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Datasheet for the decision of 5 October 2021

Case Number: T 0206/19 - 3.3.04

Application Number: 07820423.7

Publication Number: 2074141

IPC: A61K38/28, C07K14/62, C12N15/17

Language of the proceedings: EN

Title of invention:
Protease resistant insulin analogues

Patent Proprietor:
Novo Nordisk A/S

Opponent:
Eli Lilly and Company

Headword:
Protease resistant insulin/NOVO NORDISK

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 123(2)

Keyword:
Late-filed requests (AR6, AR5, AR5(b), AR3, AR3(b), AR4, AR4(b)) - submitted with the statement of grounds of appeals - requests could have been filed in first instance proceedings (yes)
Amendments (AR7, AR7(b)) - extension beyond the content of the application as filed (yes)

Decisions cited:
G 0002/10, T 0783/09

Catchword:
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Case Number: T 0206/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 5 October 2021

Appellant: (Patent Proprietor)	Novo Nordisk A/S Novo Allé 2880 Bagsværd (DK)
Representative:	Potter Clarkson The Belgrave Centre Talbot Street Nottingham NG1 5GG (GB)
Respondent: (Opponent)	Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285 (US)
Representative:	Kent, Lindsey Ruth Eli Lilly and Company Limited 8 Arlington Square West Downshire Way Bracknell, Berkshire RG12 1PU (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 21 November 2018 revoking European patent No. 2074141 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chair	A. Chakravarty
Members:	B. Rutz
	P. de Heij

Summary of Facts and Submissions

I. An appeal was lodged by the patent proprietor (appellant) against the decision of the opposition division revoking European patent No. 2 074 141 ("the patent") which is based on European patent application No. 07 820 423.7 published under the PCT as WO2008/034881 ("the application"). The patent is entitled "*Protease resistant insulin analogues*".

II. The patent was opposed on the grounds set out in Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and on the grounds of Article 100(b) EPC and Article 100(c) EPC.

III. In the decision under appeal, the opposition division held that the subject-matter of the set of claims of the main request complied with the requirements of Articles 123(2) EPC, but was not novel.

IV. The opposition division also held that claim 1 of each of auxiliary requests 1 to 23 did not meet the requirements of Article 123(2) EPC, Article 84 EPC and Rule 80 EPC.

V. With the statement of grounds of appeal, the appellant filed sets of claims of a main request, main request a, main request b, and of auxiliary requests 1, 1a, 1b, 2, 2a, 2b, 3, 3a, 3b, 4, 4a, 4b, 5, 5a, 5b, 6, 6a, 7, 7a, 7b.

VI. The opponent (respondent) replied to the appellant's statement of grounds of appeal.

VII. The board appointed oral proceedings as requested by the parties and informed them of its preliminary opinion on some of the issues in the appeal proceedings, in a communication pursuant to Article 15(1) RPBA.

VIII. With a letter dated 30 November 2020, the appellant withdrew all claim requests except for auxiliary request 6, auxiliary request 5, auxiliary request 5(b), auxiliary request 3, auxiliary request 3(b), auxiliary request 4, auxiliary request 4(b), auxiliary request 7 and auxiliary request 7(b) and requested that they be considered in that order.

Claim 1 of auxiliary request 6 reads:

"1. An insulin analogue which is stabilized against degradation by one or more enzymes selected from the group consisting of: pepsin, chymotrypsin, trypsin, Insulin-Degrading Enzyme (IDE), elastase, carboxypeptidase, aminopeptidase and cathepsin D relative to human insulin,
wherein the amino acid in position A14 is Glu, Asp or His, the amino acid in position B25 is His and which optionally further comprises one or more additional mutations, and wherein T½ is increased at least 2-fold relative to the parent insulin
with the *proviso* that said insulin analogue is not an insulin analogue wherein the amino acid in position A14 is Glu or His, the amino acid in position B25 is His and which optionally further comprises one or more additional mutations."

Claim 1 of auxiliary request 5 reads (difference to auxiliary request 6 underlined):

"1. A human insulin analogue which is stabilized against degradation by one or more enzymes selected from the group consisting of: pepsin, chymotrypsin, trypsin, Insulin-Degrading Enzyme (IDE), elastase, carboxypeptidase, aminopeptidase and cathepsin D relative to human insulin,
wherein the amino acid in position A14 is Glu, Asp or His, the amino acid in position B25 is His and which optionally further comprises one or more additional mutations, and wherein T½ is increased at least 2-fold relative to the parent insulin
with the *proviso* that said insulin analogue is not an insulin analogue wherein the amino acid in position A14 is Glu or His, the amino acid in position B25 is His and which optionally further comprises one or more additional mutations."

Claim 1 of auxiliary request 3 reads:

"1. A human insulin analogue which is stabilized against degradation by one or more enzymes selected from the group consisting of: pepsin, chymotrypsin, trypsin, Insulin-Degrading Enzyme (IDE), elastase, carboxypeptidase, aminopeptidase and cathepsin D relative to human insulin,
wherein the amino acid in position A14 is Asp or His, the amino acid in position B25 is His, one or more mutations selected from position A8 is His, position A21 is Gly, position B1 is Glu or Gln, position B16 is Glu, position B26 is Asp, position B27 is Glu, and/or position B28 is Asp, and which optionally further comprises one or more additional mutations, and wherein

T½ is increased at least 2-fold relative to the parent insulin."

Claim 1 of auxiliary request 4 reads:

"1. A human insulin analogue which is stabilized against degradation by one or more enzymes selected from the group consisting of: pepsin, chymotrypsin, trypsin, Insulin-Degrading Enzyme (IDE), elastase, carboxypeptidase, aminopeptidase and cathepsin D relative to human insulin,
wherein the amino acid in position A14 is Glu, Asp or His, the amino acid position in B16 is Glu, the amino acid in position B25 is His and which optionally further comprises one or more additional mutations, and wherein T½ is increased at least 2-fold relative to the parent insulin."

Claim 1 of auxiliary request 7 reads:

"1. An insulin analogue which is stabilized against degradation by one or more enzymes selected from the group consisting of: pepsin, chymotrypsin, trypsin, Insulin-Degrading Enzyme (IDE), elastase, carboxypeptidase, aminopeptidase and cathepsin D relative to human insulin,
wherein the amino acid in position A14 is Asp, the amino acid in position B16 is Glu, the amino acid in position B25 is His, and which optionally further comprises one or more additional mutations, and wherein T½ is increased at least 2-fold relative to the parent insulin."

Claim 1 of the "(b)"-version of requests 5, 3, 4 and 7 differs in that "parent insulin" is replaced by "human

insulin". Claim 1 of auxiliary request 7(b) in addition starts with "A human insulin analogue".

IX. Oral proceedings before the board were held by videoconference. At the end of these proceedings, the Chair announced the board's decision.

X. The appellant's arguments, relevant to the decision, are summarised as follows:

Admission of auxiliary requests 6, 5, 5(b), 3, 3(b), 4, 4(b)

The positive preliminary opinion of the opposition division together with the lack of substantiation of any arguments under Article 123(2) EPC by the respondent prior to the oral proceedings before the opposition division, placed the appellant at a procedural disadvantage when the respondent raised extensive arguments under Article 123(2) EPC during the oral proceedings. In effect, the appellant was presented with these arguments for the first time in oral proceedings before the opposition division.

Auxiliary Requests 3, 4, 5 and 6 filed with the statement of grounds of appeal were a legitimate and timely attempt to present amended claims to address the lack of novelty objections. They did this in substantially the same way as was done in a number of the auxiliary requests filed during the opposition proceedings and they were responsive to objections substantiated for the first time during the oral proceedings before the opposition division.

Auxiliary requests 6 and 5 contained a *proviso* to limit the A14 substituent to Asp (i.e. A14D). Auxiliary

request 6 was therefore identical in scope to auxiliary request 4 as filed in response to the opposition. Auxiliary request 4 was found to contravene Article 123(2) EPC by the opposition division but no clear substantive reasoning for this was provided in the decision under appeal. The only reasoning provided under Article 123(2) EPC related to requests which did not limit the A14 substituent beyond the alternatives present in the claims as granted.

In view of the lack of reasoning in the decision under appeal and the positive preliminary opinion with respect to Article 123(2) EPC, it was not clear why or even whether the opposition division considered that limiting the A14 substituent to Asp would contravene Article 123(2) EPC. Moreover, the respondent had not raised any reasoned objections against auxiliary request 4 (as on file at the time) in its submissions of 4 July 2018, but only with their submission under Rule 116 EPC and then only in a very brief manner. The alternative wording of the request (i.e. use of a *proviso* in place of deletion from a list) was a legitimate and timely attempt to address issues raised in the decision under appeal. It should therefore be held admissible.

Auxiliary Request 5 further limited the claimed subject-matter to "human" insulin. This additional limitation was responsive to issues first raised during the oral proceedings before the opposition division. This request could therefore not have been filed earlier and should be held admissible.

The auxiliary requests filed in the opposition proceedings had been found to contravene Article 123(2) EPC in part due to the alleged

generalisation of the B16 substituent. Auxiliary requests 3 and 4 addressed this issue and were each closely related to auxiliary request 1 filed with the response to the opposition. In this request position B16 was limited to Glu. Auxiliary request 3 included the "one or more additional mutations" listed on page 23, lines 21 to 23 of the application as filed, among which position B16 was Glu. These requests therefore were in direct response to the objections raised under Article 123(2) EPC against the B16 substituent, which were first substantiated at the oral proceedings before the opposition division.

Auxiliary request 4 corresponded to auxiliary request 1 as filed in response to the opposition, with the additional limitation that the insulin analogue was "human" insulin. The objection regarding this additional limitation was raised by the respondent for the first time at oral proceedings as was reflected at several points in the written decision of the opposition division.

Furthermore, despite having previously stated in its preliminary opinion that all the auxiliary requests were allowable, the opposition division then applied this new objection to all the lower ranking auxiliary requests.

Hence, the late submission of this line of argument by the respondent and the unexpected change in the position taken by the opposition division at the oral proceedings benefited the respondent but placed the appellant at a disadvantage in relation to its opportunity to comment and respond pursuant to Article 113 EPC.

The amendments made to auxiliary request 4 were a legitimate attempt to respond to the decision under appeal, responsive to the argumentation first raised during oral proceedings and in the circumstances, filed in good time.

No additional observations as to the admission of the (b) series requests were made by the appellant.

Auxiliary requests 7 and 7(b)- claim 1
Amendments (Article 123(2) EPC)

In auxiliary request 7, claim 1 specified that A14 was Asp, B25 was His and B16 was Glu. Basis for this combination could be found on page 23, lines 13 to 23 of the application as filed. Lines 13 to 15 of this passage disclosed three equal alternatives, namely A14 Glu and B25 His, A14 Asp and B25 His and A14 His and B25 His from which A14 Asp and B25 His was chosen. This could not be considered a selection from a list, as the embodiment A14 Asp and B25 His was already disclosed. The combination of this embodiment with B16 Glu chosen from a list of eight alternatives in lines 21 to 23 of page 23 therefore required selection only from a single list. The amendment of auxiliary request 7 was thus not a selection from "*multiple lists of some length*", but instead a limitation to a subset of clearly disclosed combinations. Commenting on decision T 12/81, the competent board held, in decision T 783/09, that, when dealing with selections from multiple lists of some length, the selected pair could lead to a novel combination, i.e. this was not considered an inevitability. In the situation at hand, the "lists" constituting two options for the DPP-IV agent and twenty-two options for the antidiabetic should be seen as a individual disclosure of all of forty-four

combinations. Limitation to a subset of these combinations nominally representing "selection from two lists" did not therefore contravene Article 123(2) EPC (see 5.7 and 5.9 of T 783/09). Consequently, auxiliary request 7 did not contravene Article 123(2) EPC.

No additional observations as to the amendments in auxiliary request 7(b) were made by the appellant.

XI. The respondent's arguments, as far as relevant to the decision, are summarised as follows:

Admission of auxiliary requests 6, 5, 5(b), 3, 3(b), 4, 4(b), 7, 7b

All claim requests were new to the proceedings.

Auxiliary request 6 was not "*identical in scope to Auxiliary Request 4 as filed in response to the opposition*", as alleged by the appellant, even if the appellant's reasoning with regard to the *proviso* was to be followed, because the latter limited B16 to His or Glu which was not the case in auxiliary request 6. The same applied to auxiliary request 5. The disclaimer based requests could have been filed in the first instance proceedings because the relevant prior art had been on file since the notice of opposition.

Auxiliary request 3 was not "*closely related to Auxiliary Request 1 filed with the response to the opposition*", as alleged by the appellant, because the latter limited A14 to Glu, Asp or His and B16 to Gln, His or Glu while auxiliary request 3 limited A14 to Asp or His and B16 to Glu as one alternative amongst 7 other mutations. The respondent had raised a clear and unambiguous objection against all of the auxiliary

requests due to the unallowable selection of B16 as an additional residue to be substituted.
Auxiliary request 4 did not "*correspond to Auxiliary Request 1 as filed in response to the opposition, with the additional limitation that the insulin analogue is 'human' insulin*", as alleged by the appellant, because the latter limited B16 to Gln, His or Glu while auxiliary request 4 limited B16 only to Glu.

The "b" claim requests also represented an inadmissible change in approach. The appellant had not explained why it had not filed these requests in the proceedings before the opposition division.

The appellant had made no genuine attempt to justify why the board should allow them to file nine claim requests which were all new to the proceedings. The appellant had admitted that they had decided to change their strategy, so they were presenting an entirely fresh case. These claim requests could and should have been provided in the first instance proceedings.

Auxiliary requests 7 and 7(b)- claim 1
Amendments (Article 123(2) EPC)

Claim 1 of these requests specified that the amino acid in position A14 was Asp, the amino acid in position B16 was Glu and the amino acid in position B25 was His. This combination of mutations was identical to that presented in auxiliary request 5 dealt with in the decision under appeal. The opposition division had correctly found that this request contravened Article 123(2) EPC because it required selections from multiple lists.

To arrive at the substitution where A14 was Asp, a first selection from Glu/Asp/His on page 23, second paragraph, of the application as filed, was required. The rest of the paragraph related to one or more additional mutations that might be present and described several different possibilities. The mutation at the B16 position to Glu than required a second selection from the other mutants mentioned in this paragraph, in particular from the final list, where B16 Glu was one of seven options. The specific pairing of A14 Asp and B16 Glu was not directly and unambiguously disclosed in this passage.

The fact that one of the two lists was not very long (three alternatives) was no reason to consider the subject-matter as directly and unambiguously derivable. Decisions T 7/86 and T 686/99 provided examples where combinations of even shorter lists were considered to result in new subject-matter. With regard to decision T 783/09, cited by the appellant, it had to be borne in mind that in the application in question, all 44 combinations had been described as "very preferred", i.e. there existed a pointer in the direction of the selected combinations. This was not the case for the present selection. On the contrary, on page 5 of the application as filed A14 Glu was preferred (and not Asp), on page 48, A14 Asp was only disclosed in combination with B25 His and desB30, but not with B16 Glu. In the specific embodiments disclosed in the application as filed, the B16 Glu mutation was always disclosed together with A14 Glu (and not with A14 Asp). Furthermore, the selection as claimed resulted in all disclosed working embodiments to be excluded. The application as filed therefore did not provide a direct and unambiguous disclosure of the selection of substitutions referred to in claim 1.

XII. The appellant requested, as far as relevant to the present decision:
- that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims of auxiliary request 6 (main request);
- alternatively, that the patent be maintained on the basis of one of auxiliary requests 5, 5(b), 3, 3(b), 4, 4(b), 7 or 7(b), all filed with the statement of grounds of appeal, in that order;
- that all claim requests be admitted into the proceedings.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

Admission of claim requests
General remarks

2. The statement of grounds of appeal was filed before 1 January 2020 and the reply to this was filed in due time. Thus, Article 12(4) to (6) RPBA 2020 does not apply and, instead, Article 12(4) RPBA 2007 applies to both the grounds of appeal and the reply.

3. Article 12(4) RPBA 2007 stipulates: "*(4) Without prejudice to the power of the Board to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first instance proceedings, everything presented by the parties under (1) shall be taken into account by the*

Board if and to the extent it relates to the case under appeal and meets the requirements in (2)."

Auxiliary request 6

4. The appellant stated that "*Auxiliary Request 6 is therefore identical in scope to Auxiliary Request 4 as filed in response to the opposition*" and argued that they had reacted to reasoning concerning added subject-matter (Article 123(2) EPC) which they only learned about from the decision under appeal. This had prompted them to use "*alternative wording for the request (i.e. use of a proviso in place of deletion from a list)*" (see letter of the appellant dated 30 November 2020). This *proviso* was a so-called "disclosed disclaimer" according to decision G 2/10.

5. The board cannot agree with these arguments. The aim of the disclaimer is to restore novelty over document D9 which was filed with the notice of opposition. As the appellant has stated that it was not clear why or even whether the opposition division considered that limiting the A14 substituent to Asp would contravene Article 123(2) EPC, the board fails to see how auxiliary request 6 can possibly address any issues that were raised in the decision under appeal. On the contrary, it must be regarded as an alternative attempt to overcome novelty objections that were timely raised in the proceedings before the opposition division by the respondent.

6. This request could and should have thus been filed in those proceedings.

7. The board therefore decided not to admit auxiliary request 6 into the appeal proceedings.

Auxiliary requests 5 and 5(b)

8. Claim 1 of these auxiliary requests contains an identical disclaimer as claim 1 of auxiliary request 6. Therefore, the same reasoning as for auxiliary request 6 applies.

9. The board decided not to admit auxiliary requests 5 and 5(b) into the proceedings.

Auxiliary requests 3, 3(b), 4, 4(b)

10. The appellant argued that auxiliary requests 3 and 4 represented a legitimate response to the objection in the decision under appeal regarding a "*generalisation of the B16 substituent*". In their view, auxiliary request 3 included the "one or more additional mutations" listed on page 23, lines 21 to 23 of the application as filed, among which position B16 was Glu. Auxiliary request 4 limited the B16 substitution to Glu. Thus, these requests had been filed as a direct response to the objections raised under Article 123(2) EPC against the B16 substituent, which were first substantiated only at the oral proceedings.

11. The board notes however that an objection to the generalisation of the B16 substituent was already raised in the respondent's letter filed on 4 July 2018, point 7, within the time frame of Rule 116 EPC. The fact that this objection was formulated in a brief manner is not relevant in this respect.

12. The appellant further stated that auxiliary request 3 was "*closely related to Auxiliary Request 1 filed with the response to the opposition. In this request, position B16 was limited to Glu*". The board notes that

in claim 1 of auxiliary request 1, filed with the response to the opposition (dated 25 October 2017), B16 was limited to Gln, His or Glu and A14 was limited to Glu, Asp or His. In claim 1 of auxiliary request 3, however, the limitation of the B16 substituent to three alternative residues is replaced with a list of substitutions of eight alternative residues including B16 and, in addition, the A14 substituent is limited to two instead of three alternatives.

13. The appellant stated that auxiliary request 4, in which position B16 was also limited to Glu, corresponded to auxiliary request 1 as filed in response to the opposition, with the additional limitation that the insulin analogue was "human" insulin.

14. However, this statement is factually incorrect, since in claim 1 of the latter set of claims, B16 was to be chosen from Gln, His or Glu. Claim 1 of auxiliary request 1 filed during the oral proceedings before the opposition division at 13:00 o'clock was closer to auxiliary request 4, as it also restricted the B16 position to Glu. However, it also contained the requirement that B30 was deleted and that the insulin analogue was a "human" insulin. Since the appellant was in a position to react to an objection by filing a new auxiliary request 1 (at 13:00 o'clock of the oral proceedings) which contained the amendment "human insulin", the board considers that the claim request also in that respect could have been filed earlier.

15. In conclusion, the board finds that auxiliary requests 3 and 4 contain amendments which were filed for the first time in appeal and which attempt to address issues under Article 123(2) EPC and Article 54 EPC which were raised in time during the opposition

proceedings. These requests could and should have thus been filed in those proceedings. The same reasoning applies to auxiliary requests 3(b) and 4(b).

16. The board therefore decided not to admit auxiliary requests 3, 3(b), 4 and 4(b) into the proceedings.

Auxiliary requests 7 and 7(b)

17. Since auxiliary requests 7 and 7(b) are not allowable (see below), it is not necessary to provide reasons for the admission of these requests into the proceedings.

Amendments (Article 123(2) EPC)- claim 1

18. The appellant referred to page 23, lines 13 to 15 and lines 21 to 23 as basis for the combination of A14Asp, B25His and B16Glu in claim 1. This passage, indeed states that the modification B25His can be combined with a substitution of position A14 to either Glu, Asp or His, that is a list of three possibilities (see lines 13 to 15). The third substitution (B16Glu) is disclosed in a second list of eight "additional mutations" (see lines 21 to 23).

19. The question to be asked in deciding on whether or not the amendment introduces subject-matter extending beyond the content of the application as filed is whether the selection of A14Asp and B25H is from a list of three possibilities and its combination with B16Glu from a list of eight possibilities is *"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 as filed*" (the so-called "gold-standard", see decision

G 2/10, point 4.3 of the Reasons, OJ EPO 2012, 376). The appellant in that respect referred to decision T 783/09. In the case underlying that decision each of 44 combinations represented a "*very preferred combination*" directly and unambiguously recognisable by the skilled person. From those combinations three "*basic*" combinations were chosen (see points 5.4 and 6.1 of the Reasons). The same decision also found that "*the 'disclosure status' of subject-matter individualised from lists has to be determined according to the circumstances of each specific case by ultimately answering the question whether or not the skilled person would clearly and unambiguously derive the subject-matter at issue from the document as a whole*" (see point 5.6 of the Reasons).

20. In the board's view, and in contrast to the situation dealt with in decision T 783/09, there is no pointer in the application to a combination of substituents as claimed. Instead, the combination represents a "singling out" from all of the possible combinations disclosed in the application as filed which was not disclosed (see also decision G 2/10, point 4.5.4 of the Reasons). While the passage on page 23 provides a list of three substituents at position A14 in combination with B25 His, none of those is indicated as preferred. When consulting the rest of the application the skilled person, however, learns that instead A14 Glu is preferred. In the list of embodiments (see page 4), position A14 can have different substitutions (e.g. embodiments 6, 7, 8 wherein A14 is Glu, Asp or His). However, Glu is the only substitution which is singled out in embodiment 11 (see page 5). Also most individualised examples contain Glu at position A14 (see Example 4, page 48 to 49). The only individualised example referring to A14 Asp and B25 His does not

contain B16 Glu but a deletion of B30 ("desB30", see page 49, line 5; page 24, line 10 and page 27, line 7), i.e. a combination not mentioned in claim 1. To arrive at the claimed subject-matter, the skilled person therefore had to choose a less preferred embodiment (A14 Asp and B25 His) and combine it with a further substituent (B16 Glu) from a list of eight alternatives (page 23, line 21 to 23). Moreover in the remainder of the application as filed, this feature (B16 Glu) always appears together with A14 Glu but not with A14 Asp. Furthermore, B16 Glu is always disclosed together with desB30 (see page 23, line 30, line 34; page 24, line 4, line 5; page 26, line 9, line 11; page 27, line 3; page 49, line 4, line 9, line 14, line 15) which is not mentioned in present claim. The combination of A14 Glu, B25 His and B16 Glu therefore constitutes a combination of substituents which was not disclosed in the application as filed.

21. As the same combination of substituents is mentioned in claim 1 of auxiliary request 7b, the same reasoning applies.

22. Claim 1 of auxiliary requests 7 and 7(b) extends the subject-matter beyond the content of the application as filed (Article 123(2) EPC).

23. In view of the above considerations no admitted claim request meets the requirements of Article 123(2) EPC and the appeal therefore cannot be allowed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

I. Aperribay A. Chakravarty

Decision electronically authenticated