/or venous puncture needles still being in place and the patient still being connected to the blood circuit when the blood pump is activated for an unconnected step, which could endanger the patient's health. The invention provides a blood purification apparatus that addresses this issue. It includes a control device capable of executing, *inter alia*, a checking step in which it is checked whether the arterial puncture needle and/or the venous puncture needle is not stuck in the patient.

2. Main request – inventive step starting from D8

2.1 In the embodiment of Figure 1, D8 discloses a blood purification apparatus comprising, among other things, an arterial blood circuit 42, a venous blood circuit 44 and a blood pump 40.

2.2 D8 discloses that, after the actual haemodialysis treatment has finished, the process of separating the device from the patient begins, including a draining (emptying) step for the blood circuits (see paragraphs [0039] to [0044]). According to paragraph [0044] of D8,

the operator must manually confirm on the haemodialysis device that the patient has been disconnected before draining can begin ("*Bevor das Abpumpen beginnen kann, muss der Bediener an dem Hämodialysegerät 10 manuell bestätigen, dass alle Leitungen von dem Patienten abgenommen wurden.*").

2.3 It is common ground that the embodiment of Figure 1 of D8 anticipates all the features of claim 1 of the main request except features 1.5 and 1.6. However, the parties disagree on the problem solved by these features in relation to the apparatus disclosed in D8.

2.4 The manual confirmation required in D8 presupposes that the operator carries out a check, otherwise the confirmation step would serve no purpose. Since neither the manual check implied by D8 nor the claimed (automatic) check is necessarily error-free, no increase in patient safety can be ascribed to the distinguishing features. Therefore, the board agrees with the opponent that the problem solved is how to automate the confirmation (i.e. checking step) in D8 that the needles/lines are not connected to the patient. This is also consistent with paragraphs [0008] and [0018] of the contested patent, according to which the achievement of the apparatus of the invention is the automatic confirmation that neither needle is stuck in the patient.

2.5 Document D6 is in the same technical field of blood purification apparatuses (see the title "Blood purification apparatus and method for evaluating connection conditions of needles"). D6 addresses the situation in which, after the priming step, the patient has to be connected to the blood circuit for the blood purification treatment. According to D6, the occurrence

of a bad connection or a missed connection had been checked by visual inspection in the past, and automation was needed (see column 1, line 57 to column 2, line 2).

2.6 With reference to Figures 3 to 5, D6 discloses a method for evaluating the connection conditions of the arterial and venous needles (column 7, lines 19 to 21; see also column 6, lines 12 to 18). In the disclosed method, the clamp devices, the ultrafiltration pump and the blood pump are operated so that blood flows from the arterial needle and from the venous needle towards the dialyser (see Figure 5 and column 7, lines 43 to 51). On the basis of the detection of air bubbles and/or blood at each of the arterial blood circuit and the venous blood circuit, a connection condition evaluation device 13 determines the connection condition of each of the arterial blood circuit and the venous blood circuit. In particular, each connection is determined to be a good connection, a missed connection or a bad connection (column 7, line 52 to column 7, line 12; see also column 6, lines 16 to 18).

2.7 At the oral proceedings, the proprietor asserted that in D6 the patient was necessarily connected with the needles in, and that a "missed connection" in D6 referred not to the connection being absent (forgotten by the operator) but to the needle being misplaced, for example in the muscle instead of in an artery or vein. The board disagrees with this understanding of D6. The term "missed connection" in D6 indicates that the connection is missing, with no blood being detected (see column 8, lines 11 to 12), rather than incorrect. An incorrect connection is instead identified as a "bad connection" in D6.

2.8 The proprietor submitted that D8 would not be combined with the teaching of D6 and provided two lines of argument, which are addressed individually below.

2.9 According to a first line of argument, the confirmation in D8 related to an upcoming unconnected step (draining), whereas the verification in D6 related to an upcoming connected step. This is correct. In D6, the connection condition is evaluated after the priming step to ensure that the patient is properly connected for the subsequent haemodialysis treatment, which is a connected step. Accordingly, the desired connection condition in D6 is a "good connection", and detailed alarms are issued if either the arterial or venous connection is determined to be a "bad or missed connection" (see column 8, lines 12 to 16).

2.10 However, a person skilled in the art starting from D8 and consulting D6 would understand that the teaching in D6 for automatically evaluating the connection condition (as good, bad or missed) can be used regardless of the desired connection condition, i.e. regardless of whether a good or a missed connection is needed in the upcoming step. Therefore, the teaching in D6 would not be disregarded merely because the desired outcome of the evaluation in D6 is a good connection.

2.11 The proprietor's second line of argument relates to D8 allegedly teaching away from the solution. In particular, the proprietor construed the last sentence of paragraph [0044] of D8 in the sense that the blood pump could not be activated until after confirmation that the patient was disconnected. According to the proprietor, this was important because the draining step was done with the pump running at high speed, and activating the blood pump at high speed for draining

with a connected patient would pose a significant health risk.

2.12 This second line of argument misrepresents the disclosure of both D8 and D6. The final sentence of paragraph [0044] of D8 is reproduced and discussed in point 2.2 above. This sentence relates to the draining step, not to the activation of the blood pump. This is clear from the use of the term "*Abpumpen*" (draining), which is defined in the first sentence of paragraph [0044] as the removal of the filling fluid from the conduits 42 and 44 (i.e. the arterial and venous blood circuits). Accordingly, the final sentence of paragraph [0044] requires user confirmation that the patient has been disconnected before draining can begin ("*Bevor das Abpumpen beginnen kann*"), but it does not rule out the possibility of the blood pump being activated before draining.

2.13 Furthermore, the connection condition is evaluated in D6 by operating the clamp devices, the blood pump and the ultrafiltration pump in such a way that the flow is from the distal end of each of the venous circuit and the arterial circuit towards the dialyser (see column 7, lines 43 to 51). This differs from the operation of the device in D6 during the subsequent haemodialysis treatment, when blood flows in the forward direction in both blood circuits (see column 8, lines 28 to 32). Therefore, when combining the teachings of D8 and D6, the connection condition would be evaluated not by starting the draining process itself but by operating the device in an evaluation mode as taught in D6. The proprietor's arguments against combining D8 and D6 are thus not convincing.

2.14 In view of the above, a person skilled in the art starting from D8 and faced with the problem of automating the confirmation (i.e. checking step) that the needles/lines are not connected to the patient would have consulted D6, which is in the same technical field and teaches a solution to this problem. Following the teaching of D6, the person skilled in the art would have modified the device of D8 to automatically evaluate the connection condition of each of the arterial blood circuit and the venous blood circuit prior to draining, by causing liquid to flow from the distal end of each blood circuit towards the dialyser. This would have resulted in a device incorporating features 1.5 and 1.6, thus anticipating all the features of claim 1.

2.15 It follows that the subject-matter of claim 1 of the main request is not inventive.

3. Auxiliary requests 1 and 2 – inventive step starting from D8

3.1 D8 discloses the features added to claim 1 of auxiliary request 1, in particular a dialysate introduction line and a dialysate drain line (conduits connecting the dialyser 28 to the dialysate source 16 and to the discharge tank 36, respectively), and that the unconnected step is a draining step (paragraph [0044]). D8 also discloses the additional feature of claim 1 of auxiliary request 2, since the confirmation in paragraph [0044] of D8 occurs after a transition from a connected step (the filling of the conduits in paragraph [0043]) to an unconnected step (draining).

3.2 It follows that, for the same reasons set out in relation to the main request, claim 1 of each of

auxiliary requests 1 and 2 is rendered obvious by the combination of D8 and D6.

4. Auxiliary request 3 – added matter

4.1 The application as filed (having different paragraph numbering from the A1 publication) discloses that, during the checking step, the blood pump is operated "at a low speed" (paragraphs [0054], [0058] and [0061]), and, after completion of the checking step, it is operated such that the flow rate becomes the "predetermined level" (paragraphs [0056], [0059], [0063]).

4.2 As acknowledged by the proprietor, the term "low speed" is unclear without a reference. The proprietor submitted that the "predetermined level" (i.e. the flow rate during the unconnected step) provided the necessary reference.

4.3 The board disagrees. With regard to the embodiments of Figures 2 and 4, paragraphs [0054] and [0061] state that "to activate the blood pump 3 at a low speed, the flow rate of the blood pump 3 is set to a lower level than the flow rate of the ultrafiltration pump 7". Therefore, the reference for the blood pump's "low speed" in these embodiments is clearly the flow rate of the ultrafiltration pump.

4.4 The ultrafiltration pump is not mentioned in the embodiment of Figure 3. Instead, in relation to this embodiment, paragraph [0058] states that "the blood pump is operated at a low speed (for example, operated at an extremely low speed so that the flow rate becomes 40 mL/min or lower)". It is therefore derivable that a low speed may result in flow rates of 40 mL/min

or lower. However, the passage leaves it open whether a "low speed" can result in flow rates higher than 40 mL/min and, if so, what the upper limit is. In particular, and also in relation to the embodiment of Figure 3, it is not disclosed that operating the blood pump at a low speed means operating it "such that the flow rate of the liquid is lower than the predetermined level", as set out in claim 1 of auxiliary request 3.

4.5 In summary, claim 1 of auxiliary request 3 introduces a maximum flow rate for the blood pump during the checking step ("lower than the predetermined level") which cannot be derived directly and unambiguously from the application as filed.

4.6 It follows that auxiliary request 3 infringes Article 123(2) EPC.

5. Auxiliary requests 4 to 6 – inventive step starting from D8

5.1 D6 discloses that the connection condition is evaluated on the basis of a result of a check for the presence of blood performed by a blood-checking device (see column 8, lines 7 to 16). Combining D8 and D6 would have led to the checking step being carried out according to this teaching. Consequently, the subject-matter of claim 1 of each of auxiliary requests 4, 5 and 6 is rendered obvious by the combination of D8 and D6.

6. Auxiliary request 7 – added matter

6.1 For the same reasons set out in relation to auxiliary request 3, claim 1 of auxiliary request 7 infringes Article 123(2) EPC.

7. Auxiliary requests 8 to 11 – admittance

7.1 The proprietor filed auxiliary requests 8 to 11 by letter dated 20 March 2026 after notification of the board's communication under Article 15(1) RPBA. Therefore, these requests constitute an amendment within the meaning of Article 13(2) RPBA, which, in principle, will not be taken into account unless there are exceptional circumstances.

7.2 The proprietor argued that D6 had not played any relevant role in the first-instance proceedings and could be regarded as having been unimportant before the board's preliminary opinion.

7.3 The proprietor's submission does not correctly reflect the actual role of D6 in the opposition and opposition-appeal proceedings. The opponent had already raised an objection of lack of inventive step in view of D8 combined with D6 in its notice of opposition (section V.1 on pages 27 and 28), and this was repeated in its letter of 27 September 2022 (section II.3.1 on page 4). During the oral proceedings before the opposition division, the opponent again referred to the lack of inventive step based on the combination of D8 and D6 (point 9 of the minutes of the oral proceedings before the opposition division). This objection was therefore clearly part of the opposition proceedings and, given its reiteration by the opponent on multiple occasions, not merely raised incidentally as a side point either.

7.4 The mere fact that the opposition division did not find this objection convincing (see point 10 of the minutes of the oral proceedings before the opposition division) did not render it objectively irrelevant, nor did it

have any predictive value as to the relevance of the objection for the appeal proceedings.

7.5 The opponent maintained the objection of lack of inventive step starting from D8 in combination with D6 in the appeal proceedings. In particular, the opponent argued a lack of inventive step based on the combination of D8 and D6 in its statement of grounds of appeal (section VI.1 on pages 29 and 30), in its reply to the proprietor's appeal (section IV.1 on pages 18 and 19) and in its letters of 4 December 2023 (section I.3.2 on page 10) and 15 May 2024 (section IV.4 on pages 10 and 11). All these submissions were made before the board issued its communication under Article 15(1) RPBA, i.e. also before the proprietor filed auxiliary requests 8 to 11.

7.6 Regarding the timing of party submissions, the RPBA are based on the concept of frontloading, whereby parties are required to present their entire case at the earliest opportunity. Hence, they must not wait until receiving a preliminary opinion by the board in a communication under Article 15(1) RPBA before submitting fallback positions. Parties must take account of the possibility that their arguments do not convince the board and that the board may also, when reviewing the decision under appeal in a judicial manner pursuant to Article 12(2) RPBA, diverge from the assessment in the decision under appeal.

7.7 In the circumstances of the case in hand, the proprietor therefore had to expect that the board would assess the merits of the objection of lack of inventive step starting from D8 in combination with D6 and that the board may find this objection convincing. Accordingly, the proprietor should have already filed

fallback positions in response to this objection at the latest in its reply to the opponent's statement of grounds of appeal, not only after having received the board's preliminary opinion as set out in the communication under Article 15(1) RPBA.

7.8 The proprietor further argued that new passages of D20 had been referred to in both the opponent's statement of grounds of appeal and the board's written preliminary opinion reference. D20 is, however, different from documents D6 and D8, and the board's decision finding the main request and auxiliary requests 1 to 7 unallowable for lack of inventive step does not rely on D20.

7.9 The proprietor also pointed out that, compared with other requests on file, auxiliary requests 8 to 11 merely incorporated the features of a dependent claim into the independent claim. This on its own, however, is insufficient to establish exceptional circumstances which would justify admitting this amendment to the proprietor's appeal case.

7.10 In view of the above, the board decided not to take auxiliary requests 8 to 11 into account in the appeal proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated