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Datasheet for the decision of 11 May 2023

Case Number: T 0617/18 - 3.3.08

Application Number: 08749384.7

Publication Number: 2152862

IPC: C12N7/02, A61K39/00, A61K39/285, A61K48/00, C12N15/863

Language of the proceedings: EN

Title of invention:
PURIFICATION OF VACCINIA VIRUS- AND RECOMBINANT VACCINIA VIRUS-BASED VACCINES

Applicant:
Bavarian Nordic A/S

Headword:
Purification Vaccinia virus/BAVARIAN NORDIC

Relevant legal provisions:
EPC Art. 56, 113(1)
RPBA 2020 Art. 25(2)
RPBA Art. 12(4)

Keyword:
Main request - inventive step (no);
Auxiliary requests I and II - admission (no);
Appellant's right to be heard (yes);

Decisions cited:
T 1624/18

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0617/18 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 11 May 2023

Appellant: (Applicant)	Bavarian Nordic A/S Hejreskovvej 10 A 3490 Kvistgaard (DK)
Representative:	Bendiksen, Henrik Bavarian Nordic GmbH Patent Department Fraunhoferstraße 13 82152 Martinsried (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 September 2017 refusing European patent application No. 08749384.7 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairwoman	T. Sommerfeld
Members:	P. Julià
	A. Bacchin

Summary of Facts and Submissions

I. European patent application no. 08 749 384.7, originally filed under the Patent Cooperation Treaty (PCT) and published as International patent application WO 2008/138533 (hereinafter "the patent application"), was refused by an examining division (Article 97(2) EPC). Basis for the refusal was a set of claims 1 to 15 filed in electronic form on 22 February 2016.

II. The decision of the examining division issued on 4 September 2017 did not provide the reasons for the refusal but referred to the reasons given in a communication of the examining division issued on 20 April 2017. In this communication, the applicant was summoned to oral proceedings and informed of the examining division's preliminary opinion that the patent application did not fulfil the requirements of Article 56 EPC. The decision of the examining division to refuse the patent application was issued upon applicant's request - filed on 2 August 2017 - to issue a decision according to the state of the file and after cancellation of the oral proceedings scheduled by the examining division.

III. The applicant (appellant) lodged an appeal and, in the statement setting out their grounds of appeal, filed a main request and auxiliary requests I and II. As an auxiliary measure, oral proceedings were requested.

IV. The board summoned the appellant to attend oral proceedings scheduled to take place on 3 November 2021.

V. With submissions dated 25 October 2021, the appellant withdrew the request for oral proceedings and informed the board of their intention not to attend the oral proceedings and to rely on the arguments as set out in their statement of grounds of appeal.

VI. On 2 November 2021, the board cancelled the oral proceedings.

VII. The following documents are cited in this decision:

(6): Che-Sheng Chung *et al.*, J. Virol., February 1998, Vol. 72, No. 2, pages 1577 to 1585;

(7): Astrid Zahn and Jean-Pierre Allain, J. Gen. Virol., 2005, Vol. 86, pages 677 to 685;

(9): Che-Sheng Chung *et al.*, J. Virol., March 2006, Vol. 80, No. 5, pages 2127 to 2140;

(12): Chi-Long Lin *et al.*, J. Virol., April 2000, Vol. 74, No. 7,, pages 3353 to 3365;

(13): Wen-Ling Chiu *et al.*, J. Virol., March 2007, Vol. 81, No. 5, pages 2149 to 2157.

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

"1. An industrial-scale process for the purification of biologically active Vaccinia virus comprising:

i) loading a solid-phase matrix, to which a ligand is attached, with a Vaccinia virus contained in a liquid-phase culture, wherein the ligand is glucosamine glycan (GAG) or a GAG-like ligand;

ii) washing the matrix; and

iii) eluting the virus."

Claims 2 to 15 are directed to particular embodiments of the process of claim 1.

IX. Claim 1 of **auxiliary requests I and II** reads as claim 1 of the main request, except for the presence of the additional feature after step iii) of the claim:

"wherein the recovery rate of the Vaccinia Virus is at least 55-90%." (in auxiliary request I),

"wherein the biological activity of the Vaccinia virus is at least 75%." (in auxiliary request II)

X. The appellant's submissions, insofar as relevant to the present decision, are discussed in the Reasons, below.

XI. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, alternatively, any of auxiliary requests I or II, filed with the statement of grounds of appeal.

Reasons for the Decision

Main request

1. The main request is identical to the request underlying the decision under appeal and thus it already forms part of the appeal proceedings.

The decision under appeal

2. In the communication dated 20 April 2017 accompanying the summons to oral proceedings (see point II. above), the examining division acknowledged the set of claims 1 to 15 to comply with Article 123(2) EPC but not to fulfil the requirements of Article 56 EPC. The following reasons were given:

2.1 The process of claim 1 is not inventive in view of the combination of document (9) with document (6). The closest prior art document (9) discloses a method of purifying vaccinia virus using a sucrose gradient. As no effect is linked to the distinguishing feature between document (9) and the patent application, i.e. the use of a different method of purification, the objective technical problem is the provision of an alternative method for the purification of the vaccinia virus. Document (6) discloses that vaccinia virus binds to GAG (Figure 4) and that this virus can be isolated using heparin Sepharose beads, even though the virus is not eluted from these beads in the method disclosed in document (6). Thus, the skilled person would apply the method of document (6) for the purification of vaccinia viruses. As an aside, the examining division stated that the teaching of document (6) could be also derived from documents (12) and (13) (cf. page 3, point 2.2 of the annex to the summons to oral proceedings issued by the examining division on 20 April 2017).

2.2 The process of claim 1 is also not inventive when starting from document (6) as closest prior art and in combination with the common general knowledge or, alternatively, with document (7). The skilled person seeking to purify the virus would have added an elution step to the method disclosed in document (6), the

addition of such a step does not require the use of any inventive skill; indeed, document (7) teaches all the technical steps needed for virus purification using a heparin solid-phase matrix (cf. page 3, point 2.3 of the annex to the summons to oral proceedings issued by the examining division on 20 April 2017).

2.3 The introduction of the feature "industrial-scale" into claim 1 does not render the claimed process inventive because there is no evidence on file that the non inventive method applied as small scale purification is inadequate to be up-scaled (cf. page 3, point 2.4 of the annex to the summons to oral proceedings issued by the examining division on 20 April 2017).

Appellant's arguments on Article 56 EPC

3. In the grounds of appeal, the appellant replied to the reasons given by the examining division in the decision under appeal for refusing the application.

3.1 The appellant summarised first the contribution to the art made by the patent application, in particular the provision of a method of purification of native and recombinant vaccinia virus and/or vaccinia virus particles with high efficiency and desirable yields in terms of purity, biological activity, and stability, and which is applicable for an aseptic production process in lab-, pilot- and industrial-scale. In this context, reference was made to the disclosures of the patent application on page 1, first paragraph and on page 9, starting at the second paragraph. The patent application is concerned with an industrial-scale method of purification, leading to a biological active, stable and highly pure virus preparation in high yield.

3.2 The appellant referred then to their former submissions concerning documents (6) and (9) made at the first instance proceedings and further argued that:

3.2.1 Document (6) describes experiments with the A27L protein. In particular, document (6) shows that the A27L protein and virions can bind to heparin sulphate (Figure 4, page 1581). However, document (6) fails to describe the claimed method and thus, fails to provide a vaccinia virus preparation containing enriched intracellular mature virus (IMV). Arguably, Figure 4 of document (6) may describe "Vaccinia viruses preparation" bound to heparin-Sepharose beads but not a purified preparation. Thus, document (6) does not provide eluted vaccinia viruses, let alone eluted vaccinia viruses in the IMV form. Furthermore, in document (6) only 50% of the input viruses are bound to the beads and thus, only 50% of the input viruses can be recovered. However, the claimed method allows for a recovery of at least 55-90%. Document (6) fails to make an eluted vaccinia virus preparation containing specifically IMV available technically.

3.2.2 Document (6) does not contain a clear and unmistakable disclosure of the claimed method, including implicit features, and it fails also to provide an "enabling disclosure" for achieving what the claimed method achieves. It has been shown that conventional means and methods fail to purify/enrich vaccinia viruses.

3.2.3 In addition, besides a higher recovery rate of the claimed method of at least 55-90% as compared to what may be deduced from the disclosure of document (6) (when considering bound vaccinia viruses), the claimed method also provides a biological activity of the recovered vaccinia virus of more than 75%.

3.2.4 Document (9) neither cures this deficiency nor adds anything that would lead the skilled person to arrive at the method as claimed in the main request or, alternatively, in auxiliary requests I and II.

3.2.5 In view of the fact that none of the cited documents provides any suggestion or direction to provide a vaccinia virus preparation containing the specifically enriched IMV form of vaccinia virus, the claimed method is inventive.

Article 56 EPC - Initial considerations

4. As regards the appellant's general reference to the submissions made at the first instance proceedings, the case law of the Boards of Appeal establishes that a mere reference to earlier submissions, without actually entering into a discussion of the reasons given in the decision under appeal by the department of first instance, cannot normally replace an explicit account of the legal and factual reasons for the appeal (cf. "Case Law of the Boards of Appeal of the EPO", 10th edition 2022, V.A.2.6.5). It is neither the task nor the role of the board to make the appellant's case and try to find on its own a successful inventive step argument from the appellant's sweeping reference to their submissions at first instance proceedings (cf. "Case Law", *supra*, V.A.2.6.3.c)).

5. The board agrees with the appellant that none of the prior art documents cited under Article 56 EPC in the decision under appeal discloses the industrial-scale process for the purification of biologically active vaccinia virus of claim 1. Indeed, this is also acknowledged by the examining division since no

objection under Article 54 EPC for lack of novelty is raised in the decision under appeal but an objection under Article 56 EPC for lack of inventive step.

6. In the context of Article 56 EPC and in the discussion of the contribution to the art of the claimed process, the appellant refers to several advantageous properties of said process and the vaccinia virus preparation resulting therefrom, such as the aseptic, industrial-scale production of a biologically active, stable and highly pure virus preparation, the high yield of the process, etc. Indeed, these properties and results are also described in the patent application and some of them, such as virus recovery rate and biological activity of the recovered vaccinia virus, are shown in the examples of the patent application. However, none of these properties and results, let alone the specific conditions used in the examples of the patent application for achieving them, are required in the process of claim 1.

7. As stated in the case law, implicit restrictive features which are not suggested by the explicit wording of the (excessively broad) claim must not be taken into account for assessing the requirements of Articles 54 and 56 EPC (cf. "Case Law", *supra*, I.C.4.8 and II.A.6.3.4). Whilst the process of claim 1 is defined as being "industrial-scale" and providing "biologically active" vaccinia virus, neither the degree of purity and biological activity of the recovered virus nor the virus recovery rate (yield) of the process are defined in claim 1. Thus, claim 1 embraces embodiments for which the degree of purity and biological activity of the recovered vaccinia virus as well as the yield of the process are much lower than those referred to by the appellant. There is no feature

or requirement in claim 1 limiting any of these properties, namely purity and biological activity of the recovered vaccinia virus and the yield of the process or the recovery rate of vaccinia virus. As an aside, claim 1 does not even explicitly mention that the (infectious) form of the recovered vaccine virus is intracellular mature virus (IMV) and only claim 2 requires the process to be aseptic.

8. As regards the feature "industrial-scale", it is worth noting that the examples of the patent application are all in "lab-scale" (cf. page 28, line 19). The volumes applied to the solid-phase matrix are of two ml of "a highly concentrated and previously purified Vaccinia virus preparation" (cf. Examples 1, 2 and 7) or "a highly concentrated Vaccinia virus preparation" (cf. Examples 3 to 6); a far cry from "volumes higher than 300 L, preferably higher than 600 L" referred to in the patent application as defining or characterising an industrial purification (cf. page 7, lines 3 to 5). According to the case law, the same standard must be applied when assessing the disclosure of a prior art document and that of the patent application (cf. *inter alia*, T 1624/18, point 12.1 of the Reasons). As stated by the examining division, there is no evidence on file that the small-scale purification - referred to by the examining division on page 3, point 2.4 of the annex to the summons to oral proceedings - cannot be successfully up-scaled, the more so because none of the features (yield, purity, activity, etc.) referred to by the appellant is actually required in the process of claim 1. Indeed, in the statement of grounds of appeal, the appellant did not address the reasons given by the examining division for considering this feature not to contribute to inventive step, so that it is not possible for the board to understand why the decision

under appeal was incorrect in this respect (see also, in this context, "Case Law", *supra*, V.A.2.6.3.b), V.A. 2.6.3.c) and V.A.2.6.3.f), although concerning the admissibility of an appeal).

Article 56 EPC - The problem and solution approach

9. In the decision under appeal, the examining division identified documents (6) and (9) as alternative closest prior art documents and, starting therefrom, two different problem and solution approaches were formulated. The first approach is considered by the board to be highly relevant.

9.1 The closest prior art document (9) describes the use of proteomic techniques (mass spectrometry, MS; tandem MS, MS/MS) for identifying the proteins in the vaccinia virus IMV particles (cf. page 2127, abstract, left and righ-hand columns; page 2133, right-hand column, last paragraph). As a first step, reference is made to the purification of vaccinia IMV particles by using two consecutive sucrose (gradient centrifugation) purifications (cf. page 2128, right-hand column; page 2131, left-hand column, second paragraph). The relevance of achieving maximal purity and abundant material for carrying out these studies is also explicitly stated in document (9) (cf. page 2131, left-hand column, last paragraph, to page 2132, right-hand column, second paragraph).

9.2 Starting therefrom, the objective technical problem can be formulated in the terms used by the examining division, namely "the provision of an alternative method of purification of vaccinia virus". As acknowledged in the case law, the provision of such alternative falls within the normal activities of the

notional skilled person (cf. "Case Law", *supra*, I.D. 9.12). This technical problem is solved by the process of claim 1.

9.3 Document (9) identifies the IMV surface protein A27L by LC/MS/MS and informs the skilled person that this protein is one of the (relatively) abundant proteins present in the IMV particles (cf. page 2132, left-hand column, lines 6 to 9 and 32 to 35; page 2133, left-hand column, lines 22 to 24). The role of the A27L protein in IMV-cell attachment is also mentioned in Tables 1 and 4 of document (9) (cf. pages 2131 and 2134, Tables 1 and 4, respectively); in Table 1 the bibliographic reference (39) is cited. This reference corresponds to document (6) in these proceedings.

9.4 Document (6) discloses the binding of both, the A27L protein and purified vaccinia virus virions, to heparin-Sepharose beads (cf. page 1581, left-hand column, last paragraph, and right-hand column, Figure 4; see also page 1578, left-hand column, fourth paragraph for purification of the vaccinia virus virions). As stated by the examining division, the elution of the vaccinia virus virions from the heparin-Sepharose beads would not require any undue burden or inventive skills from a notional skilled person as defined in the case law (cf. "Case Law", *supra*, I.D. 8.1.3).

9.5 Indeed, a skilled person working in the relevant technical field of vaccinia viruses and, more particularly, in the field of virus (virions) purification, would be well aware of the use of heparin-affinity chromatography for purification of virus virions: a technique commonly used in the prior art and known to provide high purity preparations and

to be, as defined in document (7), "simple, gentle and does not require special technical skills or equipment" with the advantage that it "can be readily scaled up" (cf. page 683, left-hand column, second paragraph). Thus, the expectations of success for a skilled person would certainly have been more than reasonable, all the more so because, as stated above, there is no requirement in claim 1 as regards the purity and biological activity of the recovered vaccine virus and the yield of the process or the recovery rate of vaccinia virus (cf. "Case Law", *supra*, I.D.7.1).

10. In view thereof, the board agrees with the findings of the examining division as regards the first problem and solution approach formulated and to the objection raised by the examining division under Article 56 EPC. There is thus no need for the board to consider the other approach formulated in the decision under appeal.

11. Therefore, claim 1 of the main request and thus the main request does not fulfil the requirements of Article 56 EPC.

Admission of appellant's new auxiliary requests

12. Auxiliary requests I and II were filed by the appellant with their grounds of appeal, they are new claim requests comprising features that were not present in any of the claim requests filed before the examining division. They were thus neither assessed nor considered by the examining division in the decision under appeal.

13. Since the statement of grounds of appeal was filed before the date of entry into force of the RPBA 2020, the transitional provisions set out in

Article 25(2) RPBA 2020 apply and, in the present case, the discretion of the board has to be exercised in accordance with Article 12(4) RPBA 2007. According to Article 12(4) RPBA 2007, the board may hold inadmissible, *inter alia*, requests that could have been filed at the first instance proceedings.

14. For the board to exercise its discretion in a fair and appropriate manner to decide on the admission of the appellant's new auxiliary requests I and II into the appeal proceedings, it is necessary to assess the particular procedural and substantive issues of the present case.

As regards procedural issues

15. In the statement of grounds of appeal, the appellant provided no reasons to explain why the new auxiliary requests I and II could not have been filed at the first instance proceedings and only in the appeal proceedings. Thus, it is first necessary for the board to consider the course of events at the first instance proceedings.

15.1 In a first communication issued on 1 June 2010, the examining division, upon enter of the patent application into the regional phase before the EPO, drew the applicant's attention to a pharmaceutical product/composition claim and the requirements of such type of claims by reference to Articles 54 and 84 EPC.

15.2 With submission dated 10 August 2010, the applicant replied to this first communication and filed a set of claims 1 to 21 comprising several claims directed to a pharmaceutical product/composition as well as uses thereof.

15.3 In a second communication issued on 22 May 2015, the examining division referred to the documents cited in the International Search Report and by the applicant (documents (1) to (13)), and raised an objection under Article 54 EPC for lack of novelty of the pharmaceutical product/composition claims over, *inter alia*, document (9). With reference to the combination of documents (7) and (9), or alternatively, document (6) and the common general knowledge of the skilled person, the process claims were considered not to involve an inventive step (Article 56 EPC). In this context, documents (12) and (13) were also cited. A further objection was also raised under Article 83 EPC against those claims directed to a pharmaceutical composition and uses thereof.

15.4 With submissions dated 22 February 2016, the applicant replied to this second communication and filed the set of claims 1 to 15 underlying the decision under appeal. No further claim requests were filed.

15.5 In response thereto, the examining division summoned the applicant to oral proceedings and maintained the objection raised under Article 56 EPC against the new set of claims 1 to 15 based on the same arguments and documents as those cited in the second communication.

15.6 In reply to the summons, the applicant, without taking the opportunity to file any other claim requests, requested to have a decision according to the state of the file.

16. In view of this course of events at the first instance proceedings, the board considers that the applicant/ appellant had several opportunities to file a new set

of claims in order to overcome the objections raised and to defend and argue before the examining division for the patentability of this set of claims. The board fails thus to see any reason to explain why it was not possible for the appellant to file the new auxiliary requests I and II at the first instance proceedings.

As regards substantive issues

17. None of the amendments introduced into the appellant's new auxiliary requests I and II, namely the features "wherein the recovery rate of the Vaccinia Virus is at least 55-90%" and "wherein the biological activity of the Vaccinia virus is at least 75%" (auxiliary requests I and II, respectively) after step iii) of claim 1 of these requests, was present in any of the set of claims filed at the first instance proceedings. None of the features introduced into claim 1 of the new auxiliary requests I and II is the subject-matter of a dependent claim in any of the set of claims filed at the first instance proceedings.

18. The features introduced into the new auxiliary requests I and II are not derived from the general disclosure of the patent application under the heading "Description of the Invention", but from the particular results obtained under specific experimental conditions reported in the "Examples" of the patent application. Thus, it is, *a priori*, questionable whether the patent application might provide a basis for the combination of these specific features with all other features present in claim 1 (**Article 123(2) EPC**) (cf. "Case Law", *supra*, II.E.1.5.2.a) and II.E.1.6.1).

19. The features introduced into the new auxiliary requests I and II require the claimed "industrial-

scale" process of claim 1 to achieve a specific result, namely a yield or degree of vaccinia virus recovery rate ("at least 55-90%") in auxiliary request I and a degree of vaccinia virus biological activity ("at least 75") in auxiliary request II. It is, *a priori*, questionable whether claim 1 of these new auxiliary requests indicates all the essential features necessary for achieving these results as well as whether these claims are actually supported by the description and enabled in the application (**Articles 84 and 83 EPC**) (cf. "Case Law", *supra*, II.A.3.2, II.A.5.2 and II.C. 8.2).

19.1 The patent application describes the relevance of the solid-phase matrix and the ligand as well as of the interplay between the two, and further refers to the suitable properties of both, ligand and matrix, for enhancing the purification (cf. page 16, last paragraph to page 17, line 18). There is also a description of a pre-treatment of the virus suspension prior to loading on the solid-phase matrix and a post-treatment to enhance the purity of the virus preparation (cf. page 19, last line to page 21, line 10).

19.2 The examples of the patent application are all in lab-scale, there is no example in pilot or industrial-scale. The requirements of, and results from, a lab-scale purification are different from those of a pilot or industrial-scale (cf. page 6, line 22 to page 7, line 11). In all examples of the patent application, the (2 ml) virus preparation applied to the solid-phase matrix is highly concentrated and, in Examples 1, 2 and 7, this preparation is also described as being "previously purified".

19.3 The GAG-ligand used in all examples is heparin and, except for Example 1, all examples are carried out using a membrane, most of them "a Sartobind MA75 Heparin membrane". Only Examples 1 and 7 refer to "a column with packed with Toyopearl AF-Heparin" and "a Sulfated Reinforced Cellulose membrane", respectively. Both, Sartobind MA75 and Toyopearl, are commercial solid-phase matrix having optimal properties, such as stability, (high) pressure-flow characteristics, pore and particle size, density of ligand binding, etc.

19.4 There is no biological activity reported in any of the Examples 1, 2 and 7, wherein the highly concentrated vaccinia virus preparation applied to the solid-phase matrix is previously purified. A recovery rate of "90%" (in fact of "appr. 70%-90%") is mentioned only in Example 1, the highest recovery rate in all other examples is only of ">70%" (in Examples 4 to 6).

20. In light of the case law cited above concerning the application of the same standard and the presence of essential features in the claims, it is, *a priori*, also questionable whether the introduction of the new features in auxiliary requests I and II might overcome the objection raised under **Article 56 EPC** against the main request, i.e. whether these features might provide an inventive contribution over the methods derivable from the prior art.

21. Since none of these new features introduced into appellant's new auxiliary requests I and II were present in any of the claim requests filed at first instance nor in the main request underlying the decision under appeal, the examining division had neither the opportunity nor the need to examine and assess any of the substantive issues mentioned above.

There are thus no comments, let alone a decision, on any of them from the examining division in the decision under appeal.

As regards appellant's right to be heard (Article 113(1) EPC)

22. In the present case, the appellant withdrew the request for oral proceedings after being summoned thereto by the board. The appellant also informed the board that they would not attend these oral proceedings, even though the board had not provided any provisional opinion on the issues of the present case.

23. The appellant could well have expected that the board maintains the decision of the first instance as regards the main request and that, as regards auxiliary requests I and II, their admission into the appeal proceedings would have to be first assessed by the board before entering into a detailed examination of all the substantive issues of these requests. The criteria for such assessment are well established in the case law and based on both procedural as well as substantive considerations (cf. "Case Law", *supra*, V.A. 5.1.2, V.A.5.2.2, V.A.5.3, and V.A.5.11.4.a)). The appellant however did not take the opportunity, as they would have had, to discuss admission of the auxiliary requests at the oral proceedings.

24. Thus, in view of the appellant's behaviour and requests on file, the board considers that the appellant's right to be heard is not breached or infringed by the board not admitting appellant's new auxiliary requests I and II into the appeal proceedings (Article 113(1) EPC).

Conclusion

25. According to Article 12(2) RPBA 2020, the primary function of appeal proceedings is to give a judicial decision upon the correctness of a separate earlier decision taken by a department of first instance. Accordingly, appeal proceedings are not intended to be a mere continuation of the first instance proceedings (cf. "Case Law", *supra*, V.A.1.1). In the present case, the admission of appellant's new auxiliary requests I and II into the appeal proceedings would result in a re-opening and the mere continuation of the first instance proceedings for which there is no justification.

26. In view thereof, the board, in the exercise of its discretion, decides not to admit new auxiliary requests I and II into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

L. Malécot-Grob T. Sommerfeld

Decision electronically authenticated