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**Datasheet for the decision  
of 18 October 2023**

**Case Number:** T 0747/21 - 3.3.08

**Application Number:** 14833130.9

**Publication Number:** 3090060

**IPC:** C12Q1/68, C12N15/11

**Language of the proceedings:** EN

**Title of invention:**  
METHODS FOR RNA ANALYSIS

**Patent Proprietor:**  
CureVac Manufacturing GmbH

**Opponent:**  
Müller, Christian

**Headword:**  
Methods for RNA analysis/CUREVAC

**Relevant legal provisions:**  
EPC Art. 123(2), 54, 56  
RPBA 2020 Art. 13(2)

**Keyword:**  
Main Request - requirements of the EPC met (yes)  
Amendment after summons - exceptional circumstances (no)

**Decisions cited:**

T 1875/15, T 0247/20

**Catchword:**



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Case Number: T 0747/21 - 3.3.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.08**  
**of 18 October 2023**

**Appellant:** Müller, Christian  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
24 March 2021 concerning maintenance of the  
European Patent No. 3090060 in amended form**

**Composition of the Board:**

**Chairwoman** T. Sommerfeld  
**Members:** D. Pilat  
A. Bacchin

## **Summary of Facts and Submissions**

- I. European patent No. 3 090 060 is based on European patent application No. 14 833 130.9, filed as an international application published as WO 2015/101416. The patent was opposed on the grounds of Article 100(a) in conjunction with Articles 54 and 56 EPC, and of Article 100(b) and (c) EPC. The opposition division held that the main request filed during oral proceedings in opposition fulfilled the requirements of the EPC.
- II. The opponent (appellant) lodged an appeal against the decision of the opposition division.
- III. With the reply to the statement of grounds of appeal, the patent proprietor (respondent) requested that the appeal be dismissed (main request) and filed an auxiliary request.
- IV. The parties were summoned to oral proceedings. In a communication pursuant to Article 15(1) RPBA, the parties were informed of the board's provisional, non-binding opinion on some of the legal and substantive matters of the case.
- V. Claims 1, 2 and 9 of the main request read as follows:  
  
"1. A method for analyzing an RNA molecule having a cleavage site for a catalytic nucleic acid molecule, the method comprising the steps of:  
  
a) providing an RNA molecule having a cleavage site for a catalytic nucleic acid molecule,

b) cleaving the RNA molecule with the catalytic nucleic acid molecule into a 5' terminal RNA fragment and at least one 3' RNA fragment by contacting the RNA molecule with the catalytic nucleic acid molecule under conditions allowing the cleavage of the RNA molecule, and

c) determining a physical property of the RNA molecule by analyzing the 5' terminal RNA fragment, wherein step c) comprises determining a structural feature selected from the group consisting of the orientation of the cap structure at the 5' terminus of the RNA molecule having a cleavage site for the catalytic nucleic acid molecule."

"2. A method for analyzing a population of RNA molecules, wherein the population comprises at least one RNA molecule that has a cleavage site for a catalytic nucleic acid molecule, the method comprising the steps of:

a) providing a sample containing the population of RNA molecules,

b) cleaving the at least one RNA molecule having a cleavage site for the catalytic nucleic acid molecule with the catalytic nucleic acid molecule into a 5' terminal RNA fragment and at least one 3' RNA fragment by contacting the sample with the catalytic nucleic acid molecule under conditions allowing the cleavage of the RNA molecule,

c) determining a physical property of the at least one RNA molecule having a cleavage site by analyzing the at least one 5' terminal RNA fragment obtained in step b),

wherein step c) comprises determining a structural feature selected from the group consisting of the orientation of the cap structure at the 5' terminus of the RNA molecule having a cleavage site for the catalytic nucleic acid molecule,

and

d) measuring the relative amount of the at least one 5' terminal RNA fragment obtained in step b), thereby determining the relative amount of RNA molecules having said physical properties in the RNA population."

"9. A method of determining the capping degree of a population of RNA molecules having a cleavage site for a catalytic nucleic acid molecule, the method comprising the steps of:

a) providing a sample containing the population of RNA molecules,

b) cleaving the RNA molecules with the catalytic nucleic acid molecule into a 5' terminal RNA fragment and at least one 3' RNA fragment by contacting the sample with the catalytic nucleic acid molecule under conditions allowing the cleavage of the RNA molecules,

c) separating the RNA fragments obtained in step b),

d) determining a measure for or measuring the amount of the capped and non-capped 5' terminal RNA fragments separated in step c) of said population of RNA molecules,

and

e) comparing said measures of capped and non-capped 5' terminal RNA fragments determined in step d), thereby determining the capping degree of said population of RNA molecules,

wherein the measure determined in step d) is the signal intensity of the capped and non-capped 5' terminal RNA fragments or the amount of the RNA fragments."

VI. Dependent claims 3 to 8 and 10 to 18 define specific embodiments of the methods of claims 1, 2 and 9.

VII. The following documents are cited in this decision:

- D3 Peng Z.-H. *et al.*, *Organic Letters*, Vol. 4, No2, pages 161 to 164, (2002)
- D4 Cunningham C.C., *BUMC Proc*, Vol. 15(3), pages 247 to 249, (2002)
- D5 Karikó K. *et al.*, *FEBS Letters*, Vol. 352, pages 41 to 44, (1994)
- D6 Basturea G.N., *Mater Methods*, Vol. 3, No. 186, (2013)
- D7 US 7,074,596 B2
- D8 Nakamura K. *et al.*, *Journal of Reproduction and Development*, Vol. 52, No.1 pages 73 to 80, (2006)
- D9 Khan A.U., *Clinica Chimica Acta*, Vol. 367, pages 20 to 27, (2006)
- D10 Kashani-Sabet, M., *J Investig Dermatol Symp Proc*, Vol. 7, pages 76 to 78, (2002)
- D11 WO 2014/152659 A1
- D15 Kikovska E. *et al.*, *Proc. Natl. Acad. Sci. USA*, Vol. 104(7), pages 2062 to 2067 (2007)
- D16 Duss O. *et al.*, *Nucleic Acids Research*, Vol 38 e188, pages 1 to 10 (2010)
- D17 Tanner N.K, *FEMS Microbiology Review*, Vol. 23(3), pages 257 to 275, (1999)

- VIII. The parties' submissions relevant for this decision are discussed in the Reasons below.
- IX. The appellant requested that the decision under appeal be set aside and the patent be revoked in its entirety.
- X. The respondent requested that the appeal be dismissed and the patent be maintained on the basis of the main request, or alternatively on the basis of the auxiliary request filed with the reply to the appeal.

### **Reasons for the Decision**

#### *Main request*

#### *Amendments (Article 123(2) EPC)*

1. The appellant argued that the subject-matter of claims 1 and 2 added subject-matter, contrary to the requirements of Article 123(2) EPC.
2. Claims 1 and 2 of the main request (for the full wording see section V. above) are based on the combination of claim 18 as filed with claims 1 and 2 as filed, respectively. In fact claims 1 and 2 differ from claims 1 and 2 as filed by the addition of the feature "wherein step c) comprises determining a structural feature selected from the group consisting of the orientation of the cap structure at the 5' terminus of the RNA molecule having a cleavage site for the catalytic nucleic acid molecule". This added feature is based on claim 18 as filed, which reads: "The method according to any one of claims 1 to 17, wherein the RNA molecule having a cleavage site for the catalytic nucleic acid molecule comprises a cap structure at the 5' terminus and step c) comprises determining the



orientation of the cap". It is true that, as argued by the appellant, claims 1 and 2 of the main request do not incorporate the whole wording of claim 18 as filed, since they do not explicitly state that the RNA molecule comprises a cap structure at the 5' terminus. The board considers however, in agreement with the respondent, that, by requiring that the orientation of the cap at the 5' terminus of the RNA molecule be determined, it is implicit that the RNA molecule necessarily comprises such a cap structure at its 5' terminus. The board thus considers that claim 18 as filed provides sufficient basis for the amendments introduced into claims 1 and 2.

3. The appellant's arguments that there was added matter in view of the fact that claim 18 as filed was not fully introduced in part (c) of amended claims 1 and 2 are, for the reasons given above, not deemed convincing. The appellant moreover argued that the requirement in the claimed methods for determining both a physical property and a structural feature also added matter, because claims 14 and 15 and page 39 lines 25 and ff. of the patent application as filed disclosed these features only as separate alternatives; likewise, page 44, lines 25 ff. of the patent application as filed related only to determining a structural feature and only in the context of the purpose of the method and not as a determining step in the method.
4. The board disagrees with the appellant that there is no basis in the patent application as filed for methods as claimed in claims 1 and 2 requiring a determination of both a physical property and a structural feature. Firstly, as discussed above, the combination of claim 18 as filed with claims 1 and 2 as filed already provides a basis for the subject-matter of claims 1 and

2 of the main request. Step c) in both claims 1 and 2 as filed refers to "determining a physical property of the RNA molecule..." and "determining a physical property of the at least one RNA molecule...", respectively (emphasis added by the board). The added feature from claim 18 as filed then requires "determining of a structural feature..." (emphasis added by the board), but this structural feature is then defined as being the orientation of the cap, so exactly what is required in claim 18 as filed. There is thus no need to look for further basis in other passages of the application as filed. It is hence irrelevant that other passages of the application as filed may indicate determination of a structural feature or of a physical parameter as two alternatives. Moreover, and solely for the sake of completeness, it is noted that, in view of claims 14 and 18 as filed being dependent on claims 1 and 2 as filed, their features cannot be seen as alternatives to the features of claims 1 and 2 as filed since, by definition, dependent claims comprise all features of the claims they depend upon.

5. Thus, the board concludes that the claimed subject-matter of the main request complies with Article 123(2) EPC.

*Novelty (Article 54 EPC)*

6. In the appealed decision, the opposition division came to the conclusion that the claimed subject-matter was novel over the disclosures of documents D1/D1a, D2, D15 and D16 (decision under appeal, section 15). In appeal, the appellant has only raised novelty objections over documents D15 and D16 (statement of grounds of appeal, section 4). As regards document D1/D1a, the appellant

merely stated in section 4.1 of the statement of grounds of appeal that the opposition division had decided that the subject-matter of the main request would lack novelty over document D1, which is of course incorrect. Hence, the board sees no reason to deviate from the conclusions drawn in the decision under appeal under section II point 15.2 as regards novelty over documents D1/D1a and D2.

7. Document D15 discloses a method comprising the steps of (i) providing an RNase P substrate, i.e., an RNA molecule having a cleavage site for a catalytic nucleic acid, (ii) cleaving, in a sequence-specific manner, the RNA substrate with the RNA moiety of RNase P into a 5' and at least one 3' fragment, and (iii) determining a physical property of the 5' end of the 5' cleavage product, namely the presence of pGp. The presence of pGp at the 5' end of the 5' matured cleavage product is on the resulting 3' large fragment Figure 3B.

Document D16 discloses a method comprising the steps of (i) providing an RNA molecule having a cleavage site for a catalytic nucleic acid, (ii) cleaving, in a sequence-specific manner, the RNA substrate with the catalytic nucleic acid a 5' and at least one 3' fragment, and (iii) determining a physical property of the 5' end of the 5' cleavage product, namely the absence of a 5' cap.

8. As admitted by the appellant, in the methods of document D15 or D16 the RNA molecule does not comprise a cap. Already for this reason, the board considers that these documents cannot anticipate the subject-matter of claims 1, 2 and 9, which require that the method includes a step of determining the orientation of the cap structure at the 5' terminus of the RNA

molecule, implying that the RNA molecule comprises such a cap (as concluded in the context of Article 123(2) EPC, see point 2. above).

9. The appellant argued that, while the methods of documents D15 and D16 did not disclose analysis of an RNA molecule with a cap, the claims of the main request also encompassed analysis of an RNA molecule not expected to contain a cap. Moreover, it was obvious that the method steps disclosed in document D16 would be suitable for analysing capped RNA as well. For the reasons discussed in relation to Article 123(2) EPC, the board however disagrees that the claims of the main request do encompass analysis of uncapped RNA molecules. Moreover, it is undisputed that neither documents D15 nor D16 disclose a step of determining the orientation of the cap structure, nor can this be considered implicit: to the contrary, if the RNA molecules do not contain such a cap, there can be no step of determining the orientation of such a cap structure. Finally, it is irrelevant whether document D16 may render obvious or not that the method can be applied to capped RNA as well, because obviousness is not the standard for novelty but rather direct and unambiguous disclosure.
10. The claims of the main request are thus novel over documents D15 and D16 (Article 54(2) EPC).

*Inventive step (Article 56 EPC)*

11. The invention is in the field of RNA analysis and concerns methods for analysing the 5' terminal structures of an RNA molecule having a cleavage site for a catalytic nucleic acid molecule. In particular, the invention concerns a method for determining the

orientation of the cap structure in a capped RNA molecule having a cleavage site for a catalytic nucleic acid molecule and a method for determining relative amounts of correctly capped RNA molecules and reverse-capped RNA molecules in a population of RNA molecules (patent, paragraph [0001]). The 5' cap structure and the 3' poly(A) tail are important features for the efficient translation of mRNA and protein synthesis in eukaryotic cells (patent, paragraph [0006]).

*Closest prior art, difference and objective technical problem*

12. The appellant held that documents D3 and D11 may both represent the closest prior art. The board agrees that both documents are suitable starting points for the discussion of inventive step.
13. It is uncontested that the claimed methods according to claims 1, 2 and 9 differ from the methods disclosed in documents D3 or D11 in that at least a catalytic nucleic acid is used, which (inherently) directly cleaves the RNA to be analysed at a specific cleavage site, thereby producing a 5' fragment of a suitable size for determining whether or not the 5' fragment is capped and, if so, in which orientation. In contrast thereto, the methods of documents D3 and D11 use RNase H instead of a catalytic nucleic acid.
14. RNase H is known to be not sequence-specific. RNA fragments obtained by its use show a certain variability. This leads to problems in interpreting the results of the RNA analysis (patent, paragraph [0014]). In contrast, a catalytic nucleic acid is sequence-specific thereby generating 5' fragments with defined ends and homogenous i.e. defined identical sizes, which allows for an improved accuracy of the RNA analysis.

15. The board thus agrees with the respondent's formulation of the technical problem as being the provision of means to increase the accuracy of the RNA analysis of the fragments for the orientation of their caps. In view of the technical difference identified above and the associated technical effect, the board considers that the technical problem cannot be formulated as suggested by the appellant as the provision of an alternative way in which to cleave an RNA molecule such that the 5' terminal fragment can be of a size suitable for further analysis by methods known in the art to determine the presence/absence/orientation of a 5' cap. The appellant's formulation of the technical problem disregards the increased accuracy achieved and thus the increased reliability of the results of the claimed method. However, since it is plausible that the analysis of fragments of defined sizes obtained by the use of a catalytic nucleic acid, including the determination of their 5' caps and the orientation thereof, is more accurate than the analysis of fragments of variable sizes, and there is no evidence supporting the contrary, the board agrees with the respondent that starting from document D3 or D11 the objective technical problem may be formulated as the provision of a method wherein the RNA analysis of the RNA fragments for their caps, namely for the orientation of said caps, has an increased accuracy.
  
16. The solution provided by the claimed subject-matter in claims 1, 2 and 9 consists in using a catalytic nucleic acid and the board is satisfied that the claimed solution solves the technical problem formulated above. At the oral proceedings, the appellant presented new lines of arguments that the technical effect was not solved over the entire breadth of the claims and that

the claimed solution to the technical problem was obvious from document D3 in combination with document D6. These arguments were however not admitted into the proceedings (see reasons below: point 22. ff.).

*Obviousness*

17. It remains to be assessed whether the skilled person starting from the disclosure in documents D3 or D11 and seeking a solution to the technical problem formulated above would have modified the disclosure of documents D3 or D11 in such a way as to arrive at a method falling within the scope of claims 1, 2 or 9 in an obvious manner.
18. The board considers that the skilled person had no indication in documents D3 and D11 as to which means would result in an improved accuracy of the RNA analysis. Although catalytic nucleic acids were well known from prior art documents D4, D5, D9, D10 and D15 to D17 (see below) and/or formed part of the common general knowledge at the time the application was filed, its use in methods of RNA analysis was not taught or even suggested in any of these documents.
19. Documents D4, D5 and D9 teach the advantages of using catalytic nucleic acids but in the field of RNA therapeutics and not in the field of RNA analysis (D4, page 247, left-hand column, second full paragraph; D5, left-hand column, second paragraph, D9, right-hand column, third paragraph, second section thereof). D4 and D5 relate to the application of ribozymes (catalytic nucleic acids) in oncology. Document D5 moreover teaches that the major advantage of using ribozymes is that they can cleave multiple mRNA target molecules (page 41, left-hand column, 2nd paragraph).

Document D9 is also in the field of RNA therapeutics, disclosing the use of ribozymes as "a clinical tool" (Title) and teaching that ribozymes have advantages over either oligodeoxynucleotides or antisense RNA in that they process and destroy a higher number of target molecules per molecule of ribozyme (page 24, right-hand column, 3rd paragraph). Document D10 also describes therapeutic applications of ribozymes, in particular as antiviral and anti-cancer agents (Title, abstract). Finally, document D17 is a review document about ribozymes and discusses their advantages and disadvantages by comparing different ribozymes to each other in the context of therapeutic applications (page 266, right-hand column, last few lines of penultimate paragraph). The skilled person would thus not derive any teaching from these documents to replace RNase H in the methods of document D3 or D11 by catalytic nucleic acids, in order to improve the accuracy of the RNA analysis method of documents D3 and D11.

Documents D15 and D16, on the other hand, disclose the use of catalytic nucleic acids for cleaving RNA. The appellant argued that, since the only difference between the closest prior art and the claimed subject-matter is how the RNA is cleaved, the skilled person would have looked for documents related to alternative ways for RNA cleavage. The board however notes that, in view of the technical problem being formulated as the provision of an RNA analysis method with improved accuracy, the skilled person would not look for alternative ways for RNA cleavage but rather for ways of improving the accuracy of the RNA analysis. The board considers that the skilled person would find no teaching or suggestion that the cleavage means used in



documents D15 and D16 would solve this problem, because no such advantages are taught in these documents.

Other documents cited by the appellant include documents D6 to D8. While document D6 refers to various methods for the detection and quantification of RNA modifications, document D7 is not even in the field of RNA analysis but rather of RNA synthesis and thus, already for this reason, would not necessarily have been taken into consideration by the skilled person. Moreover, they are both silent regarding the use of catalytic nucleic acids, e.g. for RNA cleavage to obtain 5' fragments for further analysis. Finally, document D8 relates to the design of a specific hammerhead ribozyme, namely, for cleaving murine Sry mRNA for the application to artificially control the sex ratios of farm animals (document D8, title and abstract). There is no apparent reason or motivation for the skilled person to use the specific hammerhead ribozyme of document D8 in the methods of documents D3 or D11.

20. It follows that none of the above cited documents provides an indication or motivation to the skilled person why the RNase H cleavage in the *in vitro* analysis of document D3 or D11 should be replaced by a catalytic nucleic acid, in order to achieve a greater RNA cleavage accuracy and greater homogeneity of RNA products compared to RNase H.
  
21. Consequently, on the basis of the findings above, the board concludes that the claimed subject-matter of the main request involves an inventive step (Article 56 EPC).

*Admittance of new lines of arguments under Article 56 EPC -  
Article 13(2) RPBA*

22. During oral proceedings before the board, the appellant presented new lines of arguments for inventive step, which had not been submitted before in appeal: first, that the alleged effect of an improvement was shown neither in the patent nor in the prior art; second, that the effect was not shown over the entire breath of the claims; third, that the claimed solution to the technical problem (see point 15. above) was obvious when starting from document D3 in combination with the disclosure on pages 5 and 7, second paragraph and second half of the last paragraph respectively, of document D6 or in combination with the common general knowledge as represented for instance in document D17. The appellant furthermore presented a new interpretation of the meaning and definition of the terms "catalytic acid molecule" and the "population of RNA molecules".
23. The appellant did not contest that this argumentation was not in the statement of grounds of appeal but essentially argued that it was not based on new facts, that the issues had been already discussed extensively in opposition proceedings, that the appellant should have the right to react to the respondent's submissions based on page 163 of document D3 and presented in the reply to the statement of grounds of appeal and that interpretation of the claims and of their scope was an issue that could be picked up by the board and the parties at any time.
24. The statement of grounds of appeal must contain the party's complete appeal case (Article 12(3) RPBA). The board does not concur with the appellant that the

admittance of lines of arguments raised for the first time during oral proceedings in appeal does not actually involve new allegations of facts in appeal, just because the issues were already discussed during opposition proceedings and because no new documents have been submitted. A reference to lines of arguments not presented in the statement of grounds of appeal consists in an amendment to the party's case, which after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned (Article 13(2) RPBA).

25. Even if it were true that the interpretation of the scope of the claims was always a core issue, it is neither for the board nor for the respondent to identify the issues that may still be a matter of dispute among those raised in each and every submission in the previous proceedings, but for the appellant to bring forward in the statement of grounds of appeal all their line(s) of argument and all the facts and evidence on which they rely in appeal proceedings. In particular, absent an apparent justification, a party cannot wait until the oral proceedings for presenting a new analysis of the scope of the claims or to reintroduce a previous abandoned analysis raised during the opposition proceedings but not taken up in the statement of grounds of appeal.
  
26. Without disregarding that the purpose of the oral proceedings is not merely to present a repetition of the arguments put forward in writing, but instead that the parties must be allowed to refine their arguments, provided they stay within the framework of the arguments and the evidence, submitted in a timely

fashion in the written proceedings (see e.g. T 247/20, Catchword), the board finds that in the present case the arguments on the scope of the claims are neither a mere fine tuning of the existing line of argument, which was submitted with the statement of grounds of appeal, nor a mere development or expansion on it. In particular, the argument that a proper understanding of the terms "catalytic acid molecule" and "population of RNA molecules" would not support that the alleged effect is achieved over the whole scope of the claims goes beyond the existing line of argument as presented in the statement of grounds of appeal (at page 10, second and third paragraph, and page 11). Indeed, no argument has been submitted that there was an issue of interpretation of terms, namely how and what is to be understood by a catalytic nucleic acid and/or population of RNA molecules, or that, as a result of this interpretation, the technical effect associated with the identified difference would not have been demonstrated over the full scope of the claims.

27. The board agrees that the appellant must be given the right to react to arguments submitted with the reply to the appeal (such as the argument based on the passage at page 163 of document D3). However this cannot be a valid reason for the appellant to wait until the oral proceedings before the board for raising new lines of argumentation involving the allegation of new facts, such as that the claimed effect is not shown in the patent, based on evidence in the patent, and that the effect is not achieved over the whole scope of the claims. The right to be heard does not mean the right to file submissions at any stage of the proceedings, if these submissions involve the allegation of new facts. The appellant had the opportunity to react, if needed,

to the respondent's reply to the statement of grounds of appeal much earlier than the oral proceedings.

28. As to document D6, the board finds no reference to pages 5 and 7 of document D6 in the appellant's statement of grounds of appeal. Although document D6 was referred to in point 16.13 of the decision under appeal, this point of the decision was not contested in the statement of grounds of appeal. Consequently, this argument also constitutes an amendment of the appellant's case contrary to Article 13(2) RPBA. The filing of a document does not allow a party to rely on it for submitting any line of argument that can be derived from it at any time in the proceedings.
29. Contrary to the appellant's argument, the discretionary power not to admit new allegations of fact, if these are late filed, is not just a new practice under the most recent RPBA but has a basis in Article 114(2) EPC and was established jurisprudence also under the previous rules of procedure (see e.g. T 1875/15, Catchword and the further decisions cited in the Case Law of the Boards of appeal, 10th edition 2022, A.V. 5.10.1).
30. Considering all the circumstances of the present case, the board finds that there are no exceptional circumstances justifying admittance of these new lines of arguments relating to lack of inventive step and filed during the oral proceedings before the board, let alone justified with cogent reasons. Contrary to the appellant's submissions, these lines of arguments indeed involve new allegations of facts; if admitted, they would substantially add to and considerably change the complexity of the matter to be discussed and decided upon; not least, they would take the respondent

by surprise. For these reasons, the board sees no reason to admit and consider any of them in the appeal proceedings (Article 13(2) RPBA).

## Order

### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairwoman:



C. Rodríguez Rodríguez

T. Sommerfeld

Decision electronically authenticated