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**Datasheet for the decision
of 28 October 2025**

Case Number: T 1898/23 - 3.2.02

Application Number: 17794901.3

Publication Number: 3525706

IPC: A61B18/02, A61B18/00

Language of the proceedings: EN

Title of invention:

COLD ATMOSPHERIC PLASMA TREATMENT OF ACTINIC KERATOSIS AND NON-
MELANOMA SKIN CANCER

Patent Proprietor:

Wirtz, Michelle

Opponents:

Adtec Europe Ltd
Cinogy GmbH

Headword:

Relevant legal provisions:

EPC Art. 54(5), 56

Keyword:

Novelty - novelty of use - second (or further) medical use
Inventive step - reasonable expectation of success (yes)

Decisions cited:

G 0005/83, T 2003/08, T 0773/10, T 1491/14, T 1758/15,
T 1252/20, T 0264/17

Catchword:



Beschwerdekammern

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Case Number: T 1898/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 28 October 2025

Appellant:
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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 12 October 2023
rejecting the opposition filed against European
patent No. 3525706 pursuant to Article 101(2)
EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. Opponent 2 filed an appeal against the decision of the Opposition Division to reject the opposition.
- II. Oral proceedings before the Board took place on 28 October 2025 in the absence of the appellant (as announced by letter dated 6 October 2025) and the other party (opponent 1).
- III. The appellant requested that the decision be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained as granted (main request) or on the basis of one of auxiliary requests 1 to 5 filed with the reply to the statement of grounds of appeal.

- IV. This decision refers to the following documents.

D1 US 2013/0345620

D22 Dodds et al., "Actinic Keratosis: Rationale and Management", *Dermatol. Ther.* 4(1), 2014, 11-31

- V. Claim 1 of the main request reads as follows.

"Cold atmospheric plasma for use in treating therapy-refractory actinic keratosis in a patient in need thereof, wherein the cold atmospheric plasma is an argon-containing plasma."

- VI. Claim 1 of auxiliary request 1 reads as follows.

"Cold atmospheric plasma for use in treating therapy-

refractory actinic keratosis in a patient in need thereof, wherein the cold atmospheric plasma is cold argon plasma."

VII. Claim 1 of auxiliary request 2 reads as follows.

"Cold atmospheric plasma for use in treating therapy-refractory actinic keratosis in a patient in need thereof, previously treated with diclofenac or imiquimod or ingenol mebutate or 5-fluorouracil or 5-fluorouracil with salicylic acid and/or with photodynamic therapy, preferably using (methyl)aminolevulinic acid or a salt thereof, wherein the cold atmospheric plasma is an argon-containing plasma."

VIII. Claim 1 of auxiliary request 3 reads as follows.

"Cold atmospheric plasma for use in treating therapy-refractory actinic keratosis in a patient in need thereof, previously treated with diclofenac or imiquimod or with photodynamic therapy, preferably using (methyl)aminolevulinic acid or a salt thereof, wherein the cold atmospheric plasma is an argon-containing plasma."

IX. Claim 1 of auxiliary request 4 reads as follows.

"Cold atmospheric plasma for use in treating therapy-refractory actinic keratosis in a patient in need thereof, previously treated with diclofenac or imiquimod or with photodynamic therapy, preferably using (methyl)aminolevulinic acid or a salt thereof, wherein the cold atmospheric plasma is cold argon plasma."

X. Claim 1 of auxiliary request 5 reads as follows.

"Cold atmospheric plasma for use in treating therapy-refractory actinic keratosis in a patient in need thereof, wherein the cold atmospheric plasma is an argon-containing plasma and wherein the patient suffers from actinic keratosis Olsen grade I, II or III."

XI. The appellant's arguments can be summarised as follows.

Articles 54(4) and (5) EPC - substance or composition

In accordance with G 5/83, an active substance or composition had to be formulated and made up into doses. This was not possible for a plasma as the active substance. Rather, in a plasma, unknown substances in unknown concentrations would be created.

Furthermore, in accordance with the decision in case T 773/10, a substance had to be a product of the pharmaceutical industry.

Hence, the plasma mentioned in claim 1 could not be regarded as a substance or composition, and the provisions of Article 54(4) and (5) EPC did not apply.

Article 54(5) EPC - selected patient group

None of the three criteria mentioned in decision T 1491/14 were fulfilled with regard to the patient group of therapy-refractory patients.

Criterion i) (the patient group is not disclosed in the relevant prior art) was not met as the group of therapy-refractory patients was disclosed in the relevant prior art, for instance, in D22 (Figure 1).

Criterion ii) (the patients belonging to the group can be distinguished from those of the prior art by their physiological or pathological status) was not met since, as long as patients had not received any treatment at all, patients with therapy-refractory actinic keratosis could not be distinguished by their physiological and pathological status from patients with non-refractory actinic keratosis.

Criterion iii) (there is a functional relationship between their characterising physiological or pathological status and the therapeutic treatment and thus the selection of the patients is not arbitrary) was not met either as there was no functional relationship between the therapy-refractory actinic keratosis and the therapeutic effect of the plasma treatment. Rather, the therapeutic effect on a patient was the same irrespective of whether the patient was therapy-refractory. The experimental data in the patent did not disclose any surprising technical effect. Thus, the selection of patients was arbitrary.

Thus, the subject-matter of claim 1 lacked novelty in view of D1 since D1 disclosed the treatment of patients having actinic keratosis among which there were inherently some patients with therapy-refractory actinic keratosis.

Article 56 EPC - inventive step starting from D1

D1 disclosed the treatment of actinic keratosis with a cold atmospheric plasma (CAP) (paragraphs [0006] and [0010]). Since the plasma was made of air, it inherently contained argon since air naturally contained argon.

According to the Opposition Division, the subject-matter of claim 1 differed from the disclosure of D1 in that therapy-refractory actinic keratosis was treated.

Starting from D1, and considering the objective technical problem to be "finding a patient group which particularly benefited from the treatment with CAP", the use of CAP in the treatment of patients who were refractory to other therapies would be obvious for the person skilled in the art. Applying the reasoning in T 1491/14 (point 3.6), it was evident to the person skilled in the art that this group of patients, in which customary therapies had failed, would benefit from the plasma treatment due to its different therapeutic mechanism. Furthermore, the effect of the plasma treatment on therapy-refractory patients was not unexpected. It was obvious for the person skilled in the art to use an alternative therapy with a different therapeutic mechanism if a previous therapy had not been effective.

Hence, the subject-matter of claim 1 did not involve an inventive step when starting from D1.

XII. The respondent's arguments can be summarised as follows.

Articles 54(4) and (5) EPC - substance or composition

The "argon-containing plasma" as defined in claim 1 of the main request was generated by ionisation of argon gas (patent, [0021], lines 34 to 38), and it contained argon only in the form of argon ions.

The argon-containing plasma qualified as a composition

in line with Article 54(4) and (5) EPC since the claimed therapeutic effect could be ascribed to the chemical properties of the composition.

In line with decision T 2003/08 and with reference to G 5/83, the term "substance or composition" referred to products which qualified as chemical entities or compositions of chemical entities. The products further had to be the active agent in the medical use.

In accordance with T 1758/15, a product was a substance or composition within the meaning of Article 54(4) and (5) EPC if both:

- (i) the therapeutic effect was achieved by the substance or composition
- (ii) the achievement of the therapeutic effect could be ascribed to the chemical properties of the substance or composition

As mentioned in paragraph [0021] of the current patent, the CAP was a (partially or fully) ionised gas composed of multiple chemically active species, including reactive oxygen and nitrogen species, OH radicals, ions and activated argon species, to which the therapeutic effect could be ascribed. The plasma also contained electrons, photons and ultraviolet light, but these components merely had a synergistic effect on the therapy.

For the therapeutic effect, there was no need to differentiate between the separate components within the composition. The therapeutic effect was instead to be ascribed to the chemical properties of the composition as a whole. In the case at hand, the therapeutic effect of the plasma composition was shown by experimental data (patent, Tables 1 and 2; Figure

1/1).

It was not required that the therapeutic mechanism was entirely clear.

Hence, the argon-containing plasma was a defined composition in line with Article 54(5) EPC that was effective in the treatment of therapy-refractory actinic keratosis (patent, Example 1). Claim 1 of the main request was an allowable second medical use of a composition.

D1 did not disclose an argon-containing plasma as the amount of argon present in air was too low. D1 also did not disclose experimental data concerning the treatment of actinic keratosis.

Article 54(5) EPC - selected patient group

The therapeutic use as claimed in claim 1 related to the treatment of a subgroup of patients suffering from actinic keratosis, namely patients who had been previously treated with standard medication which, however, had not resulted in a satisfactory treatment and/or clearance of the disease (paragraph [0028] of the patent).

This group of patients was not disclosed in the prior art, in particular not in D22. Figure 1 of D22 did not mention or suggest that patients with diagnosed therapy-refractory actinic keratosis should be treated as a separate patient group.

The characterising feature "therapy-refractory actinic keratosis" required a purposive diagnostic selection of a group of patients, based on a previous treatment history. Accordingly, "therapy-refractory actinic

keratosis" was a medical indication based on objective diagnostic criteria which determined whether a previous treatment had been successful.

Furthermore, the data of the patent provided evidence of the functional relationship between the actinic keratosis conditions and the therapeutic outcome. Treatment of therapy-refractory patients with argon-containing CAP had resulted in a significant decrease of lesion count and grade and, thus, in an evidently successful treatment of actinic keratosis (Table 2, columns 3 to 5, of the patent).

Hence, the claimed therapy-refractory patient group fulfilled the above criteria (i) to (iii) mentioned in T 1491/14 and, thus, represented a new therapeutic use in accordance with Article 54(5) EPC.

Article 56 EPC - inventive step starting from D1

Claim 1 of the main request was directed to a second-line treatment of actinic keratosis in which argon-containing CAP was used for treating a group of patients who were resistant to a previous first-line treatment.

Decision T 1491/14 was the most relevant case law for new therapeutic applications based on a new group of patients to be treated. This decision applied *mutatis mutandis* to the case at hand.

Claim 1 of the main request differed from the disclosure of D1 in that the claim was directed to the treatment of the subgroup of patients with therapy-refractory actinic keratosis and in that the plasma used for the treatment was argon-containing plasma.

The technical problem to be solved was to be seen in finding a patient group which particularly benefited from the treatment with argon-containing CAP.

In Table 2, the patent provided experimental proof that the therapy-refractory actinic keratosis patient group was a suitable group for the solution of this problem.

Starting from D1, it would not have been obvious for the skilled person to select the subgroup of patients being therapy-refractory to a first-line treatment for use in the treatment in a second-line medication with argon-containing CAP. D1 did not provide any suggestion that argon-containing CAP produced therapeutic benefits in treating patients that were therapy-refractory to other standard actinic keratosis therapies.

Paragraphs [0005] and [0006] explicitly referred to topical drugs aiming at infectious diseases caused by infectious pathogens for which a pathogenic resistance might occur, e.g. due to the administration of antibiotics, leading to a decreased efficacy of the treatment. However, actinic keratosis was not an infectious disease but a disease of the epidermis related to genetic mutations. Consequently, the person skilled in the art would not have gained any motivation from paragraph [0006] of D1 to use argon-containing CAP in the treatment of therapy-refractory actinic keratosis.

Moreover, D1 did not provide any experimental or clinical data to show a therapeutic effect of the plasma technique for treating non-refractory actinic keratosis with CAP.

D1 did not prompt the person skilled in the art to select argon as a supply gas for the generation of plasma as argon was not included in the list of gas supplies mentioned in paragraph [0153] ("nitrogen, helium, oxygen, air, xenon, neon, krypton or a combination thereof"). The teaching of D1 instead taught away from using argon as the plasma gas supply.

Hence, the subject-matter of claim 1 of the main request involved an inventive step over D1.

Reasons for the Decision

1. Subject-matter of the patent

1.1 Plasma, sometimes referred to as the fourth state of matter, can be generated by ionising gas molecules through the use of energy in the form of heat or electromagnetic fields. A distinction is made between thermal and nonthermal plasma. The latter is also referred to as cold plasma and is characterised by the temperature of the heavy particles being much lower than that of the electrons.

The current invention concerns an argon-containing cold atmospheric plasma (CAP) for the treatment of therapy-refractory actinic keratosis.

1.2 The development of devices generating CAP has allowed the use of CAP in several applications without the potential to harm the treated tissue.

Actinic keratosis, sometimes called solar keratosis, is

a pre-cancerous area of thick, scaly or crusty skin. Actinic keratosis is a disorder of epidermal keratinocytes induced by ultraviolet (UV) light exposure, e.g. sunlight.

- 1.3 "Therapy-refractory actinic keratosis" means, according to the patent, that the plasma is used for treating patients that had previously obtained some other therapy, which, however, did not result in a satisfactory clearance.
2. Main request - Article 54(4) and (5) EPC
 - 2.1 Claim 1 relates to a CAP for use in the treatment of therapy-refractory actinic keratosis. It is undisputed that both CAP itself and its use in the treatment of actinic keratosis are comprised in the state of the art (see paragraph [0011] of the patent).
 - 2.2 In accordance with Article 54(5) EPC, a substance or composition comprised in the state of the art can be patentable for any specific use in a method of treatment by therapy provided that the use is not comprised in the state of the art.

Hence, it has to be considered:

- (a) whether claim 1 concerns a substance or composition within the meaning of Articles 54(4) and (5) EPC
- (b) if (a) is answered positively, whether the novelty of the claimed substance or composition can be acknowledged on the basis of its use in treating therapy-refractory actinic keratosis, in other words, whether this use qualifies as a specific use in a method referred to in Article 53(c) EPC which is not comprised in the state of the art

2.3 In the Board's view, (a) and (b) are questions which must be answered separately. Conflating them could lead to a situation in which the same entity is or is not recognised as a substance or composition depending on its use.

3. Main request - Article 54(4) and (5) EPC - substance or composition

3.1 With regard to how the phrase "substance or composition" in Article 54(4) and (5) EPC (paragraph 5 referring to "any substance or composition referred to in paragraph 4") must be interpreted, the Board firstly points out that the ordinary meaning of this phrase is broader than that of "medicament" or "pharmaceutical product". This understanding is confirmed by the preparatory work for the EPC 1973, in which the drafters of the predecessor provision to Article 54(4) EPC deliberately chose a wording which was less restrictive than the term "medicament" (see Travaux Préparatoires on Article 52E EPC 1973, page 101).

The respondent essentially argued, with reference to T 2003/08, Reasons 15 (itself referring to G 5/83, Reasons 10), that a substance or composition within the meaning of Article 54(4) and (5) EPC had to be understood as a product which qualifies as a chemical entity or a composition of chemical entities. The Board sees no reason to deviate from this.

While this "subgroup of the larger group of 'products'" (see T 2003/08, Reasons 12) excludes medical devices (see T 1252/20, Reasons 6.1, with further references), it does not seem justified to say that any product which does not qualify as a medical device because of e.g. a lack of shape automatically

qualifies as a substance or composition within the meaning of Article 54(4) and (5) EPC (contrary to what seems to be indicated in T 1252/20, Reasons 7.1). If that were so, any shapeless physical entity (e.g. electromagnetic radiation or ultrasound waves) could qualify as a substance or composition, regardless of whether it is a chemical entity. Having said this, the current Board agrees that whether something qualifies as a substance or composition within the meaning of Articles 54(4) and (5) EPC should be decided, in the first place, on the basis of what is claimed as such and not on the basis of its mode of action (see T 1252/20, Reasons 12; compare also T 264/17, point 4.5.2).

- 3.2 It is undisputed by the respondent that the claimed plasma contains a variety of charged and neutral components. The only chemical entity explicitly mentioned in the claim is argon, without specifying whether it is in the form of ions. The nature and quantity of further chemical entities in the plasma will depend on the conditions of its generation and transmission. However, according to paragraph [0021] of the description, these components include reactive oxygen and nitrogen species, OH radicals, ions, electrons, photons and UV light. While some of these qualify as chemical entities and hence as a substance or composition (e.g. reactive oxygen and nitrogen species, OH radicals and ions), others do not (e.g. electrons, photons and UV light).
- 3.3 In order to benefit from the notional novelty afforded by Article 54 (4) and (5) EPC, it must be a substance or composition - as opposed to other subject-matter not qualifying as such - which is used in a method referred to in Article 53(c) EPC, this use not having been

comprised in the state of the art. In the case at hand, where the method relates a treatment by therapy, it must thus be assessed whether the therapeutic effect can be ascribed to the chemical entities in the plasma or (only) to the other entities, such as the photons.

The respondent did not dispute this. It argued, however, that there was no evidence that those plasma components which might not qualify as a chemical entity - which were, in its view, photons and UV light - were responsible for the alleged therapeutic effect, at least not alone.

The Board refers to paragraph [0002] of the patent, which includes both photons and UV light in the list of active species of the claimed CAP. In the absence of any further information - the biological mode of action remaining "unclear" according to [0040] of the patent - it can thus not be ruled out that it is the photons and/or the UV light, i.e. subject-matter other than a substance or composition, which are (exclusively) responsible for the alleged therapeutic effect.

Having said this, for the sake of argument and in the respondent's favour, it is in the following assumed that the alleged therapeutic effect is indeed caused by the parts of the claimed plasma that qualify as a substance or composition within the meaning of Article 54(5) EPC.

4. Main request - Article 54(5) EPC - group of patients

4.1 As to whether the claimed use qualifies as a specific use in a method referred to in Article 53(c) EPC which is not comprised in the state of the art, the parties agree that the following three criteria mentioned in

the decision T 1491/14 have to be fulfilled for the treatment of the same disease with the same substance in a specific group of patients to be considered a new therapeutic use:

- (i) the patient group is not disclosed in the relevant prior art
- (ii) the patients belonging to the group can be distinguished from those of the prior art by their physiological and pathological status
- (iii) there is a functional relationship between the characterising physiological or pathological status and the therapeutic treatment, and thus the selection of the patients is not arbitrary

The Board agrees that a patient group fulfilling these three criteria would render the claimed subject-matter novel.

- 4.2 With regard to criterion (i), the Board agrees with the respondent that the use of claim 1 is directed to patients with actinic keratosis who have previously been treated with other therapies which have not been successful. Hence, the feature "therapy-refractory actinic keratosis" requires a purposive diagnostic selection of a group of patients, based on their previous treatment history.

As correctly submitted by the respondent, such a group of patients is not disclosed in D22. Figure 1 shows that one option for the treatment of multiple actinic keratosis lesions is the use of diclofenac 3% gel and other standard medications followed by treatment with retinoids and sun protection. However, D22 does not disclose whether these treatments were successful.

Thus, the prior art does not disclose the treatment of patients diagnosed with therapy-refractory actinic keratosis.

- 4.3 The Board also agrees with the respondent that the actinic keratosis patients who were not successfully treated can be distinguished from patients who were successfully treated. It is assumed that the patients who turned out to be not therapy-refractory are no longer in need of any further treatment as their actinic keratosis symptoms were ameliorated. Hence, the failure of the previous therapies makes the therapy-refractory patients different from other patients from a pathological point of view.

The appellant argued that for non-treated patients, it was not possible to determine whether they were therapy-refractory. Therefore, criterion (ii) was not fulfilled.

The Board does not agree with this view. The determination of the group of therapy-refractory patients requires a previous non-successful treatment. Hence, the claimed use is not directed to non-treated patients.

- 4.4 As regards criterion (iii), it can be assumed that the technical effect resulting from the treatment of therapy-refractory actinic keratosis with CAP is the successful amelioration of the symptoms in patients whose previous treatment by standard therapies did not result in satisfactory clearance. Hence, there is a functional relationship between the physiological or pathological status of the patient group and the CAP treatment.

The appellant argued that the patent did not disclose a surprising technical effect of the treatment of therapy-refractory patients compared to all or non-refractory patients. However, it is not required that the technical effect be surprising for criterion (iii) to be fulfilled.

5. Main request - inventive step starting from D1

5.1 The following reasoning is based on the assumption that the use of claim 1 differs from the disclosure of D1 in the group of therapy-refractory patients to which it was directed.

5.2 Both parties agreed that, based on this distinguishing feature, the objective technical problem may be formulated as finding a patient group which particularly benefits from the treatment with CAP.

5.3 D1 discloses the use of CAP in the treatment of skin diseases or conditions, for instance, actinic keratosis (paragraph [0005]). As correctly stated by the respondent, D1 mentions in this paragraph and the first sentence of paragraph [0006] the shortcomings of topical drugs in the treatment of infectious diseases, and actinic keratosis is not an infectious disease. However, in the second part of paragraph [0006], D1 refers to topical drugs, such as imiquimod, which are used for the treatment of actinic keratosis. It is mentioned that these topical drugs can cause severe skin irritation and erythema.

Imiquimod is also mentioned in the current patent as a known therapy of actinic keratosis (paragraph [0014]). Some patients subject to the clinical trial referred to in Example 1 were previously treated with imiquimod

(e.g. patients 3 and 4, Table 1), and this treatment was not successful. Hence, imiquimod belongs to the therapies the patients in the patent were refractory to.

- 5.4 Hence, from D1 the person skilled in the art learns that treatment with CAP is effective against actinic keratosis in patients who suffer from side effects involved in previous treatment with imiquimod. Knowing that, the person skilled in the art would have had a reasonable expectation that patients who were refractory to other therapies (including imiquimod) could particularly benefit from the CAP treatment.

The respondent argued that D1 did not provide any experimental or clinical data to show the therapeutic effect of the treatment with CAP on patients with therapy-refractory actinic keratosis and that therefore the person skilled in the art would not be prompted to use CAP in the treatment of therapy-refractory patients.

However, D1 discloses that the CAP treatment avoids the disadvantages and side effects of current actinic keratosis therapies like topical or systemic drugs or heating therapy (paragraphs [0006] to [0008]). This is because CAP therapy is based on a different therapeutic mechanism. As correctly pointed out by the appellant, the person skilled in the art would have had a reasonable expectation that this therapy would not only be beneficial for patients in which the therapeutic outcome of the current therapies was overshadowed by those side effects but also for patients in which the current therapies were not successful at all.

5.5 The respondent further argued that D1 did not disclose that the CAP was an argon-containing plasma and that the person skilled in the art would have no reason to select argon as a supply gas for the generation of plasma.

However, as mentioned by the appellant, D1 implicitly discloses an argon-containing plasma since air, which naturally contains a certain amount of argon, is mentioned in the list of gas supplies in paragraph [0153].

Even assuming, for the sake of argument, that D1 does not disclose that the CAP is an argon-containing plasma, the selection of argon for generating the plasma would be obvious for the person skilled in the art as argon is a customary gas source for plasma generation, as for instance described in WO 2007/031250, mentioned in paragraph [0021] of the patent in suit. The respondent did not provide any evidence demonstrating that the therapeutic effect of the plasma treatment was due to the fact that the plasma contained argon species.

5.6 Hence, the subject-matter of claim 1 of the main request does not involve an inventive step.

6. Auxiliary requests

6.1 Claim 1 of auxiliary request 1 relates to the specific use of cold atmospheric argon plasma in treating actinic keratosis in therapy-refractory patients. The observations in point 5 also apply to claim 1 of this request.

- 6.2 Claim 1 of auxiliary requests 2 and 3 relates to the specific use of argon-containing CAP in treating actinic keratosis in patients who were previously treated, for instance, with imiquimod. As mentioned above, the use of CAP in patients previously treated with imiquimod is known from D1. Hence, the subject-matter of claim 1 of auxiliary requests 2 and 3 also lacks an inventive step.
- 6.3 Claim 1 of auxiliary request 4 is a combination of claim 1 of auxiliary request 1 and claim 1 of auxiliary request 3. Hence, the subject-matter of claim 1 of this request also lacks an inventive step.
- 6.4 Claim 1 of auxiliary request 5 relates to the use of argon-containing CAP in treating therapy-refractory patients who suffer from actinic keratosis of Olsen grade I, II or III. The Olsen clinical classification scheme grades lesions according to their thickness and degree of hyperkeratosis in three grades (I, II and III). Hence, this feature does not impart any limitation on the claimed subject-matter, which therefore still lacks an inventive step.
- 6.5 Hence, auxiliary requests 1 to 5 are not allowable either.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated