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**Datasheet for the decision
of 28 November 2024**

Case Number: T 0203/23 - 3.3.07

Application Number: 08866933.8

Publication Number: 2234963

IPC: A61K9/22, A61K31/198,
A61K45/06, C07C229/00

Language of the proceedings: EN

Title of invention:

CONTROLLED RELEASE FORMULATIONS OF LEVODOPA AND USES THEREOF

Patent Proprietor:

Impax Laboratories, LLC

Opponents:

Luigi, Rumi
Teva Pharmaceutical Industries Ltd

Headword:

Controlled release levodopa/IMPAX

Relevant legal provisions:

EPC Art. 113(1), 123(2)
EPC R. 103(1)(a)
RPBA 2020 Art. 13(2)

Keyword:

Right to be heard - substantial procedural violation (no)
Amendments - added subject-matter (yes)
Auxiliary request filed at the oral proceedings - cogent reasons (no)

Decisions cited:

G 0001/16



Beschwerdekammern

Boards of Appeal

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Case Number: T 0203/23 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 28 November 2024

Appellant: Impax Laboratories, LLC
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 1 December 2022
revoking European patent No. 2234963 pursuant to
Article 101(3)(b) EPC**

Composition of the Board:

Chairman A. Usuelli
Members: J. Molina de Alba
 L. Basterreix

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's decision revoking European patent No. 2 234 963. It is based on the claims of a main request and 15 auxiliary requests.

In the decision, the opposition division concluded that claim 1 of the main request added subject-matter. For the same reasons, claim 1 of each of auxiliary requests 1 to 15 also added subject-matter.

II. The patent proprietor (appellant) filed an appeal against the decision. With its statement of grounds of appeal, the appellant requested the reimbursement of the appeal fee because the opposition division had allegedly committed a substantial procedural violation. In addition, the appellant filed 31 sets of claims as its main request and auxiliary requests 1 to 30.

The main request and auxiliary requests 16 to 30 were identical to the main request and auxiliary requests 1 to 15 on which the decision under appeal was based. Auxiliary requests 1 to 15 were new in these appeal proceedings.

Claim 1 of the main request read as follows:

"1. A multiparticulate, controlled release oral solid formulation comprising 50 to 600 mg of levodopa and 10 to 80 mg of carbidopa, wherein the multiparticulates are in a capsule form and further comprise:

a. a controlled release component comprising

(a1) beads or granules comprising a core of levodopa, carbidopa, and a carboxylic acid, coated with one or more enteric polymers, or

(a2) beads or granules, comprising a core of levodopa and carbidopa, coated with one or more enteric polymers, and beads or granules comprising a carboxylic acid core coated with one or more enteric polymers;

b. an immediate release component comprising a mixture of levodopa and carbidopa;

wherein the carboxylic acid is a carboxylic acid selected from the group consisting of tartaric acid, adipic acid, succinic acid, citric acid, benzoic acid, acetic acid, ascorbic acid, edetic acid, fumaric acid, lactic acid, malic acid, oleic acid, sorbic acid, stearic acid, palmitic acid, and mixtures thereof; and wherein the ratio of moles of carboxylic acid to levodopa is greater than 1:4 and less than 3:2."

Claim 1 of auxiliary request 1 differed from claim 1 of the main request in that the minimum amount of carbidopa was increased to 20 mg.

Claim 1 of auxiliary request 2 differed from claim 1 of the main request in that the "granules" feature was removed from options (a1) and (a2) of the controlled release component.

Claim 1 of auxiliary request 3 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 1 and 2.

Claim 1 of auxiliary request 4 differed from claim 1 of the main request in that the formulation additionally contained a carboxylic acid component.

Claim 1 of auxiliary request 5 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 1 and 4.

Claim 1 of auxiliary request 6 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 2 and 4.

Claim 1 of auxiliary request 7 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 1, 2 and 4.

Claim 1 of auxiliary request 8 differed from claim 1 of the main request in that option (a1) was removed from the controlled release component.

Claim 1 of auxiliary request 9 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 1 and 8.

Claim 1 of auxiliary request 10 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 2 and 8.

Claim 1 of auxiliary request 11 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 1, 2 and 8.

Claim 1 of auxiliary request 12 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 4 and 8.

Claim 1 of auxiliary request 13 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 1, 4 and 8.

Claim 1 of auxiliary request 14 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 2, 4 and 8.

Claim 1 of auxiliary request 15 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 1, 2, 4 and 8.

Claim 1 of auxiliary request 16 differed from claim 1 of the main request in that it contained the following additional limitation:

"wherein the multiparticulate, controlled release oral solid formulation has a levodopa plasma or serum concentration profile comprising: a) a time of administration; b) a first concentration; and c) a second concentration, wherein, the first concentration is equal to the maximum concentration of said profile; the second concentration is the minimum concentration occurring at a time no later than said first concentration and earlier than or equal to about six hours following the time of administration; and wherein the second concentration is greater than or equal to about fifty percent of the first concentration"

Claim 1 of auxiliary request 17 differed from claim 1 of the main request in that it contained the following additional limitation:

"wherein the enteric polymers in the coat target the drug release in the upper small intestine, where the pH is above 5.5"

Claim 1 of auxiliary request 18 differed from claim 1 of the main request in that it contained the following additional limitation:

"wherein the coat comprises Eudragit® L100-55, which targets the drug release in the upper small intestine, where the pH is above 5.5"

Claim 1 of auxiliary request 19 differed from claim 1 of the main request in that the molar ratio of carboxylic acid to levodopa was limited to greater than 2:3 and less than 4:3.

Claim 1 of auxiliary request 20 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 16 and 19.

Claim 1 of auxiliary request 21 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 17 and 19.

Claim 1 of auxiliary request 22 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 18 and 19.

Claim 1 of auxiliary request 23 differed from claim 1 of the main request in that the carboxylic acid was limited to tartaric acid.

Claim 1 of auxiliary request 24 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 16 and 23.

Claim 1 of auxiliary request 25 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 17 and 23.

Claim 1 of auxiliary request 26 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 18 and 23.

Claim 1 of auxiliary request 27 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 19 and 23.

Claim 1 of auxiliary request 28 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 16, 19 and 23.

Claim 1 of auxiliary request 29 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 17, 19 and 23.

Claim 1 of auxiliary request 30 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 18, 19 and 23.

III. In their replies to the statement of grounds of appeal, opponent 1 (respondent 1) and opponent 2 (respondent 2) requested that the appeal be dismissed.

In addition, respondent 1 requested that auxiliary requests 2, 4 to 6, 8 to 14, 17 to 19, 21 to 27, 29 and 30 not be admitted into the appeal proceedings, and respondent 2 requested that auxiliary requests 1 to 15 not be admitted into the appeal proceedings.

IV. The board scheduled oral proceedings via videoconference, in line with the parties' requests,

and issued a communication with its preliminary opinion.

- V. Oral proceedings were held before the board in the absence of respondent 1, which had been previously notified. During the oral proceedings, the appellant filed an additional set of claims as auxiliary request 31.

Claim 1 of auxiliary request 31 differed from claim 1 of the main request in that it contained the limitations of auxiliary requests 2, 8 and 23 and in that the immediate release component was required to comprise beads of a mixture of levodopa and carbidopa.

At the end of the oral proceedings, the board announced its decision.

- VI. The appellant's arguments relevant to the present decision can be summarised as follows.

Substantial procedural violation

The opposition division committed a substantial procedural violation that justified the reimbursement of the appeal fee. The opposition division considered in its written preliminary opinion that claim 1 of the main request had a basis in the application as filed. The opinion dealt in detail with all the arguments put forward by the respondents in their notices of opposition and the respondents did not react to it during the written proceedings. However, at the beginning of the oral proceedings, the opposition division announced that it had reconsidered its position and that the main request added subject-matter. In spite of the appellant's enquiry as to why

the opposition division then considered that claim 1 had no basis in the application as filed, the opposition division gave no details. This left the appellant in a position in which it could not properly address the objection. The detailed reasons for the opposition division's conclusion were first set out in the decision and contained aspects on which the appellant had not had the opportunity to be heard. Therefore, the conduct of the opposition division violated the appellant's legitimate expectations raised by the written preliminary opinion and deprived the appellant of a fair defence. As the ultimate consequence of this violation was an unexpected revocation of the patent, it constituted a substantial procedural violation.

Added subject-matter - main request

Claim 1 of the main request had a basis in the application as filed. The purpose of the application was the preparation of levodopa formulations having a longer period of efficacy. This aim was achieved by a controlled release formulation based on the unexpected finding that a carboxylic acid controlled levodopa absorption and provided steadier levodopa plasma concentrations (page 1, lines 11 to 16; page 3, lines 20 to 23; page 5, lines 18 to 20; page 8, lines 21 to 23).

The primary basis for claim 1 of the main request in the application as filed was claim 27 or its equivalent passage on page 10, lines 18 to 25. Even if in these passages the carboxylic acid was defined as a component in itself, it was apparent from a reading of the application as a whole, including the examples and the structure of the claims, that the carboxylic acid could

be comprised within the controlled release component. In that case, an additional carboxylic acid was not necessary, i.e. it was not required to have two carboxylic acids if one of them was within the controlled release component. This interpretation was in line with the context provided in the last paragraph on page 8 which explained that the carboxylic acid could (rather than should) be physically separated from the levodopa and the decarboxylase inhibitor. The same teaching was derivable from page 11, lines 10 to 12 and 16 to 19, which referred to a controlled release carboxylic acid component. In summary, the application taught that it was essential to have a carboxylic acid for a controlled release and it was not required that the carboxylic acid be separate from the controlled release component.

With regard to the combination of features in option (a2) of claim 1, page 11, lines 16 to 18 and claim 41 of the application as filed disclosed that the controlled release component could comprise a carboxylic acid coated with one or more enteric polymers, and page 12, lines 1 to 3 and claim 40 disclosed that the controlled release component comprised a core of levodopa and decarboxylase inhibitor coated with one or more enteric polymers. These features were also disclosed for the formulation as a capsule, in accordance with page 9, lines 15 to 17 and the examples.

Admittance of auxiliary request 31

Auxiliary request 31 should be admitted into the proceedings as a reaction to a new argument raised by respondent 2 at the oral proceedings before the board, namely that page 11, lines 2 to 4 of the application as

filed required that also the immediate release component be manufactured in the form of beads. Auxiliary request 31 rendered the new argument moot and responded to the other added subject-matter objections. The limitations in auxiliary request 31 were based on auxiliary request 10, rendered the claimed subject-matter closer to Example 5 and did not introduce complexity to the proceedings.

VII. The respondents' arguments relevant to the present decision can be summarised as follows.

Substantial procedural violation

The opposition division's deviation from its non-binding preliminary opinion did not constitute a substantial procedural violation. As indicated by the opposition division at the oral proceedings, its change of mind was not based on any new objection but on a reconsideration of the respondents' submissions. This was also clear from the decision, which relied only on arguments raised by the respondents in their notices of opposition. In addition, the issue of added subject-matter was fully discussed at the oral proceedings and the appellant had a fair opportunity to defend its case. Moreover, when the opposition division concluded that all the requests on file added subject-matter, it gave the appellant sufficient time to reflect on how to proceed, with the appellant deciding not to file any further claim requests.

Added subject-matter - main request

Claim 1 of the main request added subject-matter because it defined a combination of features that in the application as filed were disclosed independently.

Claim 27 and page 10, lines 18 to 25 of the application as filed defined three separate components while claim 1 of the main request combined two of these components into one, namely the carboxylic acid component and the controlled release component. The passage on page 11, lines 27 to 29 taught that, in addition to the carboxylic acid component, another carboxylic acid could be present in the controlled release component. Thus, if a carboxylic acid was present in the controlled release component, the formulation needed to contain at least two carboxylic acids. This was in line with the summary of the invention in the paragraph bridging pages 3 and 4. The same teaching was conveyed on page 11, lines 10 to 20.

As to the combination of features in option (a2) of claim 1, the passage on page 12, lines 1 to 3 referred to an independent embodiment which was not disclosed in combination with the embodiment on page 11, lines 16 to 18. Furthermore, the coating of the components was not preferred but optional. There was no direct and unambiguous disclosure that the active ingredients on the one hand and the carboxylic acid on the other hand were both coated. The same conclusion could be drawn from claims 40 and 41, which related to separate embodiments that were not disclosed in combination.

In addition, the features in option (a2) were not disclosed in combination with a capsule. According to page 9, lines 15 to 17, capsules were one out of three options including tablets and sprinkle forms. The examples disclosed both tablets and capsules. The application as filed did not teach that a capsule was the most preferred formulation.

Admittance of auxiliary request 31

Auxiliary request 31 should not be admitted under Article 13(2) RPBA. The added subject-matter objections had not changed. The argument that page 11, lines 2 to 4 of the application as filed required that the immediate release component be also in the form of beads was raised by respondent 2 in its reply to the statement of grounds of appeal (paragraph 5.16).

VIII. The parties' final requests were the following.

- The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of one of the main request and auxiliary requests 1 to 30 filed with the statement of grounds of appeal or, alternatively, auxiliary request 31 filed at the oral proceedings before the board.

The appellant further requested the reimbursement of the appeal fee on the basis of an alleged substantial procedural violation committed by the opposition division.

- Respondent 1 had requested in writing that the appeal be dismissed and that auxiliary requests 2, 4 to 6, 8 to 14, 17 to 19, 21 to 27, 29 and 30 not be admitted into the appeal proceedings.
- Respondent 2 requested that the appeal be dismissed and that auxiliary requests 1 to 15 and 31 not be admitted into the appeal proceedings.

Reasons for the Decision

1. *Alleged substantial procedural violation (Article 113(1) and Rule 103(1)(a) EPC)*
 - 1.1 The appellant considered that the opposition division had committed a substantial procedural violation and that therefore the appeal fee had to be reimbursed.
 - 1.2 In the written proceedings, the opposition division issued a communication with a preliminary opinion based on the parties' submissions. The communication gave detailed reasons as to why claim 1 of the main request had a basis in the application as filed. The respondents, then the opponents, did not react to the opposition division's communication during the written proceedings. Nevertheless, before discussing the issue of added subject-matter at the oral proceedings, the opposition division announced that its preliminary opinion had changed and that claim 1 of the main request was considered to add subject-matter (minutes of oral proceedings, paragraph bridging pages 1 and 2). The opposition division indicated that this change of mind was based on a reconsideration of the principles on multiple selections established in the Guidelines and the case law and that it affected at least the combination of features in option (a1) of claim 1. After discussion with the parties and deliberation, the opposition division confirmed its view that the main request added subject-matter. In addition, it indicated that this conclusion also applied to all the auxiliary requests then on file. The appellant was given time to reconsider its defence strategy. After that time, it

did not file any further claim request. As a consequence, the patent was revoked.

1.3 According to the appellant, the opposition division's communication with a positive preliminary opinion and the absence of a reaction from the respondents during the written proceedings created legitimate expectations that the main request did not add subject-matter. Therefore, the opposition division's change of mind announced at the beginning of the oral proceedings took the appellant by surprise. As the opposition division refused to give details as to why it considered that the main request added subject-matter, the appellant was left in a situation where it lacked sufficient information to properly address the objection. Consequently, its right to be heard had been violated. This was allegedly confirmed by the fact that, at the oral proceedings, the opposition division referred only to option (a1) of claim 1 as a matter of concern, while the decision contained further reasons on which the appellant had not had the opportunity to be heard, namely the selection of the carbidopa concentration range, the selection of a capsule, the selection of the range of molar ratios of carboxylic acid/levodopa and the combination of features in option (a2).

1.4 The board does not agree with the appellant's view.

1.4.1 The written preliminary opinion issued by the opposition division in preparation for the oral proceedings was not binding and could subsequently be reversed, even in the absence of submissions from the parties. Therefore, the appellant could not objectively have legitimate expectations based on that opinion. In addition, if the opposition division changed its mind based solely on arguments provided by the parties in

the written proceedings, it was not obliged to give detailed reasons justifying its new opinion at the oral proceedings. In any case, the opposition division provided some orientation to the appellant in that it referred to the criteria for assessing multiple selections in the Guidelines and the case law and in that it indicated that at least the selection of features in option (a1) of claim 1 was problematic. The board notes that option (a1) was in claim 1 of each of the requests then on file. Furthermore, according to the minutes of the oral proceedings (page 2, second to fourth paragraphs), the parties were heard on the issue of added subject-matter, which was discussed in detail based on the parties' written submissions.

Therefore, the board considers that the appellant had a fair opportunity to defend its case and that the manner in which the oral proceedings were conducted did not violate the appellant's right to be heard.

- 1.4.2 With regard to the content of the decision, the appellant submitted that the decision was based on arguments that had never been raised during the opposition proceedings and that the appellant had not had the opportunity to be heard on them. The appellant referred to the arguments on the selection of the carbidopa concentration range, the selection of a capsule, the selection of the range of molar ratios of carboxylic acid to levodopa and the combination of features in option (a2) in claim 1 of the main request.

The appellant's allegation is incorrect. The aspect of the selections of the carbidopa concentration range, the capsule and the range of molar ratios of carboxylic acid to levodopa was explicitly raised in paragraph 4.1 of respondent 2's notice of opposition. As to the

combination of features in option (a2) of claim 1, the objection was raised in paragraphs 4.9 and 4.10 of respondent 2's notice of opposition.

Therefore, the decision is not based on aspects of added subject-matter on which the appellant had no opportunity to comment.

1.5 It follows from the conclusions in above points 1.4.1 and 1.4.2 that the opposition division did not commit a substantial procedural violation (Article 113(1) EPC) and that a reimbursement of the appeal fee under Rule 103(1)(a) EPC is not justified.

2. *Main request - amendments (Article 123(2) EPC)*

2.1 The standard of disclosure to be applied for the assessment of added subject-matter is the gold standard, as last confirmed by the Enlarged Board of Appeal in decision G 1/16 (OJ EPO 2018, A70, Reasons 17 to 20). This standard is defined as:

"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 [the application documents] as filed"

2.2 For the reasons presented here below, the board holds that the formulation defined in claim 1 of the main request results from combining embodiments in the application as filed that were not directly and unambiguously related to each other. Therefore, claim 1 does not meet the gold standard. The board will focus on the combination of features in claim 1 that the formulation is a capsule that comprises option (a2),

i.e. beads or granules comprising a core of levodopa and carbidopa coated with one or more enteric polymers and beads or granules comprising a carboxylic acid core coated with one or more enteric polymers.

2.2.1 According to the appellant, the main basis for claim 1 of the main request in the application as filed is claim 27 or its equivalent passage in the description on page 10, lines 18 to 25. These elements define a multiparticulate, controlled release formulation of levodopa comprising:

- (a) a controlled release component comprising a mixture of levodopa, a decarboxylase inhibitor and a rate controlling excipient
- (b) a carboxylic acid component
- (c) an immediate release component comprising a mixture of levodopa and a decarboxylase inhibitor

The only decarboxylase inhibitor disclosed in the application as filed is carbidopa (see e.g. page 1, line 20; page 10, lines 23 and 24; and claim 38). Therefore, the board accepts that the skilled person would understand that components (a) and (c) comprise a mixture of levodopa and carbidopa.

2.2.2 In claim 1 of the main request, the controlled release component (a) is limited compared to claim 27 as filed or the passage on page 10, lines 18 to 25, in that it comprises as one option, namely (a2), beads or granules comprising a core of levodopa and carbidopa coated with one or more enteric polymers and beads or granules comprising a carboxylic acid core coated with one or more enteric polymers.

As indicated by the appellant, the passage on page 12, lines 1 to 3 and claim 40 of the application as filed disclose particles comprising a core of levodopa and a decarboxylase inhibitor (carbidopa) coated with one or more enteric polymers. Similarly, the passage on page 11, lines 16 to 18 and claim 41 disclose particles comprising a carboxylic acid core coated with one or more enteric polymers. However, these two embodiments are disclosed in an independent manner without any element linking them. There is no connection between the two passages in the description, and claims 40 and 41, albeit dependent on claim 27, are independent from each other. This conclusion is true irrespective of whether the carboxylic acid in component (a2) of claim 1 corresponds to the carboxylic acid in component (b) of claim 27 as filed or whether it is an additional carboxylic acid in accordance with claim 38 or page 11, lines 27 and 28 as filed.

- 2.2.3 Therefore, the combination of features in option (a2) of claim 1 is not directly and unambiguously disclosed in the application as filed. This is even more the case in combination with a capsule formulation. According to page 9, lines 11 to 20 of the application as filed, the compositions of the invention may be formulated as capsules, tablets or sprinkle forms. The passage does not disclose any preference for capsules.

The appellant referred to the examples in the application as a pointer to the claimed combination of features. However, the appellant has not demonstrated that the examples in the application as filed convey the teaching that the structural combination of features in option (a2) is the most preferred one. In addition, the examples illustrate tablets and capsules, and no preference for capsules can be derived.

Therefore, the examples do not provide a direct and unambiguous basis for a capsule in which the controlled release component contains beads or granules in accordance with option (a2) of claim 1.

2.3 Therefore, claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

3. *Auxiliary requests 1 to 30 - amendments (Article 123(2) EPC)*

Claim 1 of each of auxiliary requests 1 to 30 defines a capsule comprising particles in accordance with option (a2) in claim 1 of the main request. Therefore, irrespective of the issue of their admittance, auxiliary requests 1 to 30 do not comply with Article 123(2) EPC for the reasons set out for the main request.

4. *Admittance of auxiliary request 31 (Article 13(2) RPBA)*

According to the appellant, auxiliary request 31 was filed at the oral proceedings before the board in response to a new argument raised by respondent 2 during those oral proceedings.

In its discussion on the basis in the application as filed for claim 1 of the main request, the appellant relied on the passage on page 11, lines 2 to 4. Respondent 2 then argued, allegedly for the first time, that this passage required that not only the controlled release component be manufactured in the form of beads but also the immediate release component. This condition was missing from claim 1 of the main request.

As correctly noted by respondent 2, the alleged new argument had been raised in point 5.16 of its reply to the statement of grounds of appeal, which stated:

"With regard to basis for the term 'beads' the Proprietor refers to the application at page 11, lines 2-4. However, this passage is not suited to providing support for claim 1 since in this embodiment all of the controlled release component, the immediate release component and the carboxylic acid component are manufactured as beads; whereas, in claim 1 only the controlled release component is specified as beads." (emphasis in the original)

For this reason alone, there were no exceptional circumstances, justified with cogent reasons by the appellant, to file auxiliary request 31 at the oral proceedings before the board. Consequently, the board did not admit auxiliary request 31 under Article 13(2) RPBA.

Order

For these reasons it is decided that:

1. The appeal is dismissed.
2. The appellant's request for reimbursement of the appeal fee is rejected.

The Registrar:

The Chairman:



A. Vottner

A. Uselli

Decision electronically authenticated