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Datasheet for the decision of 9 June 2022

Case Number: T 1671/18 - 3.2.02

Application Number: 08865227.6

Publication Number: 2224974

IPC: A61M1/06

Language of the proceedings: EN

Title of invention:
BREAST PUMP FOR EXPRESSING MILK FROM A BREAST

Patent Proprietor:
Koninklijke Philips N.V.

Opponent:
Medela Holding AG

Headword:

Relevant legal provisions:
EPC Art. 54(3), 56
RPBA 2020 Art. 13(2)

Keyword:

Novelty - main request and auxiliary request I - (no)
Inventive step - auxiliary request II - (yes)
Amendment after summons - exceptional circumstances (no)
- taken into account (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1671/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 9 June 2022

Appellant: (Opponent)	Medela Holding AG Lättichstrasse 4b 6340 Baar (CH)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Respondent: (Patent Proprietor)	Koninklijke Philips N.V. High Tech Campus 52 5656 AG Eindhoven (NL)
Representative:	Philips Intellectual Property & Standards High Tech Campus 52 5656 AG Eindhoven (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 April 2018 rejecting the opposition filed against European patent No. 2224974 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	C. Schmidt

Summary of Facts and Submissions

I. The opponent appealed against the Opposition Division's decision, posted on 9 April 2018, to reject the opposition against European patent No. 2 224 974.

The patent was opposed on the grounds of lack of novelty and lack of inventive step.

II. The Board summoned the parties to oral proceedings and sent its preliminary opinion in a communication dated 3 December 2021. In this communication, the Board expressed the view that the subject-matter of claim 1 of the main request and auxiliary request 1 appeared to lack novelty.

The subject-matter of claim 1 of auxiliary request II appeared to be novel and none of the documents cited by the appellant on appeal appeared to disclose the distinguishing feature.

III. By letter dated 28 January 2022, the appellant raised objections of lack of novelty on the basis of document:

A14: US 2007/0060873 A1

IV. By letter dated 8 April 2022, the respondent filed further auxiliary requests, including auxiliary request Ia.

V. Oral proceedings took place on 9 June 2022.

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

The respondent requested that the appeal be dismissed - i.e. that the patent be maintained as granted and confirmed by the Opposition Division - or that the patent be maintained on the basis of one of auxiliary requests I, Ia, II, IIa, III, III', IV, V, Va, V', VI, VI', VII, VII', VIII, VIII', IX, X, X' and XI, filed with the letter dated 18 December 2018 (auxiliary requests I, II, IV, VI and IX, where, with this letter, auxiliary requests IV, VI and IX were filed as auxiliary requests III, IV and V) and with the letter dated 8 April 2022 (auxiliary requests Ia, IIa, III, III', V, Va, V', VI', VII, VII', VIII, VIII', X, X' and XI).

VI. The following documents are also mentioned in this decision:

A1: EP 2 142 232 A0 (published as WO 2008/127991 A1)
A2: US 2005/004367 A1
A4: WO 00/57934 A1
A6: DE 38 20 211 C2

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

"Breast pump for expressing milk from a breast, comprising at least one breast cup (2) for receiving a breast, a pumping system (10) in fluid connection (11) with the at least one breast cup (2) for applying a negative pressure on said breast and a detection unit (3) comprising a pressure sensor (4) for measuring a parameter during use of the breast pump (1), wherein the breast pump (1) is adapted for optimizing breast pump settings by actively controlling at least one breast pump pumping property, based on measurements of the pressure sensor (4), during a period of use of the breast pump (1), in order to personalize operation of

said breast pump (1) for a particular user, the pressure sensor (4) being configured to measure an actual negative pressure applied to the breast during use of the pump (1) such that the breast pump pumping property is controllable based on the measurement of said actual pressure applied to the breast."

Claim 1 of **auxiliary request I** reads as claim 1 of the main request with the addition of the following wording at the end of the claim:

", wherein the at least one breast pump pumping property is at least one of pumping power and pumping frequency, wherein the breast pump (l) further comprises a control unit (8) adapted to analyze data output from the detection unit (3) based on said sensor measurements and wherein the control unit (8) is adapted to control the pumping system (10) in dependence of the data output, for instance by adapting the pumping power and/or the pumping frequency".

Claim 1 of **auxiliary request Ia** reads as claim 1 of the main request with the addition of the following wording at the end of the claim:

", wherein the at least one breast pump pumping property is pumping power and pumping frequency, wherein the breast pump (1) further comprises a control unit (8) adapted to analyze data output from the detection unit (3) based on said sensor measurements and wherein the control unit (8) is adapted to control the pumping system (10) in dependence of the data output by adapting the pumping power and the pumping frequency".

Claim 1 of **auxiliary request II** reads as claim 1 of the

main request with the addition of the following wording at the end of the claim:

", wherein the pressure sensor (4) is provided in the breast cup (2), wherein the at least one breast pump pumping property is at least one of pumping power and pumping frequency, wherein the breast pump (1) further comprises a control unit (8) adapted to analyze data output from the detection unit (3) based on said sensor measurements and wherein the control unit (8) is adapted to control the pumping system (10) in dependence of the data output, for instance by adapting the pumping power and/or the pumping frequency".

VIII. The appellant's arguments relevant to the decision are summarised as follows.

Admittance of auxiliary request Ia and the objections based on A14

Compared with claim 1 of auxiliary request I, claim 1 of auxiliary request Ia had been amended by deleting alternatives. This amounted to an amendment of the respondent's appeal case made after the notification of the summons to oral proceedings in the absence of any exceptional circumstances. The Board's preliminary opinion was not an exceptional circumstance justifying the amendment. Hence, auxiliary request Ia should not be admitted into the appeal proceedings under Article 13(2) RPBA.

A14 had been admitted and considered in the first-instance proceedings. The objections based on A14 had to be considered as clarifications of previous arguments which had become necessary after receipt of the Board's preliminary opinion. Hence, the objections

based on A14 should be admitted into the appeal proceedings. Not admitting them would limit the appellant's right to be heard as it would deprive the appellant of its only opportunity to reply to the arguments expressed by the Board in the preliminary opinion in view of auxiliary request II, which had been submitted only on appeal.

Main request and auxiliary request 1 - Novelty

The subject-matter of claim 1 of the main request and of auxiliary request I was not novel in view of A1, which was prior art under Article 54(3) EPC.

A1 disclosed a breast pump adapted for optimising breast pump settings by actively controlling at least one breast pump pumping property based on measurements of the pressure sensor. This was performed by controlling a valve in response to the measured pressure. Opening and closing the valve influenced the pressure applied by the breast pump in terms of pumping power and pumping frequency (paragraph [0084]).

A1 also disclosed that an actual negative pressure applied to the breast during use of the pump was measured. Claim 1 of the main request and auxiliary request I did not imply a measurement in the breast cup as the claims did not specify where the pressure was measured and the description disclosed that a pressure sensor could be provided in other locations for that purpose (paragraph [0011]). An actual pressure within the meaning of these claims was a pressure present and directly measurable in the system in contrast to a pressure which had to be calculated from indirect measurements or assumptions. In any case, A1 explicitly disclosed a pressure transducer which could "relatively

precisely determine the pressure being effected" (paragraph [0084]) and detect "actual pressure within said breastshield" (claims 48, 49 and 60).

Auxiliary request II - Inventive step

The subject-matter of claim 1 of auxiliary request II was not inventive when starting from A2, A4 or A6.

Each of these documents disclosed a breast pump as defined in claim 1 of auxiliary request II with the exception of a pressure sensor provided in the breast cup.

This distinguishing feature addressed the problem of determining the real pressure at the breast or of providing an alternative breast pump as the exact location of the pressure sensor did not bring about any advantage for the control of the pump (confirmed by paragraph [0011] of the patent).

Providing a pressure sensor in the breast cup or elsewhere in the system for measuring the pressure applied to the breast was within the competence and the design skills of the person skilled in the art. Moreover, it would be obvious to provide the pressure sensor in the breast cup as it was the pressure at the breast which had to be regulated (A2, paragraph [0007]; A4, page 2, lines 23 to 27; A6, column 1, lines 8 to 16).

IX. The respondent's arguments relevant to the decision are summarised as follows.

Admittance of auxiliary request Ia and the objections based on A14

Compared with claim 1 of auxiliary request I, claim 1 of auxiliary request Ia had been amended by deleting alternatives. Hence, its subject-matter was already included in claim 1 of auxiliary request I. It followed that the filing of auxiliary request Ia did not amount to an amendment of the respondent's appeal case. Moreover, auxiliary request Ia had been filed in direct response to the Board's preliminary opinion, which differed from the impugned decision. Auxiliary request Ia had to be admitted into the appeal proceedings.

The objections based on A14 had been filed late in the absence of any exceptional circumstances. Auxiliary request II had been on file since 2018. The appellant had had plenty of time to react to this request and did not have to wait for the Board's preliminary opinion. Moreover, *prima facie*, A14 was irrelevant as it did not disclose a pressure sensor in a breast cup. Hence, the objections based on A14 should not be admitted into the appeal proceedings.

Main request and auxiliary request 1 - Novelty

The subject-matter of claim 1 of the main request and auxiliary request I was novel.

A1 did not disclose a breast pump adapted for optimising breast pump settings by actively controlling at least one breast pump pumping property to personalise operation of the breast pump for a particular user based on measurements of the pressure sensor. In view of the description (e.g. column 1, lines 31 to 38 of the patent) and the knowledge of the

person skilled in the art, the pump settings which were optimised were the frequency of suction cycles and the suction power of the breast pump, as set by the user (column 4, lines 46 to 51). Paragraph [0027] of the patent explained in detail how these settings were adjusted. A valve could not perform the optimisation of the breast pump settings as defined in claim 1 as it did not change the operation of the breast pump. More generally, A1 did not disclose any adaptation of the settings of the breast pump. Claim 1 of auxiliary request I was more specific as it defined the settings as at least one of pumping power and pumping frequency.

Moreover, A1 disclosed (Figure 7) a pressure transducer 460 which measured the pressure at a position along a vacuum line 418 close to a vacuum pump mechanism 416. The measured pressure was not the pressure actually applied to the breast. In the breast cup, the pressure conditions varied dynamically, there were several narrow passages between the vacuum line and the breast, and air-tightness between the breast cup and the breast could not be ensured. It followed that the pressure detected by pressure transducer 460 at vacuum line 418 relatively close to vacuum pump mechanism 416 significantly differed from the actual negative pressure applied to the breast. The kind of pump in document A1, typically a diaphragm pump, contributed to the difference between the pressure measured by pressure transducer 460 and the actual negative pressure applied to the breast. The explicit mention of the detection of an "actual pressure within said breastshield" in claims 48, 49 and 60 of A1 had to be understood in this technical context.

Auxiliary request II - Inventive step

The subject-matter of claim 1 of auxiliary request II was inventive.

None of A2, A4 or A6 disclosed a breast pump with a pressure sensor provided in the breast cup.

This distinguishing feature allowed more easily measuring the pressure actually applied to the breast. The problem solved was how to find good pump settings and hence provide a high quality, easy-to-manufacture breast pump. None of the available prior art disclosed the distinguishing feature. Moreover, the implementation of this feature in the devices of A2, A4 or A6 would have required a complete re-design of these devices.

Reasons for the Decision

1. The invention

The invention relates to a breast pump for expressing milk from a breast.

Such pumps are typically used by a mother if the baby is not able to extract the milk, or when the baby has to be separated from the mother, or in case of excessive milk production or other breast problems.

Generally, negative pressure is applied cyclically to the breast to simulate the sucking action of the baby, as shown in Figure 2 of the patent, reproduced below.

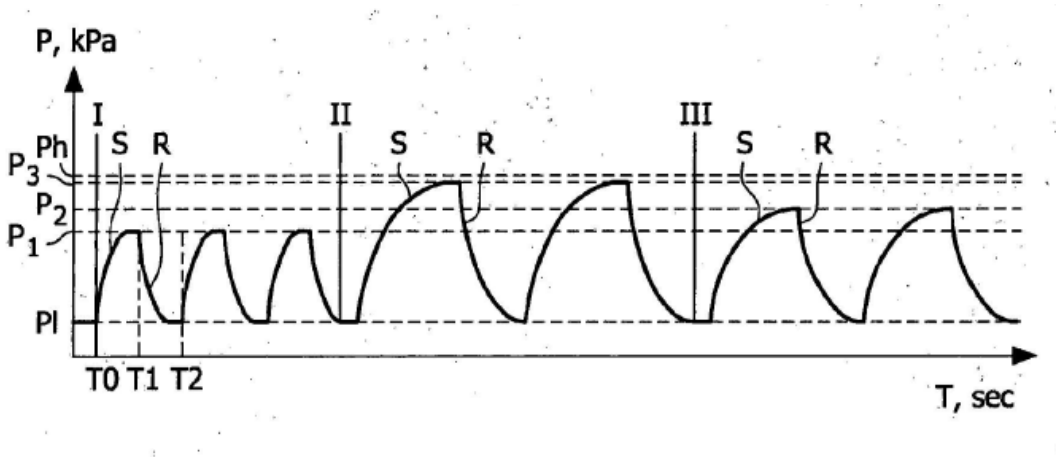

FIG. 2

The breast pump as claimed comprises a breast cup, a pumping system in fluid connection with the breast cup for applying a negative pressure on the breast and a detection unit comprising a pressure sensor.

The breast pump is adapted for optimising breast pump settings by actively controlling at least one breast pump pumping property based on measurements of the pressure sensor.

The controlled pumping properties could include, for example, a maximum and a minimum negative pressure applied to the breast and the frequency and duration of a pumping cycle.

The pressure sensor is configured to measure an actual negative pressure applied to the breast during use of the pump. According to the patent (paragraph [0007]), "[b]y measuring the actual negative pressure applied to the breast during use of the breast pump, the user does not have to find out and try which are the optimal settings of the breast pump". Furthermore, damage of

the delicate breast tissue can be prevented.

2. Admittance of auxiliary request Ia and the objections based on A14

Auxiliary request Ia and objections based on A14 were filed on appeal after the notification of the summons to oral proceedings.

In accordance with Article 13(2) RPBA 2020, any amendment to a party's appeal case made after the notification of a summons to oral proceedings must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

2.1 The respondent argued that the filing of auxiliary request Ia did not amount to an amendment of the respondent's appeal case since the subject-matter of claim 1 of auxiliary request Ia was already included in claim 1 of auxiliary request I.

This argument is not convincing. The deletion of alternatives from claim 1 of auxiliary request I results in a change of the claim scope requiring different technical considerations and is therefore an amendment of the respondent's case. A similar conclusion was reached in case T 2091/18 on the deletion of claims (points 3 to 5 of the Reasons).

The respondent did not put forward any exceptional circumstances justifying this amendment. The Board's preliminary opinion cannot amount to such exceptional circumstances even when it differs from the impugned decision as the primary object of the appeal proceedings is to review the decision under appeal in a

judicial manner (Article 12(2) RPBA 2020). It is inherent in such a review that the Board may deviate from the conclusions reached in the impugned decision.

For these reasons, auxiliary request Ia is not admitted into the appeal proceedings in accordance with Article 13(2) RPBA 2020.

2.2 As regards the objections based on A14, the appellant argued that A14 had been admitted and considered in the first-instance proceedings.

However, the admittance of A14 in the first-instance proceedings does not mean that objections based on this document can be raised any time on appeal. On the contrary, under Article 12(3) RPBA 2020, the appellant's statement of grounds of appeal should have contained the appellant's complete appeal case. It should have set out clearly and concisely the reasons why it was requested that the decision under appeal be reversed. Submitting new objections on the basis of A14, in the absence of any such objections in the statement of grounds, amounts to an amendment of the appellant's appeal case, which has to be considered in light of the provisions of Article 13(2) RPBA 2020.

The objections based on A14 cannot be considered clarifications of previous arguments as the statement of grounds contained no arguments on the basis of A14.

As explained above, the receipt of the Board's preliminary opinion cannot be considered an exceptional circumstance justifying an amendment of the appellant's appeal case after notification of the summons to oral proceedings. The fact that auxiliary request II was filed by the respondent only on appeal does not amount

to such an exceptional circumstance either since the appellant could have reacted to this request and made use of its right to be heard well before the notification of the summons, which took place almost three years after the filing of this request.

In the absence of any exceptional circumstances for the filing of the objections on A14 after notification of the summons to oral proceedings, these objections are not admitted into the appeal proceedings in accordance with Article 13(2) RPBA 2020.

3. Main request and auxiliary request 1 - Novelty

A1, which is state of the art under Article 54(3) EPC, discloses a breast pump depicted in Figures 6 and 7, reproduced below. In Figure 7, an embodiment of the control of the pump with pressure sensor 460 is shown.

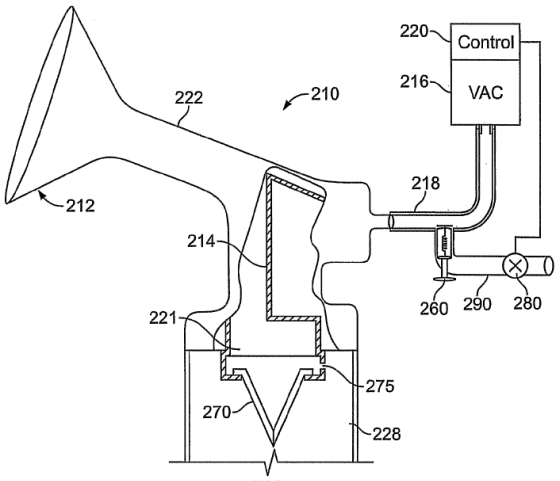

FIG. 6

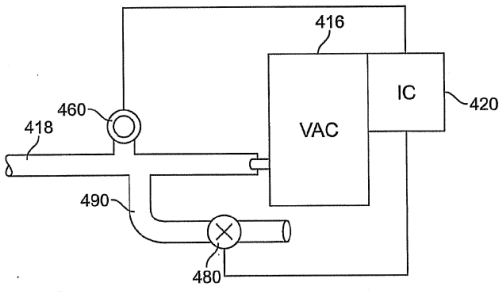

FIG. 7

The breast pump comprises a breast cup (breastshield 212), a pumping system (vacuum pump mechanism 216, 416 including solenoid valve 480) in fluid connection with the breast cup, a detection unit (pressure transducer 460) comprising a pressure sensor, and a control unit (controller 220, 420) adapted to analyse data output from the detection unit.

3.1 The respondent argued that A1 did not disclose a breast pump adapted for optimising breast pump settings by actively controlling at least one breast pump pumping property to personalise operation of the breast pump for a particular user based on measurements of the pressure sensor. However, these features are disclosed in paragraph [0084] of A1. This paragraph discloses that "various maximum, minimum and pressure points in between can thus be set by the user or preprogrammed" and that pressure transducer 460 may send a signal to controller 420 to govern operation. The controller adjusts solenoid valve 480 "to maintain a desired minimum pressure" and "to automatically transition the pressure within the breastshield from a maximum pressure to a minimum pressure (or ambient), and optionally to a pressure(s) in between".

The respondent submitted that in view of the description and the knowledge of the person skilled in the art, the optimised pump settings were the frequency of suction cycles and the suction power of the breast pump, as set by the user. However, the language of claim 1 of the main request and auxiliary request I is more general. This is common, as the claims, which define the matter for which protection is sought, often generalise the teaching of the description.

The respondent's assertion that a valve as disclosed in A1 could not perform the optimisation of the breast pump settings as claimed is not accepted. Valve 480 belongs to the pumping system of the breast pump according to A1 and affects the pressure ultimately applied to the breast, i.e. the pumping power according to the claim language, by venting or not to the atmosphere. It is irrelevant whether the description of the patent discloses controlling the pumping system in a different way.

3.2 The respondent also argued that the pressure sensor of A1 could not be considered to be configured to measure an actual negative pressure applied to the breast during use of the pump.

However, A1 expressly discloses that the pressure transducer can "relatively precisely determine the pressure being effected" (page 16, lines 16 to 18) and detects "actual pressure within said breast shield" (claims 48, 49 and 60). The pressure measurement is used to maintain a vacuum within the breastshield between a minimum and a maximum value along a relatively smoothly rising and falling sequence (page 17, lines 21 to 23).

In accordance with this disclosure, Figures 6 and 7 of A1 show a pressure transducer 460 in direct fluid communication with the breastshield, without any major fluidic resistance in the fluid path. Clearly, the actual pressure within the breastshield can only be measured with the level of incertitude intrinsic to the measurement in the system under consideration.

The respondent's argument that the pressure transducer of A1 would not measure "an actual pressure applied to

the breast" because of its distance from the breastshield and the dynamical variation of the pressure in the breast during use is not convincing.

The pressure behaviour in the breast cup according to the patent is similar to that in the breastshield of A1. In a dynamic system such as that of the patent and of A1, the precise measure of "an actual negative pressure applied to the breast" can only be a relative concept since the pressure at a given time will be different even along the breast. Moreover, the patent itself states that the pressure sensor could be provided at a (sensible) distance from the breast cup and still be able to measure "the actual applied pressure" (paragraph [0011]) in the absence of any disclosure of a specific arrangement for this purpose. Finally, the patent does not assign any importance to the precision of the measurement of "an actual negative pressure" for the correct control of the pump.

Hence, there is no reason why the degree of incertitude of a measurement of a pressure present and directly measurable in the system, obtained by a pressure sensor according to A1, should be so different from that obtained by a pressure sensor as disclosed in the patent, making it unsuitable for measuring "an actual negative pressure applied to the breast" within the meaning of claim 1.

This is all the more so because in view of the patent as a whole there is no reason to believe that in order for the optimisation of the pump settings to work satisfactorily, a pressure measurement with a precision higher than that obtainable by the arrangement of A1 should be required.

3.3 It follows that the subject-matter of claim 1 of the main request and auxiliary request I is not novel (Article 54(1) and (3) EPC) over A1. Hence, the main request and auxiliary request I are not allowable.

4. Auxiliary request II - Inventive step

It is common ground that the subject-matter of claim 1 of auxiliary request II is novel over the available prior art.

The appellant argued that it was not inventive when starting from A2, A4 or A6.

It is also common ground that none of these documents, which all concern breast pumps, disclose a pressure sensor provided in the breast cup of a breast pump.

The claimed location of the pressure sensor can provide more reliable instant measures of the negative pressure applied to the breast. This has the technical effect that the breast pump can better react to changes in that pressure.

The appellant argued that a problem solved by the distinguishing feature would be how to better determine the real pressure at the breast. However, this problem contains elements of the solution, i.e. the location on the breast. Hence this problem cannot be accepted as the objective technical problem in the problem-solution approach.

The problem of providing an alternative breast pump is not acceptable either as it disregards the technical effect provided by the distinguishing feature. Paragraph [0011] of the patent as granted, referred to

by the appellant, does not state that the technical effect established above on the basis of apparent technical considerations is not achieved. It merely states that other locations of the pressure sensor may also be acceptable.

In the Board's view, the objective technical problem is how to ensure better control of the breast pump.

In the absence of any disclosure of the distinguishing feature in the cited documents in relation to this problem, the person skilled in the art would have had no obvious reason to modify the position of the pressure sensors in the devices of A2, A4 or A6, especially because, as the respondent argued, this would have required some redesign of those devices.

In conclusion, the subject-matter of claim 1 of auxiliary request II is inventive (Article 56 EPC).

5. None of the appellant's objections prejudice the maintenance of the patent on the basis of auxiliary request II.

The respondent provided an adapted description to these claims, against which the appellant had no objections.

The Board does not have any other objections either.

Hence, the patent is to be maintained on the basis of auxiliary request II in accordance with Article 101(3) (a) EPC.

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 with the order to maintain the patent in the following version:

   - claims 1 to 11 of auxiliary request II filed with the letter dated 18 December 2018

   - description pages 2 to 5 as filed during the oral proceedings before the Board and page 6 of the patent specification

   - drawings of the patent specification

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated