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**Datasheet for the decision  
of 8 September 2025**

**Case Number:** T 1403/24 - 3.3.07

**Application Number:** 18157578.8

**Publication Number:** 3345607

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A61K31/7088, A61K31/713,  
C07K16/22

**Language of the proceedings:** EN

**Title of invention:**

METHODS OF ALTERING BONE GROWTH BY ADMINISTRATION OF SOST OR  
WISE ANTAGONIST OR AGONIST

**Patent Proprietor:**

Ossifi-Mab LLC

**Opponents:**

UCB Pharma GmbH / UCB Pharma S.A.  
J A Kemp LLP  
Amgen Europe B.V.  
Hightone Management Limited

**Headword:**

Sost antagonist/OSSIFI-MAB

**Relevant legal provisions:**

EPC Art. 99(1), 100(c), 76(1), 123(2)

**Keyword:**

Admissibility of opposition - (yes)

Amendments - added subject-matter (yes)

**Decisions cited:**

G 0003/97, G 0004/97, T 0009/00



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Case Number: T 1403/24 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 8 September 2025**

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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 9 December 2024  
revoking European patent No. 3345607 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman** A. Usuelli  
**Members:** M. Steendijk  
A. Jimenez

## **Summary of Facts and Submissions**

- I. European patent 3 345 607 ("the patent") was granted on the basis of nineteen claims.

It derived from the application EP18157578.8, which was filed as divisional application of the application EP07875255.7, which was originally published as the international application 2009/131553 A2.

Independent claim 1 as granted defined:

"A sclerostin antagonist antibody which specifically binds to sclerostin for use in a method of increasing bone density in a patient with low bone mass, wherein the sclerostin antagonist antibody is serially administered with an antiresorptive drug."

- II. Four oppositions were filed against the grant of the patent on the grounds that its subject-matter lacked novelty and inventive step, that the claimed invention was not sufficiently disclosed and that the patent comprised subject-matter extending beyond the content of the parent and subsequent divisional application as originally filed.

The patent proprietor filed the appeal against the decision of the opposition division to revoke the patent.

The decision was based on the patent as granted (main request), auxiliary requests 1-28 as filed on 20 December 2023, auxiliary request 29 filed on 27 September 2024 (originally numbered as "AR19a") and

auxiliary request 30 filed during the oral proceedings held on 29 October 2024.

Claim 1 of auxiliary request 1 corresponded to claim 1 of the main request with the more specific definition of systemically increasing bone density and the mammalian patient.

Claim 1 of auxiliary request 2 corresponded to claim 1 of auxiliary request 1 with the definition of the patient having osteoporosis (low bone mass deleted).

Claim 1 of auxiliary request 3 corresponded to claim 1 of the main request.

Claim 1 of auxiliary request 4 corresponded to claim 1 of the main request with the more specific definition that the antiresorptive drug is a bisphosphonate, Vitamin D or denosumab.

Claim 1 of auxiliary request 5 corresponded to the main request with the more specific definition that the antiresorptive drug is a bisphosphonate or denosumab.

Claim 1 of auxiliary request 6 corresponded to claim 1 of the main request with the more specific definition that the antiresorptive drug is denosumab.

Claim 1 of auxiliary request 7 corresponded to claim 1 of auxiliary request 2.

Claim 1 of auxiliary request 8 corresponded to claim 1 of auxiliary request 4.

Claim 1 of auxiliary request 9 corresponded to claim 1 of auxiliary request 2 with the further amendment of auxiliary request 4.

Claim 1 of auxiliary request 10 corresponded to claim 1 of auxiliary request 2 with the further amendment of auxiliary request 5.

Claim 1 of auxiliary request 11 corresponded to claim 1 of auxiliary request 2 with the further amendment of auxiliary request 6.

Claim 1 of auxiliary request 12 corresponded to claim 1 of auxiliary request 2 with the the replacement of "serially" by "sequentially" and defines:

"A sclerostin antagonist antibody which specifically binds to sclerostin for use in a method of systemically increasing bone density in a mammalian patient with osteoporosis, wherein the sclerostin antagonist antibody is sequentially administered with an antiresorptive drug."

Claim 1 of auxiliary request 13 corresponded to claim 1 of auxiliary request 12 with the further amendment of auxiliary request 5.

Claim 1 of auxiliary request 14 corresponded to claim 1 of auxiliary request 12 with the further amendment of auxiliary request 6.

Claim 1 of auxiliary request 15 corresponded to claim 1 of auxiliary request 2 with the addition definition of the feature "to increase bone formation" and defines:

"A sclerostin antagonist antibody which specifically binds to sclerostin for use in a method of systemically increasing bone density in a mammalian patient with osteoporosis, wherein the sclerostin antagonist antibody is serially administered with an antiresorptive drug to increase bone formation."

Claim 1 of auxiliary request 16 corresponded to claim 1 of auxiliary request 15 with the further amendment of auxiliary request 5.

Claim 1 of auxiliary request 17 corresponded to claim 1 of auxiliary request 15 with the further amendment of auxiliary request 6.

Claim 1 of auxiliary request 18 corresponded to claim 1 of the main request.

Claim 1 of auxiliary request 19 corresponded to claim 1 of the main request with the more specific definition of a mammalian patient and the systemic delivery of the antibody.

Claim 1 of auxiliary request 20 corresponded to claim 1 of auxiliary request 2 with the more specific definition of systemic delivery of the antibody by injection.

Claim 1 of auxiliary request 21 corresponded to claim 1 of the main request with the more specific definition that the antibody is a monoclonal antibody.

Claim 1 of auxiliary request 22 corresponded to claim 1 of the main request with the more specific definition that the antibody is humanized.

Claim 1 of auxiliary request 23 corresponded to claim 1 of the main request with the more specific definition that the antibody is systemically delivered at dose of 0.01-200mg/kg.

Claim 1 of auxiliary request 24 corresponded to claim 1 of main request with the more specific definition that the patient is a human patient.

Claim 1 of auxiliary request 25 corresponded to claim 1 of the main request with the more specific definition that the antibody is administered as multiple doses over a period of time.

Claim 1 of auxiliary request 26 corresponded to claim 1 of the main request with the more specific definition in claim 1 that the antibody operates through LRP5 or LRP6 to increase the bone density.

Claim 1 of auxiliary request 27 corresponded to claim 1 of auxiliary request 26.

Claim 1 of auxiliary request 28 corresponded to claim 1 of auxiliary request 26 with the further amendment of auxiliary request 2.

Claim 1 of auxiliary request 29 corresponded to claim 1 of auxiliary request 19.

Claim 1 of auxiliary request 30 corresponded to claim 1 of the main request with the more specific definition definition that the antibody is a monoclonal antibody and that the patient is a mammalian patient.

The opposition division arrived at the following conclusions:

- (a) The opposition by opponent 2 was admissible.
- (b) Claim 1 as granted involved the combination of at least four selections from the original disclosure, namely: the selection of serial administration, the selection of an antibody as the sclerostin (Sost) antagonist, the selection of the patient, and the selection of the target.

The additional features of dependent claims 2, 13, 14 and 16-19 as granted gave rise to further objections of added subject-matter.

The patent as granted therefore contravened Articles 76(1) and 123(2) EPC.

- (c) Auxiliary requests 1 to 11, 15 to 29 were admitted but contravened Articles 76(1) and 123(2) EPC, because these requests still involved multiple selections from the original disclosure.

Auxiliary requests 12-14 were not admitted into the proceedings, because they did not comply with Rule 80 EPC. Auxiliary request 30 was not admitted, because it should have been filed at an earlier stage of the proceedings.

III. With the statement of grounds of appeal the patent proprietor maintained its main request and filed auxiliary requests 1-30 corresponding to auxiliary requests 1-30 on which the decision under appeal was based.

The patent proprietor contested the conclusions in the decision under appeal concerning the admissibility of

the opposition by opponent 2, the subject-matter of the claims extending beyond the original disclosure, and the non-admittance of auxiliary requests 12-14 and 30.

IV. In its communication pursuant to Article 15(1) RPBA, the Board expressed the preliminary opinion that

- the opposition by opponent 2 was admissible
- the combination of the feature relating to the increase in bone density in a patient with low bone mass and the feature of serial administration with an antiresorptive drug, as defined in claim 1 as granted, could not be directly and unambiguously derived from the application as filed
- auxiliary requests 12-14 and 30 were to be admitted into the proceedings, but the concerns mentioned in relation to claim 1 of the main request were equally applicable to auxiliary requests 1-30.

V. Oral proceedings were held on 8 September 2025.

VI. The arguments of the patent proprietor relevant to the present decision are summarized as follows:

(a) Admissibility of the opposition by opponent 2

Opponent 2 was acting on behalf of opponent 1 or opponent 3. This followed from the citation of document D24 in the notice of opposition by opponent 2, because document D24 concerned the non-public infringement complaint by the patent proprietor against opponent 1 and opponent 3 in Germany. Moreover, opponent 2 had previously represented a member of the same UCB entity to

which opponent 1 belongs in the opposition against the parent patent. Furthermore, the notices of opposition filed on the same day by opponent 2 and opponent 3 included large sections of identical language. As explained in T 9/00, it would be an abuse of procedure for one opponent to file two oppositions. The filing of the opposition by opponent 2 on behalf of opponent 1 or opponent 3 thus represented an attempt to circumvent the law, which was in view of the considerations in G 3/97 and G 4/97 not admissible.

- (b) Compliance with the provisions of Articles 76(1) and 123(2) EPC

The application as originally filed disclosed in claim 23 and paragraph [0020] the specific embodiment directed to the method for increasing bone density in a patient in need thereof comprising the steps of administering a Sost antagonist together with an antiresorptive drug. This method of increasing bone density inherently involved a patient with low bone mass. This was confirmed in paragraph [0080]. In the context of the patent, the skilled person would interpret the disclosed administration of the Sost antagonist together with an antiresorptive drug broadly and the skilled person would understand that it encompasses the serial or sequential administration of the agents. The terms serial and sequential were in this context synonymous. The serial or sequential administration was specifically described in paragraphs [0043] and [0085] of the application as originally filed. Moreover, paragraph [0085] expressed a preference for sequential dosing, stating that the sequential

dosing of a Sost antagonist with one or more further additional medicaments allows for the optimization of treatment. The application as filed furthermore conveyed a clear preference for Sost antagonists in the form of anti-Sost antibodies. Accordingly, the combination of features as defined in the claims was directly and unambiguously derivable from the content of the application as originally filed.

VII. The arguments of the opponents relevant to the present decision are summarized as follows:

(a) Admissibility of the opposition by opponent 2

In decision T 9/00, the filing of a second opposition by the same company that had already effectively submitted an opposition was deemed inadmissible. In the present case, opponent 2 was a distinct legal entity from opponent 1 and opponent 3. Opponent 2 is not acting on behalf of either opponent 1 or opponent 3. It was furthermore common practice for different opponents to exchange documents and collaborate during opposition proceedings.

(b) Compliance with the provisions of Articles 76(1) and 123(2) EPC

The application as originally filed disclosed, in the description and the independent claims, a variety of different therapeutic uses of Sost antagonists. The administration of a Sost antagonist together with an antiresorptive drug for increasing bone density in a patient with low bone

mass as disclosed in paragraph [0020] and claim 23 therefore implied a first selection.

The application as filed did not specifically disclose the serial or sequential administration of the drugs for this particular therapeutic use. The option of serial or sequential administration as mentioned in paragraphs [0043] and [0085] was not encompassed by the administration of the Sost antagonist together with the antiresorptive drug for increasing bone density as described in paragraph [0020] and claim 23 of the application as filed. Moreover, with respect to the options in paragraphs [0043] and [0085] the restriction to serial or sequential administration as opposed to simultaneous co-administration or co-formulation in a cocktail still implied an additional selection with respect to the content of the original disclosure. The application as originally filed did not disclose any pointer towards the combination of the selected therapeutic indication and the selected serial or sequential administration of the Sost antagonist and the antiresorptive drug.

Accordingly, this combination of features as defined in claim 1 as granted comprised subject-matter extending beyond the content of the application as originally filed.

The amendments according to the auxiliary requests did not overcome the objection against claim 1 as granted.

VIII. The appellant-patent proprietor requested that the decision under appeal be set aside and the case be remitted to the opposition division for examination of

the patent as granted regarding the raised grounds of opposition not considered in the decision under appeal.

As an auxiliary measure the patent proprietor requested that the case be remitted to the opposition division for consideration of the other grounds of opposition in relation to one of auxiliary requests 1-30 filed with the statement of grounds of appeal. The patent proprietor requested in this context that auxiliary requests 12-14 and 30 be admitted into the appeal proceedings.

The patent proprietor further requested that the opposition by opponent 2 be held inadmissible.

IX. The appellants-opponents requested that the appeal be dismissed.

### **Reasons for the Decision**

1. Admissibility of the opposition by opponent 2

In decision T 9/00, the filing of a second opposition by the same legal entity who had already filed an opposition was considered inadmissible for lack of an interest in judicial relief (see T 9/00, reasons 2c: "mangels Rechtsschutzbedürfnisses").

In contrast to the situation in T 9/00, opponent 2 is a distinct legal person from opponent 1 and opponent 3. The considerations in T 9/00 are therefore not applicable to the admissibility of the opposition filed by opponent 2.

According to decisions G 3/97 and G 4/97 an opposition filed on behalf of a third party is inadmissible, if

the involvement of the opponent is to be regarded as circumventing the law by abuse of process, in particular if the opponent is acting on behalf of the patent proprietor or on behalf of a client without possessing the relevant qualifications required by Article 134 EPC. The decisions G 3/97 and G 4/97 explicitly concluded that a circumvention of the law by abuse of process does not arise purely because a professional representative is acting in its own name on behalf of a client and that the burden of proof regarding the circumvention of the law by abuse of process is to be borne by the party alleging that the opposition is inadmissible.

Given the shared interest among opponents in revoking the patent, it is not uncommon for them to exchange documents and coordinate their submissions during opposition proceedings. The citation of document D24 by opponent 2, and the presence of similar or identical passages in the notices of opposition filed by Opponents 2 and 3, do therefore not establish that opponent 2 acted on behalf of opponent 1 or opponent 3. The patent proprietor has thus not provided convincing evidence that the opposition filed in the name of opponent 2 was filed on behalf of opponent 1 or opponent 3 to circumvent the law by abuse of process.

Accordingly, the Board has confirmed the admissibility of the opposition filed by opponent 2.

2. Main request - Articles 76(1), 123(2), 100(c) EPC

2.1 It was common ground that the technical content of the divisional application as originally filed from which the patent derives corresponds to the content of the earlier application as published in WO 2009/131553 A2.

The Board therefore refers to this content as published in WO 2009/131553 A2 for the assessment of the requirement that amendments may not result in subject-matter extending beyond the content of the original application, as formulated in Articles 76(1) and 123(2) EPC, and as reflected in the ground of opposition under Article 100(c) EPC.

2.2 The original application describes in paragraphs [0014]-[0026] under the heading "Summary of the invention" various objects of the claimed invention.

Disclosed are *inter alia* the object of providing a method of promoting local bone growth by local administration of a sclerostin (Sost) antagonist (see paragraph [0014]), the object of providing a method of increasing bone density involving the administration of a Sost antagonist together with an antiresorptive drug (see paragraph [0020]), the object of providing a method of reducing bone involving the administration of a Sost agonist (see paragraph [0022]), and the object of providing a method of protecting a mammalian kidney from chemical injury involving the administration of a Sost antagonist (see paragraph [0024]). It is explained that the Sost antagonists or agonists are administered locally with or without an osteoconductive matrix or in conjunction with an antiresorptive agent, or alternatively systemically in conjunction with an antiresorptive (see paragraph [0025]).

In this context paragraph [0020] specifically describes:

"It is a still further object of the present invention to provide a method of increasing bone

density both systemically (whole body) and locally, comprising the steps of administering, to a mammalian patient in need thereof, a therapeutic amount of a Sost antagonist together with an antiresorptive drug."

The original application describes under the heading "Detailed description of the invention" in paragraphs [0043]-[0044] that the claimed invention is directed to methods of promoting local bone deposition in mammals using materials that antagonize Sost proteins, in particular Sost-recognizing antibodies, and that the antagonist may be coadministered or serially administered with an antiresorptive drug to increase or hasten bone formation:

"The present invention is directed to methods for promoting local bone deposition in mammals using materials that antagonize Sost proteins. Suitable antagonists may be provided by blocking antibodies. (...) The antagonist may be coadministered or serially administered with an antiresorptive drug if desired to increase or hasten bone formation. (...) These blocking Sost-recognizing antibodies may be made readily by those of ordinary skill in this art by conventional techniques."

The original application continues to describe the utility of Sost agonists in methods for reducing bone (see paragraph [0045]) and the further utility of Sost antagonists in methods of protecting kidneys from chemical injury (see paragraph [0046]).

In the subsection "Therapeutic applications" the original application explains in paragraph [0080]:

"Individuals to be treated using methods of the present invention may be any mammal, for example local increase in bone may be used for fracture healing, fusion (arthrodesis), orthopedic reconstruction, and periodontal repair. Systemic increase in bone would be for treatment of low bone mass, i.e. osteoporosis. Bone reduction would be used to treat unwanted heterotopic bone formation, ossification of longitudinal ligament, ossification during cervical stenosis, or osteosarcoma."

The original application further explains in paragraph [0085]:

"The methods of the present invention include application of SOST antagonists in cocktails including other medicaments, for example, antibiotics, fungicides, and anti-inflammatory agents. Alternatively, the methods may comprise sequential dosing of an afflicted individual with a SOST antagonist and one or more additional medicaments to optimize a treatment regime. In such optimized regimes, the medicaments, including the granulation inhibitor may be applied in any sequence and in any combination."

This disclosure of subject-matter is reflected in the independent claims of the application as filed, which define:

- "A method of promoting local bone growth, comprising the steps of administering a therapeutic amount of a Sost, Wise, or LRP antagonist locally to a mammalian patient in need thereof" (claim 1)

- "A method of promoting bone growth, comprising the steps of administering locally, to a mammalian patient in need thereof, a therapeutic amount of a Sost, Wise, or LRP antagonist together with a BMP recombinant protein" (claim 4)
  
- "An orthopedic or periodontal medical device, comprising a structural support, wherein an implantable portion of said structural support is adapted to be permanently implanted within a mammalian body, said implanted structural support being retained in said body by local bone growth, said structural support bearing at least a partial external coating of a Sost antagonist" (claim 13)
  
- "A method of increasing bone density, comprising the steps of administering, to a mammalian patient in need thereof, a therapeutic comprising an effective amount of a Sost, Wise, or LRP antagonist together with an antiresorptive drug" (claim 23)
  
- "A method of reducing bone, comprising the steps of administering either a systemic or local therapeutic amount of a Sost or Wise agonist to a mammalian patient in need thereof" (claim 35)
  
- A method of protecting a mammalian kidney from chemical injury resulting in renal damage (or glomerulonephritis), comprising administering, to a patient in need thereof, a therapeutic amount of a Sost or Wise antagonist (claim 40).

Notably, claim 23 is followed by dependent claims which further define that the bone density is increased systemically (claim 24) or increased by local application of the therapeutic (claim 25).

2.3 Claim 1 as granted combines the feature of the utility of the Sost antagonist antibody for increasing bone density in a patient with low bone mass with the feature that the Sost antagonist is serially administered with an antiresorptive drug.

2.3.1 As demonstrated in section 2.2 above, the administration of a Sost antagonist together with an antiresorptive drug for increasing bone density in a patient in need thereof as disclosed in paragraph [0020] and claim 23 of the original application only represents one of several therapeutic methods disclosed in the original application.

Moreover, paragraph [0020] and claims 23-25 of the original application explicitly refer to patients in need of an increase in bone density either locally or systemically (whole body). The skilled person understands that these patients may thus suffer from a local or systemic low bone density. However, claim 1 as granted additionally defines the patient to be treated as a patient with low bone mass. It is not evident that this definition of a patient with low bone mass encompasses, in the context of the patent and the application as originally filed, in addition to patients with systemic low bone density also patients with only a local low bone density. On the contrary, the only passage in the patent (see paragraph [0086]) and the original application (see paragraph [0080]) which mentions the term "low bone mass" relates this term to patients in need of a systemic increase in bone by stating: "Systemic increase in bone would be for low bone mass, i.e. osteoporosis".

The Board therefore agrees with the opponents that the administration of a Sost antagonist together with an antiresorptive drug for increasing bone density in a patient with low bone mass represents a first selection from a list of therapeutic indications for Sost antagonists described in the original application.

- 2.3.2 As indicated in section 2.2 above, the original application describes in paragraph [0043] that the antagonist may be co-administered or serially administered with an antiresorptive drug if desired to increase or hasten bone formation, and in paragraph [0085] that the methods of the claimed invention include the application of Sost antagonists in cocktails including other medicaments, for example, antibiotics, fungicides, and anti-inflammatory agents or, alternatively, the sequential dosing of an afflicted individual with a Sost antagonist and one or more additional medicaments to optimize a treatment regimen.

Insofar as the option of serial or sequential administration described in paragraphs [0043] and [0085] may be considered as encompassed by the administration of the Sost antagonist together with the antiresorptive drug for increasing bone density as described in paragraph [0020] and claim 23 of the original application, the Board observes that the definition of serial or sequential administration in any case represents a further selection with respect to the modes of administration mentioned in paragraphs [0043] and [0085], which also included co-administration or co-formulation in a cocktail.

- 2.3.3 The Board agrees with the opponents that the original application does not convey any preference or otherwise

provide any pointer to the combination of the selected feature of the utility of the Sost antagonist antibody for increasing bone density in a patient with low bone mass with the selected feature that the Sost antagonist is serially or sequentially administered with an antiresorptive drug.

The patent proprietor's argument that paragraph [0085] of the original application expresses a preference for sequential dosing by indicating that the sequential dosing of a Sost antagonist with one or more further additional medicaments allows for the optimization of treatment is not considered persuasive. Paragraph [0085] discloses that the methods of the claimed invention include the application of Sost antagonists in combination with other medicaments, including antibiotics, fungicides and anti-inflammatory agents, either in a cocktail or by sequential dosing to optimize a treatment regimen. This passage does not specifically address any optimization from the combination of a Sost antagonist with an antiresorptive drug, let alone the optimization from serial or sequential administration of this combination of drugs as opposed to its administration in a cocktail.

Notably, the original application does not present any example which could otherwise serve as a pointer towards the defined combination of features in claim 1 as granted.

- 2.4 It is established jurisprudence that, when an amendment involves the combination of features selected from more than a single list, there generally needs to be a pointer in the original disclosure towards this combination of selected features for the amendment to be directly and unambiguously derivable from the

content of the original application and thus to comply with Articles 76(1) or 123(2) EPC (see Case Law of the Boards of Appeal of the EPO, 11th edition, 2025, II.E. 1.6).

As explained above in section 2.3.2, claim 1 as granted defines the combination of selected features from different lists, namely the selected therapeutic indication for the Sost antagonist directed at increasing bone density in a patient with low bone mass and the selected feature of the serial or sequential administration of the Sost antagonist with an antiresorptive drug. Moreover, as explained in section 2.3.3 above, the original application provides no pointer towards this combination.

Claim 1 as granted therefore comprises subject-matter extending beyond the content of the application as originally filed. The main request can therefore not be allowed.

3. Auxiliary requests 1-30 - Articles 76(1), 123(2) EPC

Following the announcement during the oral proceedings that claim 1 as granted is considered not to comply with the requirements of Articles 76(1) and 123(2) EPC, the Board indicated, as already suggested in the communication pursuant to Article 15(1) RPBA, that its considerations regarding claim 1 as granted also appeared to apply to the independent claims of auxiliary requests 1-30. The Board explained that the independent claims as amended in all auxiliary requests still seemed to involve the unallowable combination of the selection of the therapeutic indication for the Sost antagonist antibody with the selection of serial

or sequential administration of the Sost antagonist with an antiresorptive drug.

In response, the patent proprietor maintained auxiliary requests 1-30, but did not present any additional arguments regarding the basis of the independent claims as amended in these requests in the original application.

The Board therefore confirms its conclusion that the auxiliary requests 1-30 do not comply with the requirements of Articles 76(1) and 123(2) EPC for the same reasons as set out for the main request.

Accordingly, a decision on the admittance of auxiliary requests 12-14 and 30 is not required.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated