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Datasheet for the decision of 27 January 2026

Case Number: T 0201/24 - 3.3.04

Application Number: 20164728.6

Publication Number: 3718565

IPC: A61K39/12, A61P11/00, C07K16/10

Language of the proceedings: EN

Title of invention:
Respiratory virus vaccines

Patent Proprietor:
ModernaTX, Inc.

Opponents:
BioNTech SE
SANOFI
Withers & Rogers LLP
Pfizer Inc.

Headword:
Coronavirus vaccine/MODERNA

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Divisional application - subject-matter extends beyond content of earlier application (yes)

Decisions cited:
G 0002/10, T 1462/24

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Beschwerdekammern

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Case Number: T 0201/24 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 27 January 2026

Appellant: (Patent Proprietor)	ModernaTX, Inc. 325 Binney Street Cambridge, MA 02142 (US)
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Respondent IV: (Opponent 4)	Pfizer Inc. 66 Hudson Boulevard East New York, NY 10001-2192 (US)
Representative:	Eder, Michael df-mp Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 7 December 2023 revoking European patent No. 3718565 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	D. Luis Alves
	L. Bühler

Summary of Facts and Submissions

I. The patent proprietor (appellant) filed an appeal against the decision of the opposition division to revoke European patent No. 3 718 565, entitled "*Respiratory virus vaccines*". The patent in suit was granted on European patent application No. 20 164 728.6, a divisional application of European patent application No. 16 858 406.8. The latter had been filed as an international application published as WO 2017/070626 (the earlier application as filed).

II. Four oppositions had been filed, invoking grounds for opposition under Article 100(a) EPC, lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), and under Article 100(b) and (c) EPC.

III. In its decision, the opposition division considered a main claim request and 117 auxiliary claim requests. It held, *inter alia*, that each request related to subject-matter extending beyond the content of the application and the earlier application as filed (Articles 123(2) and 76(1) EPC).

IV. With the statement setting out the grounds of appeal, the appellant filed a set of claims of auxiliary request 118 and document D133.

V. Opponent 1 (respondent I) submitted a reply to the statement of grounds of appeal and document D134.

VI. Opponent 4 (respondent IV) also submitted a reply to the statement of grounds of appeal.

VII. Opponents 2 and 3 (respondents II and III) did not make any substantive submissions in appeal proceedings.

VIII. The board sent a summons to oral proceedings and a communication pursuant to Article 15(1) RPBA in which it set out its preliminary view on the appeal.

IX. Oral proceedings were held as scheduled, in the presence of the appellant and respondents I and IV. Respondents II and III did not attend, as announced by letters dated 21 November 2025 and 5 January 2026, respectively.

At the oral proceedings, the appellant renumbered auxiliary request 6 as auxiliary request 1 and withdrew all remaining auxiliary requests on file. Respondent I clarified that it did not request that the appeal be dismissed as unsubstantiated.

At the end of the oral proceedings, the chair announced the board's decision.

X. Claim 1 of the **main request** reads:

"1. A betacoronavirus (BetaCoV) messenger RNA (mRNA) vaccine comprising at least one mRNA polynucleotide having an open reading frame encoding at least one BetaCoV antigenic polypeptide;
wherein the at least one BetaCoV antigenic polypeptide is (a) a spike (S) protein or immunogenic fragment thereof, or (b) an S1 subunit or an S2 subunit of S protein or an immunogenic fragment thereof;
wherein the BetaCoV vaccine is formulated in a lipid nanoparticle, wherein the lipid nanoparticle comprises 40-60% cationic lipid, 5-15% non-cationic lipid, 1-2% PEG lipid, and 30-50% cholesterol."

Claim 1 of **auxiliary request 1** reads:

"1. A betacoronavirus (BetaCoV) messenger RNA (mRNA) vaccine comprising at least one mRNA polynucleotide having an open reading frame encoding at least one BetaCoV antigenic polypeptide;
wherein the at least one BetaCoV antigenic polypeptide is a spike (S) protein;
wherein the BetaCoV vaccine is formulated in a lipid nanoparticle, wherein the lipid nanoparticle comprises 40-60% cationic lipid, 5-15% non-cationic lipid, 1-2% PEG lipid, and 30-50% cholesterol."

XI. The following documents are referred to in this decision:

D133: Expert report of Professor Alabi, filed with The High Court of England and Wales (Patents Court), excerpt, pages 1 to 11 and 29 to 33.

XII. The appellant's arguments relevant to this decision may be summarised as follows.

Main request
Article 76(1) EPC - extension beyond the content of the earlier application as filed - claim 1

The opposition division did not apply the gold standard and focused instead on whether the features were taken from lists. Applying the gold standard required a technical assessment of the overall circumstances of the case (G 2/10, Headnote and Reasons 4.5.1 and Case Law of the Boards of Appeal of the EPO, 11th edn., 2025 (CLBA), II.E.1.3.1). Tests did not replace the gold standard (T 1261/21, Reasons 4.2.12 and 4.2.13). What

was relevant was whether the skilled person was presented with new technical information.

The earlier application as filed taught that there was no interrelation between the encoded protein and the composition of the lipid nanoparticle (LNP) (CLBA, II.E.1.3.2, last paragraph, and T 367/20) for the reasons that follow.

The LNPs were not *per se* the invention as the earlier application as filed taught that LNPs were known in the art (page 51, lines 30 to 31). Indeed, the skilled person knew how to formulate LNPs with a cationic lipid to promote encapsulation of the nucleic acid, together with the other components for their supporting function. The information encoded by the mRNA did not influence how the LNP functioned.

Rather, the invention lay in the formulation of mRNA in LNPs and was not restricted to specific viruses or antigens (see page 4, lines 19 to 22 and 25 to 27, and page 8, disclosing coronavirus). LNP delivery was superior to other formulations and enhanced the effectiveness of the vaccine (page 50, line 18 to page 51, line 30), and the same class of LNP worked for different antigens (see page 51, lines 8 to 13 and 20 to 25). The earlier application as filed disclosed a class of LNPs for delivering all the antigens mentioned (see page 50, line 30, disclosing "*a class of formulations for delivery of mRNA vaccines*"). The skilled person understood that there was no need to adapt the LNP depending on the encoded polypeptide (see LNP components on page 14, lines 21 to 22, and summary of the examples on page 26, first paragraph). What was relevant for the composition of the LNP was that it was for delivering a polyanionic molecule, not the sequence

of amino acids encoded. The combination of the proteins and LNP composition in claim 1 was already envisaged, as could be seen from example 20.

Moreover, the examples showed that the same LNP composition was used to deliver antigens from different viruses (see examples 13, 18, 20 and 26). This demonstrated that there was no interrelation between the LNP composition and the antigen. The LNP composition worked excellently for all the respiratory viruses, including betacoronavirus. The fact that none of the viruses performed better than the others with this LNP could not be to the detriment of the inventors.

Claim 1 merely limited the subject-matter to the encoded polypeptide used in the working examples, without presenting new technical information. The ranges given in claim 1 for the four classes of components of the LNP were the broadest disclosed. They were also consistent with the examples. The proteins in claim 1 did not constitute a selection for the following reasons. Structural proteins were emphasised in the application, in particular the S, S1 and S2 proteins (see pages 43 to 44 and summary of the invention, page 8, lines 28 to 30, and page 9, second paragraph). The working examples used the S, S1 and S2 proteins.

Example 20 linked all the features in claim 1. It disclosed the proteins S, S1 and S2 - no selection was required. Further, it disclosed LNP compositions on a generic level without specifying the lipid compounds to be used for each component class. It therefore provided a pointer to the composition in claim 1. The ranges in claim 1 were also disclosed on page 95, lines 6 to 9

and 15 to 31. Contrary to the respondents' arguments, the ranges in claim 83 could not be given more weight than those in the examples. That would not constitute a reasonable technical assessment of the disclosure in the earlier application.
There was a consistent teaching of four components, even if other LNPs were mentioned.

Auxiliary request 1

Article 76(1) EPC - extension beyond the content of the earlier application as filed - claim 1

In claim 1, the encoded antigen was limited to the S protein. This was not an arbitrary selection as examples 23 and 24 demonstrated a remarkable efficacy of the vaccination with this antigen (see also Figure 18 and page 51). The earlier application made a distinction between the S protein, on the one hand, and the S1 and S2 subunits, on the other hand (page 9, first paragraph).

XIII. The respondents' arguments relevant to this decision may be summarised as follows.

Main request
Article 76(1) EPC - extension beyond the content of the earlier application as filed - claim 1

The application did not disclose that the LNP must comprise at least four components and disclosed also LNPs comprising a single lipid (see page 91, line 30). In fact, liposomes and lipoplexes were also disclosed for mRNA delivery, and their compositions were disclosed in detail (see page 96 and page 97, second

paragraph). Further, there was an interrelation between the components of the LNP (see page 91, line 4).

The examples did not provide a basis for generalisation. Example 20 had not been carried out. Moreover, in view of the interrelation between the LNP components (see page 91, line 4), one component could not be varied in isolation. On the other hand, there was no pointer on how to generalise from the composition in example 20.

The assessment based on lists was a suitable tool which was not superseded by the gold standard. Claim 1 combined certain ranges, a type of pathogen and an antigen protein, without any pointer to this combination. Contrary to the appellant's arguments, the antigen in claim 1 resulted from a selection from a list. Claim 44 as filed showed that the S protein and its S1 and S2 subunits formed one group. An immune response was elicited against the S protein, irrespective of whether the antigen was the full protein or one of its S1 and S2 subunits. Therefore, claim 1 did not relate to a list of three antigens as argued. In claim 1, this group was selected instead of one of the other structural proteins, namely, the envelope protein (E), the nucleocapsid protein (N) or the membrane protein (M). However, the group formed by the S protein and its subunits was not singled out from the other structural proteins (see page 43, line 29 to page 45, line 18). Thus, claim 1 resulted from different sections of the earlier application as filed in the absence of any pointer to their combination. A mix and match of preferred and non-preferred features was not allowable. Of the claims, only claim 83 provided an LNP composition, this being the only pointer to a preferred composition. This composition

was not, however, the one in claim 1. Further alternative ranges were provided, for example, on page 17, lines 11 to 12; page 92, lines 22 to 23; and page 94, lines 20 to 22. The skilled person reading the earlier application as filed would not know what the preferred ranges and antigen were.
The mere fact that examples provided a composition within the scope of a claim was not enough support. It did not provide a pointer to the ranges in claim 1 as the formulation it disclosed fell within several other ranges disclosed in the earlier application as filed.

The application contained no evidence that the LNP composition was independent of the encoded antigen. It could not be stated that there was no functional interrelation between the LNP and the encoded antigen because different antigens had different requirements for inducing an immune response. Some were located inside the virus and others outside. For the S protein, a cell-based immune response would be required. Specific LNP compositions, as in example 20, corresponded to specific properties for the delivery of the antigen (see page 112, lines 5 and following, line 15 and following).

While the combination of features in claim 1 might be encompassed by the disclosure in the application, there was no pointer to it. Sentences mentioning different possibilities did not constitute credible disclosure that certain combinations of features were envisaged.

Auxiliary request 1
Article 76(1) EPC - extension beyond the content of the earlier application as filed - claim 1

The same conclusions should apply as for the main request. The limitation of claim 1 to the S protein did not overcome the objection as it still required a selection. In light of claim 44 of the earlier application, which presented the S protein and the S1 and S2 subunits as the same antigen, this was in fact not a limitation.

Further, it was disputed that examples 23 and 24 demonstrated superior results for the S protein. Additionally, these examples concerned MERS coronavirus instead of betacoronavirus and did not indicate the composition of the LNP. Therefore, even more generalisation was required to arrive at the vaccine defined in claim 1 of this request.

Moreover, the application as a whole made clear that the antigen could be selected from the M, E, N and S proteins.

XIV. The relevant requests of the parties were as follows.

The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the set of claims of the main request or auxiliary request 1, which is identical to auxiliary request 6 considered in the decision under appeal.

Respondents I and IV both requested that the decision under appeal be upheld and that the appeal be dismissed.

Respondent I further requested that none of the auxiliary requests be admitted into the appeal proceedings.

Reasons for the Decision

Main request

Article 76(1) EPC - extension beyond the content of the earlier application as filed - claim 1

1. Claim 1 is directed to a vaccine comprising an mRNA encoding an antigen of betacoronavirus formulated in a lipid nanoparticle (LNP). The antigen is a spike (S) protein, an S1 or S2 subunit of it, or immunogenic fragments of the S protein or its S1 or S2 subunits. The LNP is defined by three classes of lipids and one specified lipid (cholesterol), each present in a range defined in the claim.

2. In the decision under appeal, the opposition division held that claim 1 of the main request related to subject-matter extending beyond the content of the application and the earlier application as filed. In essence, the opposition division considered that whereas the combination of the features betacoronavirus, mRNA and LNP was disclosed in the earlier application as filed, the feature cholesterol, the features defining the LNP composition and the feature defining the antigen each required a selection

such that the combination of features was not directly and unambiguously derivable from the application as filed.

3. This decision focuses on the feature defining the antigen and the features defining the LNP by the classes of components and the ranges in which they are present. The board assessed the allowability of the amendments in the form of claim 1 only in respect of Article 76(1) EPC, and therefore reference is to the disclosure in the earlier application as filed. The passages cited by the parties also referred to the earlier application as filed.

4. A major point made by the appellant was that the opposition division focused on whether the features in the claim were selected from lists instead of applying the gold standard. All parties made submissions on this point.

5. The Enlarged Board held in decision G 2/10, OJ EPO 2012, 376, that the gold standard for assessing any amendment for its compliance with Article 123(2) EPC, as established in opinion G 3/89 and decision G 11/91, is that "*any amendment to the parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) [...] can [...] only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of these documents*" (see Reasons 4.3). Determining whether or not this is the case requires a technical assessment of the overall technical circumstances of the case (see Headnote 1b.).

6. In the board's view, the gold standard does not preclude assessing whether the claimed subject-matter amounts to combinations from selections made from several lists. The board refers to recent decision T 1462/24, published after the oral proceedings in the present case, for an analysis of the relevant case law (see Reasons 24 and 24.1 to 24.3). Indeed, the approach relying on selections from lists is a means of assessing the amendments vis-à-vis the application as filed (or the earlier application as filed) that serves the purpose of applying the gold standard. However, there is no need of a detailed discussion in the present case, since the board did not rely on this approach.

7. The earlier application as filed concerns mRNA vaccines for respiratory diseases. It describes advantages of RNA- versus DNA-based vaccines (page 3, line 34 to page 4, line 4 and page 4, lines 19 to 22). It discloses vaccines where the RNA is formulated in a cationic LNP (page 4, lines 25 to 27) as well as vaccines with flagellin adjuvants or with mRNA encoding flagellins (page 4, lines 28 to 31).

Possible compositions of the LNP include the component classes cationic lipid, PEG-modified lipid, sterol and non-cationic lipid (page 14, lines 21 to 22). Advantages of using LNPs for delivery of mRNA are disclosed on page 50, line 18 to page 51, line 30. Delivery with LNPs is stated to be superior to "*a protamine based approach described in the literature*" and to "*other classes of lipid based formulations*". The composition of the LNPs has a dedicated section starting on page 90 and includes a cationic LNP formed by a lipid and a polycation (page 90, lines 33 to 34 and page 98, fifth paragraph), an LNP comprising at

least one lipid (page 91, lines 30 to 31) and LNPs comprising four components present in various percentages (see pages 92, second paragraph to page 95). A generally defined LNP comprising three classes of components, with a fourth class being optional, is also disclosed in this section (see page 95, lines 6 to 7). A further section is dedicated to liposomes, lipoplexes and LNPs as mRNA delivery vehicles according to the invention (see page 96, last paragraph to page 105). This section also discloses LNPs which do not necessarily comprise four components (see page 98, lines 26 to 28). Further LNPs are defined as hydrophobic polymer particles (page 108, lines 1 to 2). They may be adapted depending on the target cell for the delivery (page 112, second paragraph).

In the section dedicated to the LNP composition, LNPs comprising four component classes in a variety of ranges include: 20-60% of a cationic lipid, 25% of a non-cationic lipid, 0.5-15% of a PEG-modified lipid and 25-55% of a sterol (page 17, lines 11 to 12 and claim 83); 20-60% of a cationic lipid, 5-25% of a neutral lipid, 0.5-15% of a PEG-modified lipid and 25-55% of a sterol, where the cationic lipid is selected from three compounds and the neutral lipid from five compounds (page 92, lines 22 to 23); 20-70% of a cationic lipid, 5-45% of a neutral lipid, 0.5-15% of a PEG-modified lipid and 20-55% of cholesterol (page 94, lines 20 to 22).

The examples provide compositions for delivery of mRNA encoding antigens from a number of respiratory viruses, including for delivery of the S protein and its S1 and S2 subunits (examples 20 to 22).

8. In summary, although further inventions are presented in the earlier application as filed, the formulation of the mRNA in an LNP is the one given the greatest emphasis and detail. Although there is a focus on LNP compositions comprising four component classes, these are not always the same, nor is it apparent which combination is preferred. For example, the general classes of components include cationic lipids, non-cationic lipids, neutral lipids, structural lipids, sterols, PEG and PEG-modified lipids. In some instances, three components are generally defined by a class of compounds, and a fourth one is specified to be cholesterol. The same applies to the ranges. It is not apparent which are the broadest ranges disclosed: compositions generically defined by four component classes and their ranges may differ in one composition in the range of one component, in another in the range for another component, and the component classes may also differ between these compositions. Neither the examples nor the other parts of the description provide information on the relevance of the component classes or ranges for the virus, the encoded antigen or the targeted cell.

The board came to the conclusion that the earlier application as filed does not directly and unambiguously disclose that mRNA encoding the S protein, or one of its subunits, was to be delivered in an LNP with the composition in claim 1.

9. The appellant argued that the earlier application as filed disclosed that there was no interrelation between the two features at issue, i.e. the composition of the LNP and the antigen encoded by the mRNA.

9.1 In this context, it was argued that the LNP was already known in the art, as acknowledged in the earlier application, on page 51, lines 30 to 31, and therefore the invention did not lie in the composition of the LNP. The cited passage states that "[t]*he LNP used in the studies described herein has been used previously to deliver siRNA*". In the board's view, this passage does not imply that all LNP compositions are suitable for delivery of every antigen, as argued by the appellant, at least because it does not specify which LNP compositions are meant. As summarised above, the application generically describes compositions comprising one component, three components or four components present in a variety of ranges. If, on the other hand, the "*studies*" are the examples in the application, they relate to specific LNP compositions which are not those found in claim 1. Therefore, the board finds that this passage on its own does not support the appellant's argument.

9.2 Also, the passage on page 26, first paragraph, does not support the appellant's argument. In the board's view, this passage does not contain the information that the polyanionic nature of the mRNA is the relevant issue and that, as a consequence, there is no need to adapt the LNP composition to the encoded polypeptide, as argued by the appellant. Instead, this passage appears to relate to chemically modified versus unmodified RNA since it states that "[b]*oth the chemically modified and unmodified RNA vaccines of the invention produce better immune responses than the mRNA vaccines formulated in a different lipid carrier*".

9.3 The cited passages on pages 50 and 51 all confirm that the invention lies in mRNA delivery with an LNP, as argued by the appellant. However, they do not provide

the skilled person with the information that all LNPs are suitable for all mRNAs. In this context, the following passage was in particular highlighted: "*a class of formulations for delivery of mRNA vaccines*" (see page 50, line 30). However, it is not clear what is meant here by "*a class*", so the reader needs further information. That information, however, is not provided. It is not clarified whether the class means any particle that comprises a cationic lipid, or whether it means an NLP comprising four different classes of components. Also, the appellant's argument that the only relevant characteristic of the particle was that it serves to deliver a polyanionic molecule is not present in the application. The explanation that delivery of polyanionic molecules only requires certain components in the particle, such as a cationic lipid, was not present in the application. In fact, such information is not directly derivable from the application as a whole, which focuses on LNPs with four classes of components, as argued by the appellant. The passage on page 14, lines 21 to 22, does not provide this information either. The same applies to the examples.

9.4 Example 20 was highlighted for presenting all features of claim 1 together and providing a pointer to the component classes and ranges in the claim. In the board's view, even if an example, in this case example 20, uses a composition falling within the broad definition in claim 1, this does not on its own provide the skilled person with the information on how to extrapolate to other embodiments. In the current case, the experiment described in example 20 was not carried out. Example 20 does not contain any technical information other than the concept of delivering mRNA

encoding the S protein or its S1 and S2 subunits formulated in an LNP, which is defined as follows: "*In experiments where a lipid nanoparticle (LNP) formulation is used, the formulation may include a cationic lipid, a non-cationic lipid, PEG lipid and structural lipid in the ratios 50:10:1.5:38.5. The cationic lipid is DLin-KC2-DMA (50 mol%) or DLin-MC3-DMA (50mol%), the non-cationic lipid is DSPC (10 mol%), the PEG lipid is PEG-DOMG (1.5 mol%)and the structural lipid is cholesterol (38.5 mol%), for example.*" Any guidance on why this LNP composition is suitable and which criteria to apply to provide variations of the percentages in example 20 is missing. The appellant also argued that the range in claim 1 is the broadest. However, as summarised above, there are multiple disclosures on pages 90 to 95 and 98 to 105 of ranges which encompass these percentages.

9.5 For these same reasons, the fact that the specific composition of example 20 was also used for delivery of several different antigens does not provide the missing information either, namely, which other ranges or combinations of component classes among those listed in the application are suitable.

10. The appellant argued that the structural proteins of betacoronavirus were preferred for vaccines, and that, among these, the S protein and its S1 and S2 subunits were preferred. While the board agrees that there is a preference for structural proteins (see page 9, second paragraph), it is not directly derivable from the cited passages that this preference relates to the S protein and its subunits. This may appear to be the case when reading in isolation the paragraph bridging pages 8 and 9, but in multiple other passages, all structural proteins, i.e. the S protein, the envelope protein (E),

the nucleocapsid protein (N) and the membrane protein (M), are presented as equal (see page 43, line 29 to page 45, line 19). As regards the ranges of the classes of components, as set out above they are, in fact, not the broadest. So the argument that the broadest ranges may be seen as preferred and generally applicable to all embodiments of the invention cannot be accepted. This notwithstanding, the board does not agree that all ranges are generally applicable for the reasons set out above.

11. For the foregoing reasons, the board concluded that the requirements of Article 76(1) EPC are not met.

Auxiliary request 1

Admittance into the appeal proceedings

12. This request was filed in opposition proceedings as auxiliary request 6. The opposition division decided to admit it into the proceedings. Although its admittance was contested by respondent I, there is no need to give reasons for its admittance since, for the reasons given below, the request could not be allowed.

Article 76(1) EPC - extension beyond the content of the earlier application as filed - claim 1

13. The reasons set out above for the main request apply equally to this request. The finding that the earlier application as filed does not directly and unambiguously disclose that mRNA encoding the S protein, or one of its subunits, was to be delivered in an LNP with the composition in claim 1 applies to the antigen S protein in the same way as it applies to the

group formed by the S protein and its S1 and S2 subunits. The appellant argued in the context of this request that the S protein can be seen as preferred also in light of examples 23 and 24. However, this does not change the conclusion in view of example 20. Also, these examples do not provide the information missing from example 20.

Document D133

14. This document was filed by the appellant with its statement setting out the grounds of appeal, and its admittance into the appeal proceedings was disputed. The appellant referred to it in relation to the feature "cholesterol", in the context of the objections under Article 76(1) EPC. However, since this feature did not play a role for the board to come to a decision on the appeal, the document did not need to be considered, and no decision needed to be taken as to its admittance into the appeal proceedings either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

A. Vottner M. Pregetter

Decision electronically authenticated