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Datasheet for the decision
of 20 November 2025

Case Number:	T 1046/23 - 3.3.07
Application Number:	15773454.2
Publication Number:	3106199
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Language of the proceedings:	EN

Title of invention:
BALLOON COATING METHOD, COAT LAYER CONTROL METHOD AND BALLOON COATING DEVICE

Patent Proprietor:
Terumo Kabushiki Kaisha

Opponent:
Bard Peripheral Vascular, Inc

Headword:
Balloon coating/TERUMO

Relevant legal provisions:
EPC Art. 123(2), 123(3)

Keyword:
Amendments - added subject-matter (yes) - broadening of claim
(yes)

Decisions cited:
T 2221/10

Case Number: **T 1046/23 - 3.3.07**

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 20 November 2025

Appellant: (Patent Proprietor)	Terumo Kabushiki Kaisha 44-1 Hatagaya 2-chome Shibuya-ku Tokyo 151-0072 (JP)
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Appellant: (Opponent)	Bard Peripheral Vascular, Inc 850 West Rio Salado Parkway, Suite 100 Tempe, AZ 85291 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)

Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 5 April 2023 concerning maintenance of the European Patent No. 3106199 in amended form.**

Composition of the Board:

Chairman	A. Usuelli
Members:	M. Steendijk
	L. Basterreix

Summary of Facts and Submissions

I.   European patent 3 106 199 ("the patent") was granted with five claims.

Claim 1 as granted defines:

"A balloon coating method for forming a coating layer (32) containing a water-insoluble drug on an outer surface of a balloon (30) of a balloon catheter (10), the balloon coating method comprising an application step in which, where a pipe-shaped dispensing tube (94) formed from a polyolefin for supplying a coating solution containing the water-insoluble drug and a solvent is formed at its end portion with an opening portion (95) for discharging the coating solution therethrough and when the end portion side of the dispensing tube (94) is placed in contact with the outer surface of the balloon (30) while the balloon (30) is rotated about an axis of the balloon (30), the coating solution is discharged through the opening portion (95) and applied to the outer surface of the balloon (30) while the dispensing tube (94) is moved relative to the balloon (30) in an axial direction of the balloon (30);

wherein the balloon coating method is characterized in that in the application step, the coating solution discharged in a state where a continuous length of a side surface on the opening portion-formed end portion side (95) of the dispensing tube (94) is in contact with the outer surface of the balloon (30) and

wherein the contact length L is 1.0 mm to 4.1 mm."

Claim 3 as granted defines:

"A coating layer (32) control method for controlling a
degree of uniformity of a coating layer (32) that
contains a waterinsoluble drug and is formed on an
outer surface of a balloon (30) of a balloon catheter
(10), the coating layer control method comprising

an application step in which, where a pipe-shaped
dispensing tube (94) formed from a resin for supplying
a coating solution containing the water-insoluble drug
and a solvent is formed at a part thereof with an
opening portion (95) for discharging the coating
solution therethrough and when the opening portion-
formed part (95) of the dispensing tube (94) is placed
in contact with the outer surface of the balloon (30)
while the balloon (30) is rotated about an axis of the
balloon (30), the coating solution is discharged
through the opening portion (95) and applied to the
outer surface of the balloon (30) while the dispensing
tube (94) is moved relative to the balloon (30) in an
axial direction of the balloon (30);

wherein the coating layer control method is
characterized in that in the application step, the
resin material from which the dispensing tube (94) is
formed is chosen to be:

    (i) a polyolefin, wherein polyolefin is chosen to
    provide a high degree of uniformity,
    (ii) fluororesin, wherein a fluororesin is chosen
    to provide a high degree of non-uniformity, or
    (iii) polyolefin and another dispensing tube (94)
    is formed of fluororesin for sequentially coating
    balloons."

Claim 5 as granted defines:

"A balloon coating apparatus (50) for forming a coating
layer (32) containing a water-insoluble drug on an
outer surface of a balloon (30) of a balloon catheter
(10), the balloon coating apparatus (50) comprising:

> a rotation mechanism portion (60) for rotating the
> balloon (30) about an axis of the balloon (30); a
> pipe-shaped dispensing tube (94) formed from a
> polyolefin for supplying a coating solution
> containing the water-insoluble drug and a solvent;
> and a movement mechanism portion (80) for moving
> the dispensing tube (94) relative to the balloon
> (30) in an axial direction of the balloon (30);
> wherein the balloon coating apparatus (50) is
> characterized in that the dispensing tube (94) is
> flexible to allow that in the application step, the
> coating solution is discharged in a state where a
> continuous length of a side surface on the opening
> portion-formed end portion side (95) of the
> dispensing tube (94) is in contact with the outer
> surface of the balloon (30) and wherein the contact
> length L is 1.0 mm to 4.1 mm."

II.   The patent was opposed on the grounds that its subject-
       matter lacked novelty and inventive step, that the
       claimed invention was not sufficiently disclosed and
       that the patent comprised subject-matter extending
       beyond the content of the application as filed. The
       opposition division decided that the patent as amended
       in accordance with auxiliary request 1 met the
       requirements of the EPC.

The decision was based on the patent as granted (main
request) and on auxiliary request 1 submitted during
the oral proceedings held on 9 March 2023.

The following documents were cited:

D1: US 2013/209662 A1
D2: US 2013/337147 A1
D3: Translation of PCT/JP2015/058547 (WO 2015/151877).

The opposition division arrived at the following
conclusions:

(a) Claims 1 and 5 as granted comprised subject-matter
    extending beyond the content of the application as
    originally filed due to the introduced definition
    of the contact length L of 1.0 mm to 4.1 mm.

(b) Auxiliary request 1 complied with Articles 84,
    123(2) and 123(3) EPC. The patent sufficiently
    disclosed the claimed invention.

    The distinguishing features between independent
    claims 1, 3 and 5 of auxiliary request 1 and the
    prior art concerned the contact of the dispensing
    tube with the balloon in combination with the
    choice of the material of the dispensing tube. The
    distinguishing features allowed for the control of
    the uniformity of the coating of the balloon, which
    was not obvious in view of the prior art. Auxiliary
    request 1 therefore complied with the requirements
    of novelty and inventive step.

III. The patent proprietor and the opponent filed appeals
     against the opposition division's decision.

IV.   With the statement of grounds of appeal, the patent
         proprietor maintained its requests from the first
         instance proceedings, including auxiliary requests
         1-19, and submitted the new auxiliary request 20.

         The amendments of auxiliary request 1 with respect to
         the claims of the main request concern the introduction
         of the following additional feature in claims 1 and 5:

             "wherein the contact length L in contact of the
             dispensing tube (94) with the outer surface of the
             balloon (30) is calculated as a theoretical value
             which is virtually defined as the length L from an
             intersection N, at which the dispensing tube (94)
             intersects the outer surface of the balloon (30),
             to the discharge end (97) of the dispensing tube
             (94), in the case where the dispensing tube (94) is
             assumed to be non-flexible, wherein the contact
             length L is defined when the balloon (30) is
             stationary, without taking the rotation of the
             balloon (30) into account."

         The amendments of auxiliary request 2 concern in
         addition to the amendment of auxiliary request 1 the
         introduction of the following additional feature in
         claims 1 and 5 after the terms "continuous length":

             "i.e. a length which is continuous in the extending
             direction of the dispensing tube (94)".

         The amendments of auxiliary request 3 concern in
         addition to the amendment of auxiliary request 1 the
         introduction of the following additional feature in
         claims 1 and 5 after the term "non-flexible":

             "as depicted in Fig. 39,".

Auxiliary request 4 combines the amendments of auxiliary request 1-3 to granted claims 1 and 5.

Auxiliary requests 5-11 introduce various amendments to claim 3 as granted. Claims 1 and 5 as granted remain unamended in auxiliary requests 5-11.

The amendments of auxiliary request 12 with respect to the claims of the main request concern the introduction of the following additional feature in claims 1 and 3:

"wherein the load exerted on the balloon (30) by the dispensing tube (94) is 1 mN to 158 mN."

Auxiliary requests 13-19 introduce, respectively, the same amendments to claim 3 as auxiliary requests 5-11, and additionally introduce the amendments to claims 1 and 3 of auxiliary request 12. Claim 5 remains unamended in auxiliary requests 12-19.

Auxiliary request 20 introduces the same amendments to claims 1 and 5 as auxiliary request 1 and the same amendment to claim 3 as auxiliary request 11. In addition, auxiliary request 20 defines in claims 1 and 5 the contact length L to be 1.0 mm to 4.0 mm (instead of 1.0 mm to 4.1 mm).

V.   In its communication under Article 15(1) RPBA, the Board issued its preliminary opinion indicating *inter alia* that the patent did not comprise subject-matter extending beyond the content of the application as filed.

VI.   Oral proceedings were held on 20 November 2025.

As announced in its letter dated 30 September 2025, the patent proprietor did not attend the oral proceedings. The proceedings were continued in its absence in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

VII.   The arguments of the opponent relevant to the present decision are summarized as follows:

Claims 1 and 5 as granted defined that the coating solution is discharged in a state where a continuous length of a side surface of the end portion side of the dispensing tube is in contact with the outer surface of the balloon and wherein the contact length L is 1.0 mm to 4.1 mm. Without any reference in the claims to the method for determining this contact length, the skilled person would understand this feature to concern the actual length of physical contact between the side surface at the end of the dispensing tube and the balloon. The application as filed disclosed the range of 1.0 mm to 4.1 mm for the contact length L only in relation to the theoretical value calculated in accordance with the method described in paragraph [0108]. Figure 5 of the patent showed that the actual length of physical contact was not necessarily equal to the theoretically calculated virtual contact length. Accordingly, the omission of the definition of the method for determining the defined contact length in granted claims 1 and 5 resulted in subject-matter extending beyond the content of the application as originally filed.

The amendment of claims 1 and 5 of auxiliary request 1 introduced the method of measurement of the contact length L as disclosed in paragraph [0108] of the application as originally filed. Figure 5 of the patent demonstrated that, due to the curvature of the

dispensing tube when in contact with the balloon, the
virtual minimum length of 1.0 mm as defined in the
amended claims 1 and 5 of auxiliary request 1 may
correspond to an actual physical contact length of less
than 1.0 mm. Claims 1 and 5 as granted defined a
minimum value for the actual physical contact length of
1.0 mm. The amendment of claims 1 and 5 of auxiliary
request 1 therefore did not comply with Article 123(3)
EPC.

The auxiliary requests 1-20 did not overcome the
objections against the main request or auxiliary
request 1.

VIII.   The arguments of the patent proprietor relevant to the
         present decision are summarised as follows:

         The application as originally filed specifically
         disclosed the range of 1.0 mm to 4.1 mm for the contact
         length L in paragraphs [0109] and [0231]-[0233].

         The objection regarding the lacking reference to the
         method for determining the contact length L in claims 1
         and 5 as granted represented at most an objection of
         lack of clarity. However, the definite meaning of the
         contact length L was clearly explained in the
         application as filed. As indicated in T 2221/10, the
         description could according to the established case law
         be used as the patent's "dictionary" to assess the
         correct meaning of ambiguous terms used in the claims.

         Insofar as there was any doubt resulting from the
         wording of the claims, the skilled person would have
         recognized from the description that the length of the
         actual physical contact was not intended. The amendment
         in claims 1 and 5 of auxiliary request 1, which

introduced the only method of measurement for the
contact length L provided in the description of the
application as originally filed, could therefore not
result in the broadening of the claims as granted.

IX.   Insofar as relevant to the decision, the appellant-
        opponent requested that the decision under appeal be
        set aside and that the patent be revoked in its
        entirety.

X.   Insofar as relevant to the decision, the appellant-
        patent proprietor requested that the decision under
        appeal be set aside and that the patent be maintained
        as granted, or, as an auxiliary measure, that the
        patent be maintained on the basis of one of auxiliary
        requests 1-4 as filed during the oral proceedings on
        9 March 2023, auxiliary requests 5-19 filed (as
        auxiliary requests 1-15) on 9 January 2023, or
        auxiliary request 20 filed with the statement of
        grounds of appeal.

Reasons for the Decision

Main request - the patent as granted

1.   Added subject-matter - claims 1 and 5

1.1   Document D3 represents the English translation of the
        application as originally filed. For the identification
        of the content of the application as originally filed
        reference is made to the numbering of the paragraphs
        and claims in document D3.

1.2   It was common ground that granted claims 1 and 5
        correspond to original claims 1 and 7 of the

application as filed, in which the feature from
original dependent claim 3 is incorporated into the
characterizing portion, together with the additional
specification that the contact length (L) ranges from
1.0 mm to 4.1 mm. Notably, the originally filed
application specifies in paragraph [0109] that the
contact length L is not particularly limited, but is
preferably within the range of 1.0 mm to 4.0 mm.
Furthermore, paragraph [0233] indicates that the
preferred contact length extends from 0 mm to 4.1 mm,
with a more preferred range of 1.9 mm to 4.1 mm.

The dispute concerned the question whether the
definition of the contact length L as 1.0 mm to 4.1 mm
without definition of the method for determining this
contact length L in the claims as granted introduced
subject-matter extending beyond the content of the
application as filed.

1.3   Interpretation of claims 1 and 5 as granted

1.3.1   Claims 1 and 5 as granted define that the coating
         solution is discharged and applied to the outer surface
         of the rotating balloon while the dispensing tube is
         moved relative to the balloon in an axial direction of
         the balloon and that the coating solution is discharged
         in a state where a continuous length of a side surface
         of the dispensing tube is in contact with the outer
         surface of the balloon wherein the contact length L is
         1.0 mm to 4.1 mm.

1.3.2   The application as filed refers in paragraph [0108] to
         a possible method for calculating the length of the
         contact of the dispensing tube with the outer surface
         of the balloon as a theoretical value as follows:

"Note that the contact length in contact of the
dispensing tube 94 with the outer surface of the
balloon 30 can be calculated as a theoretical value
which is virtually defined as the length L from an
intersection N, at which the dispensing tube 94
intersects the outer surface of the balloon 30, to
the discharge end 97 of the dispensing tube 94, in
the case where the dispensing tube 94 is assumed to
be non-flexible, as depicted in FIG. 39. Note that
the contact length L as a theoretical value is
defined without taking the rotation of the balloon
30 into consideration; thus, the contact length L
is a value when the balloon 30 is stationary."

Figure 39 of the application as filed illustrates the
determination of this virtually defined contact length
as follows:

FIG.39
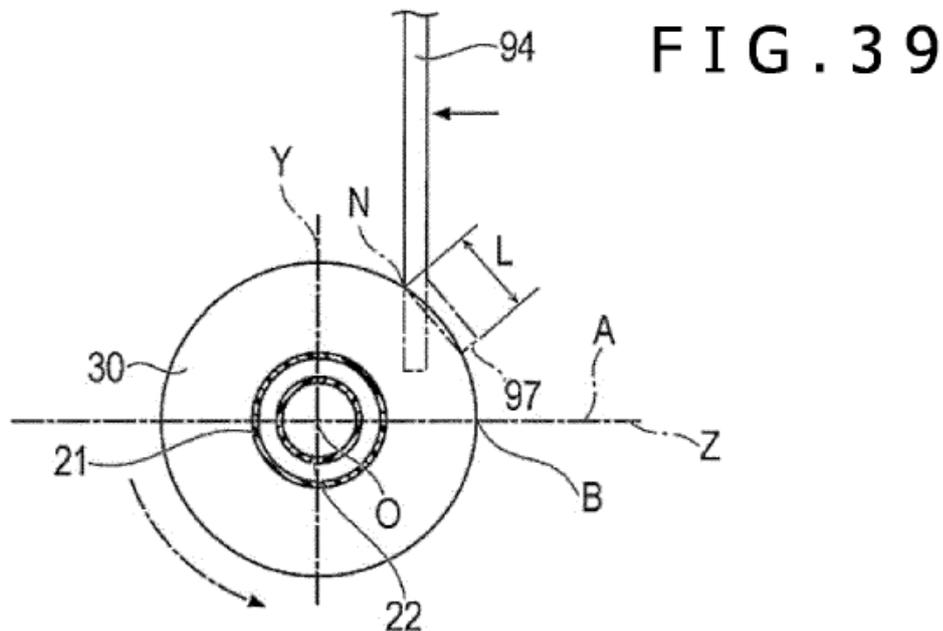
The same information is presented in paragraph [0100]
and Figure 39 of the patent.

1.3.3   The reproduction of Figure 5 of the application in the
        appellant-opponent's submission of 13 October 2025

demonstrates how this virtually defined "theoretical" contact length may differ from the "real" length of the physical contact of the dispensing tube with the outer surface of the balloon due to a curvature of a flexible tube in the state in which the coating solution is actually applied to the surface of the balloon.

FIG.5

1.3.4   The wording of claims 1 and 5 expressly refers to the state in which the coating solution is discharged onto the rotating balloon and the side surface of the dispensing tube makes physical contact with the balloon over a contact length defined as 1.0 mm to 4.1 mm.

Paragraph [0108] of the application as originally filed and paragraph [0100] of the patent merely describe the possibility of calculating a theoretical contact length in which the balloon is stationary.

The description of the patent does thereby not provide a uniquely applicable definition for the term contact length as used in claims 1 and 5 as granted, which

instead refer to the state in which the solution is discharged. The consideration that the description may in certain circumstances function as the patent's "dictionary", as referred to in T2221/10 (reasons 33), therefore does not apply.

An interpretation of the contact length in the sense of the virtual definition presented in paragraph [0100] of the patent would, absent any reference to such a definition in the claims, be inconsistent with the explicit wording of claims 1 and 5 as granted. Accordingly, consulting the description provides no compelling reason to depart from the clear language of the claims. Such an interpretation would also undermine the balance envisaged by the Protocol on the Interpretation of Article 69 EPC, which seeks to combine fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties. The Board therefore concludes that the contact length L defined in claims 1 and 5 must be understood as referring to the physical contact between the dispensing tube and the balloon surface, and not to the virtual contact length mentioned in paragraph [0100] of the description.

1.4   Range of 1.0 mm to 4.1 as disclosed in the application as filed

1.4.1   Immediately following the explanations regarding calculation of the virtually defined contact length L in paragraph [0108], the application as originally filed discloses in paragraph [0109]:

         "The contact length L in contact of the dispensing tube 94 with the outer surface of the balloon 30 is

not particularly limited, and is preferably 0 mm to
4.0 mm, more preferably 1.0 mm to 4.0 mm."

The application as originally filed further mentions in
paragraphs [0215], [0231] and [0233], in the context of
the examples, values for the contact length ranging
from 1.0 to 4.1, as follows:

"In addition, the contact length L in contact of
the dispensing tube with the balloon outer surface
was 4.1 mm, and the load exerted on the balloon
outer surface due to the contact of the dispensing
tube was 158 mN." [0215]

"According to Examples 10 to 21, therefore, the
contact length of the tube is preferably 0 mm to
4.0 mm, more preferably 1.0 mm to 4.0 mm." [0231]

"According to Examples 22 to 25, therefore, the
contact length of the tube is preferably 0 mm to
4.1 mm, more preferably 1.9 mm to 4.1 mm."[0233].

Notably, the application as originally filed expressly
states in paragraph [0189], referring to example 11:

"In addition, the contact length L (theoretical
value; see FIG. 39) in contact of the dispensing
tube with the balloon outer surface was 3.2 mm."

The application as originally filed further provides in
paragraph [0227] a collective presentation of the
examples in Table 1, including the determined contact
lengths.

1.4.2   From the disclosure of the range of 1.0 mm to 4.0 mm in
paragraph [0109] of the application as filed

immediately following reference to the virtually
defined contact length L in paragraph [0108], the
skilled person could infer that the mentioned range
paragraph [0109] related to the virtually defined
theoretical value for the contact length L. Moreover,
from the explicit reference in paragraph [0189] to the
theoretical value for the contact length L in
example 11 and the collective presentation of the
contact lengths of the examples in Table 1, the skilled
person would understand that the contact lengths
mentioned for the examples, including the values 1.0 mm
and 4.1 mm, concern calculated theoretical values and
not the length of physical contact of the tube with the
balloon in the state in which the coating solution is
discharged.

1.5   The application as originally filed thus describes the
       range of 1.0 mm to 4.1 mm in the context of the
       virtually defined theoretical value for the contact
       length L, whereas claims 1 and 5 as granted define the
       range of 1.0 mm to 4.1 mm for the length of the
       physical contact of the dispensing tube with the outer
       surface of the balloon.

       As explained in section 1.3.3 above, the virtually
       defined "theoretical" contact length may differ from
       the "real" length of the physical contact of the
       dispensing tube with the outer surface of the balloon.

       Accordingly, due to the introduction of the definition
       of the contact length L of 1.0 mm to 4.1 mm in claims 1
       and 5, the patent as granted comprises subject-matter
       extending beyond the content of the application as
       originally filed, contrary to the provision of Article
       123(2) EPC.

Auxiliary request 1

2.   Extension of scope of protection - claims 1 and 5

2.1   For the reasons as set out in section 1.3 above, claims
        1 and 5 as granted are considered to define the range
        of 1.0 mm to 4.1 mm for the length of the physical
        contact of the dispensing tube with the outer surface
        of the balloon.

        Claims 1 and 5 of auxiliary request 1 define the range
        of 1.0 mm to 4.1 mm for the contact length as being
        calculated as the theoretical value in accordance with
        paragraph [0108] of the description of the application
        as originally filed and paragraph [0100] of the granted
        patent.

2.2   As explained in section 1.3.3 above, the virtually
        defined theoretical contact length may differ from the
        length of the physical contact of the dispensing tube
        with the outer surface of the balloon. Notably, due to
        the curvature of a flexible tube in the state in which
        the coating solution is actually applied to the surface
        of the rotating balloon, the minimum of 1.0 mm for the
        virtually defined theoretical contact length may
        correspond to a length of the actual physical contact
        of the dispensing tube with the outer surface of the
        balloon of less than 1.0 mm.

        Accordingly, the amendment according to auxiliary
        request 1 extends the scope of protection of claims 1
        and 5 by allowing for a lower minimal length of the
        physical contact of the dispensing tube with the outer
        surface of the balloon than the 1.0 mm as defined in
        claims 1 and 5 as granted, contrary to the provision of
        Article 123(3) EPC.

Auxiliary requests 2-4

3.   Like auxiliary request 1, auxiliary requests 2-4 also
        introduce in claims 1 and 5 the definition that the
        range of 1.0 mm to 4.1 mm for the contact length is
        calculated as the theoretical value in accordance with
        paragraph [0108] of the description of the application
        as originally filed and paragraph [0100] of the granted
        patent.

        Accordingly, auxiliary request 2-4 do not comply with
        Article 123(3) EPC for the same reason as set out in
        section 2 above in relation to auxiliary request 1.

Auxiliary requests 5-19

4.   According to auxiliary requests 5-11, claims 1 and 5 as
        granted remain unamended.

        According to auxiliary requests 12-19, claim 5 as
        granted remains unamended.

        Moreover, the amendment to claim 1 according to
        auxiliary requests 5-11 merely concerns the
        introduction of the feature that the load exerted on
        the balloon by the dispensing tube is 1 mN to
        158 mN, which leaves the definition of the length of
        1.0-4.1 mm for the physical contact of the dispensing
        tube with the outer surface of the balloon unchanged.

        Accordingly, auxiliary request 5-19 do not comply with
        Article 123(2) EPC for the same reason as set out in
        section 1 above in relation to the main request.

Auxiliary request 20

5. Auxiliary request 20 also introduces in claims 1 and 5
    the definition that the contact length is calculated as
    the theoretical value in accordance with paragraph
    [0108] of the description of the application as
    originally filed and paragraph [0100], albeit with the
    range defined as 1.0 mm to 4.0 mm.

    For the same reasons as set out in section 2.2 above,
    the amendment according to auxiliary request 20 extends
    the scope of protection of claims 1 and 5 as granted by
    allowing for a lower minimal length of the physical
    contact of the dispensing tube with the outer surface
    of the balloon than the 1.0 mm as defined in claims 1
    and 5 as granted.

    Accordingly, auxiliary request 20 does also not comply
    with Article 123(3) EPC.

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. Vottner   A. Usuelli

Decision electronically authenticated