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**Datasheet for the decision
of 9 March 2023**

Case Number: T 1648/18 - 3.2.01

Application Number: 12703836.2

Publication Number: 2675502

IPC: A61M5/20, A61M5/32

Language of the proceedings: EN

Title of invention:
AUTO-INJECTOR

Patent Proprietor:
SANOFI

Opponent:
OWEN MUMFORD LIMITED

Headword:

Relevant legal provisions:

EPC Art. 52(1), 54, 56, 83, 111(1), 123(2)
RPBA 2020 Art. 11, 25(2)
RPBA Art. 12(4)

Keyword:

Novelty - main request (no) - auxiliary request (yes)
Inventive step - auxiliary request (yes)
Sufficiency of disclosure - (yes)
Amendments - extension beyond the content of the application
as filed (no)
Late-filed auxiliary request - submitted with the statement of
grounds of appeal
Late-filed auxiliary request - request clearly allowable (yes)
Late-filed auxiliary request - procedural economy not
negatively affected
Late-filed auxiliary request - admitted (yes)
Appeal decision - remittal to the department of first instance
for further prosecution (no)

Decisions cited:

T 0840/93, G 0009/91

Catchword:



Beschwerdekammern
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Case Number: T 1648/18 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 9 March 2023

Appellant: SANOFI
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
17 April 2018 concerning maintenance of the
European Patent No. 2675502 in amended form.**

Composition of the Board:

Chairman G. Pricolo
Members: V. Vinci
O. Loizou

Summary of Facts and Submissions

- I. The appeal filed by the appellant (patent proprietor) is directed against the interlocutory decision of the opposition division to maintain the European patent No. 2 675 502 in amended form.
- II. In its decision, the opposition division held that the subject-matter of independent claim 1 according to the main request lacked novelty within the meaning of Articles 52(1) and 54 EPC and that the auxiliary requests I to X did not comply with the requirements of Articles 123(2) EPC. The opposition division came to the conclusion that the auxiliary request XI met the requirements of Articles 83 and 123(2) EPC and that the subject-matter of independent claim 1 was novel and involved an inventive step within the meaning of Articles 52(1), 54 and 56 EPC over document:

D1: WO-A-2009095701

In the course of the appeal proceedings following additional evidence was submitted by the appellant (patent proprietor):

P1: Pages 15, 254 to 264 and 267 to 270 from *"Handbook of Human Factors in Medical Device Design"*, 1st Edition.

P2: International Standard ISO 9355-3:2006(E), *"Ergonomic requirements for the design of displays and control actuators"* - Part 3: Control actuators, 1st Edition.

P3: Pages 464, 465 and 470 from *"Human Factors Design"*

Handbook", 2nd Edition, by Wesley Woodson, Peggy Tillman and Barry Tillman.

P4: Extract from the online "*Oxford English Dictionary*", giving technical definitions of the term "*translate*".

III. With the communication pursuant to Article 15(1) RPBA dated 1 July 2022, the Board informed the parties of its preliminary, non-binding assessment of the appeal.

With the letter dated 20 January 2023 the respondent (opponent) informed the Board that they will not be attending the oral proceedings scheduled for 9 March 2023.

Oral proceedings pursuant to Article 116 EPC were held before the Board on 9 March 2023 by videoconference in the absence of the respondent (opponent).

IV. The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained according to the main request underlying the decision under appeal or in the alternative, the patent be maintained according to the auxiliary requests 1 to 15 filed with the statement of grounds of appeal.

The respondent (opponent) requested in writing that the appeal be dismissed.

V. Independent claim 1 according to the main request reads as follows (labelling of the features of the claim introduced by the Board):

1-1 "*Auto-injector (1) for administering a dose of a liquid medicament (M), comprising:*

1-2 an elongate case (12) arranged to be held by a user,

1-3 a tubular chassis (2) telescopable in the case (12) and biased against the case (12) so as to proximally protrude from the case (12),

1-4 a syringe (3) with a hollow injection needle (4), a drive spring (8) and a plunger (9) for forwarding load of the drive spring (8) to a stopper (6) of the syringe (3),

1-5 a trigger button (13) which is initially abutted against the case (12) thus preventing actuation, wherein

1-6 the chassis (2) is arranged to translate into the case (12) against the bias, characterized in that

1-7 the trigger button (13) is at least initially coupled to the chassis (2) in such a manner that the trigger button (13) emerges from the case (12) when the chassis (2) is being translated towards the case (12) for starting an injection cycle, wherein the trigger button (13) is arranged distally in or on the case (12)."

Independent claim 1 according to the auxiliary request 1 reads as follows (amendments with respect to the main request emphasised by the Board):

1-1 "Auto-injector (1) for administering a dose of a liquid medicament (M), comprising:

1-2 an elongate case (12) arranged to be held by a

user,

1-3 a tubular chassis (2) telescopable in the case (12) and biased against the case (12) so as to proximally protrude from the case (12),

1-4 a syringe (3) with a hollow injection needle (4), a drive spring (8) and a plunger (9) for forwarding load of the drive spring (8) to a stopper (6) of the syringe (3),

1-5 a trigger button (13) which is initially abutted against the case (12) thus preventing actuation, wherein

1-6 the chassis (2) is arranged to translate into the case (12) against the bias, characterized in that

1-7 the trigger button (13) is at least initially coupled to the chassis (2) in such a manner that the trigger button (13) emerges from the case (12) when the chassis (2) is being translated towards the case (12) so as to allow actuation of the trigger button (13) by the trigger button (13) being translated towards the case for starting an injection cycle, wherein the trigger button (13) is arranged distally in or on the case (12)."

Reasons for the Decision

MAIN REQUEST

Novelty: Articles 52(1) and 54 EPC

1. The subject-matter of claim 1 according to the main request does not meet the requirements of Articles 52(1) and 54 EPC as correctly stated in the decision under appeal.
- 1.1 With their appeal, the appellant (patent proprietor) contested the assessment of the opposition division that the subject-matter of independent claim 1 lacked novelty over document D1 in view of the embodiment in Figures 1 to 8E. It was alleged that this prior art auto-injector did not comprise a *"trigger button"* according to feature 1-5 of claim 1. The appellant (patent proprietor) argued that, contrary to the interpretation of the opposition division and the respondent (opponent), the *"operating button (40)"* of the auto-injector disclosed in Figures 1 to 8E of D1, in view of its functionality as described in this prior art document, was not a *"trigger button"* in the meaning that a person skilled in the art would confer to this term in the relevant technical context of medical devices, namely an activation button operated by pushing/pressing it axially toward the case of the auto-injector. The appellant (patent proprietor) put forward that the *"trigger button"* recited in claim 1 had to be understood as a *"push button"* of the kind disclosed in the handbooks P1 and P3 and in the International ISO Standard P2 submitted with the statement of grounds of appeal. The appellant (patent proprietor) also argued that the fact that the actuating element (40) of the auto-injector of D1 was

named *"button"* in this prior art document did not mean that it had to be understood as such. It was pointed out that, in view of established case law of the boards of appeal, the term *"button"* should not be interpreted literally and in isolation from the technical information presented in D1, but rather in the technical context of this prior art document as a whole. By applying this principle the person skilled in the art realized that the activation element (40), even though being named *"button"*, was actually not a button in the meaning generally conferred to this term in the relevant technical field, but rather a pivoting activation element well distinguished from a *"push button"*.

- 1.2 Furthermore, the appellant (patent proprietor) alleged that, in any event, the wording of claim 1, read as whole, inherently implied that the *"trigger button"* was operated by axially pushing/depressing it toward the case in order to activate the auto-injector, whereas the *"operating button (40)"* of the known auto-injector was tilted/pushed laterally upon activation. Finally, it was contested that it could be directly and unambiguously derived from document D1 that the *"operating button (40)"* was *"initially abutted against the case thus preventing actuation"* as required by feature 1-5 of claim 1 of the main request. In this respect it was also argued that even in the initial retracted position shown for example in Figure 1 of D1 it would be in principle possible to activate the auto-injector by grasping and pulling and/or twisting the operating button (40) to cause breakage of the neck (37).
- 1.3 The arguments of the appellant (patent proprietor) are not convincing for the following reasons:

The Board shares the view of the opposition division and the respondent (opponent) that the operating button (40) of the known auto-injector shown in Figures 1 to 8E of D1 embodies a *"trigger button"* in the meaning and with the functionality of feature 1-5 of claim 1. Firstly, the Board agrees with the opposition division and the respondent (opponent) that the term *"trigger button"* in claim 1, although broad, is clear per se, so that a narrower interpretation in view of the description as proposed by the appellant (patent proprietor) is not justified in the present case. The Board, unlike the appellant (patent proprietor), does not see why the term *"trigger button"* should be interpreted more narrowly than simply meaning any means suitable for triggering an operation by being pushed in any direction with the finger tip. In fact, the Board is convinced that the term *"trigger button"* does not mandatorily and inherently imply that it is operated by axially pressing/pushing it towards the case from which it protrudes as instead assumed by the appellant (patent proprietor). While this surely represents one of the possible meanings that the person skilled in the art would confer to this term, other arrangements are considered to fall under the the meaning of *"trigger button"* as, for example, a pivoting switch or the operating button (40) of the auto-injector of D1. The latter, beside being literally defined in D1 as *"button"*, also shows a geometry commonly associated to an activation button.

- 1.4 Furthermore, contrary to the appellant's (patent proprietor's) allegation, it is irrefutable that the operating button (40) in its retracted initial position shown for example in Figures 1, 8A and 8B *"is initially abutted against the case"* as required by feature 1-5 of claim 1, the abutting interface being represented by

the radially inward pointing surfaces of the element (42) of the case, as convincingly explained by the opposition division and the respondent (opponent) and confirmed by the description of D1, page 9, lines 8-10. Furthermore, in this retracted position, triggering of the injection, at least in the way foreseen by D2, namely by tilting the operating button (40) to such an extent to cause breakage of the neck (37) (see D1, page 9, lines 22-24 and figures 8C to 8E) is also prevented, because it is not possible to tilt the operating button (40) when it is in its initial retracted position. There is no indication in D1 that activation of the injector could be carried out in the manner alleged by the appellant (patent proprietor) which is thus considered just a matter of speculation. On the contrary, D1 clearly teaches that activation of the auto-injector when the operating button is in its initial position is prevented (see D1, page 9, lines 9-10).

- 1.5 Finally, the Board does not concur with the allegation of the appellant (patent proprietor) that the wording of claim 1 as a whole implies that the trigger button is necessarily pushed/depressed axially toward the case to activate the injection-device, thereby ruling out a tilting operation as disclosed in D1. Claim 1 only states that the trigger button is at least initially coupled to the chassis in such a manner that *"the trigger button emerges from the case when the chassis is being translated towards the case for starting an injection cycle."* While this is also the case for the operating button (40) of D1 (see page 9, lines 15-22), as correctly assessed by the opposition division, the formulation of claim 1 does not mandatorily require that the claimed auto-injector is activated by pushing/pressing the trigger button axially, but also covers

other possibilities, for example that that triggering action is achieved by applying lateral/transversal pressure. In other words, it cannot be directly and unambiguously derived from the wording of claim 1 that the claimed initial connection between the chassis and the button (see feature 1-7) mandatorily implies that the button is arranged in such a way to emerge from the case and is operable in the same direction of the axial translation of the chassis.

- 1.6 For the reasons above the assessment of the opposition division that claim 1 of the main request lacks novelty over D1 is confirmed.

AUXILIARY REQUEST 1

Admissibility

2. The auxiliary request 1, along with the auxiliary requests 2, 5 and 13, was filed for the first time with the statement of grounds of appeal of the appellant (patent proprietor).
- 2.1 The respondent (opponent) objected to the admission into the appeal proceedings of these new requests. They drew the attention to a supposed proliferation of unsubstantiated requests filed by the appellant (patent proprietor) which was not compatible with the principles of procedural economy, procedural fairness and with the provision of Article 12(2) RPBA according to which a party filing an appeal had to set out their complete case in the statement of grounds of appeal. By referring to the decision T840/93, the respondent (opponent) further pointed out that filing of an appeal on the basis of new requests raising issues not considered by the opposition division was not in

accordance with the purpose of appeal proceedings as established in G009/91 and this especially, as allegedly in this case, when divisional applications were still pending. Finally, it was objected that no substantiated inventive step arguments based on the problem-solution approach were filed in support of the new requests that also introduced new issues without directly addressing the specific objections raised by the opposition division.

- 2.2 At least as far as the admissibility of the auxiliary request 1 is concerned, the arguments submitted by the respondent (opponent) are not convincing for the following reasons:
- 2.3 The Board observes that according to Article 25(2) RPBA in the version 2020, the provisions of Article 12(4) in the 2007 version apply to the present appeal.

The Board shares the view of the appellant (patent proprietor) that the submission of auxiliary request 1 is not an attempt to change the appellant's case by introducing a new limitation into claim 1 based on subject-matter that was not discussed at first instance proceedings, but is rather a genuine effort to narrow the meaning of the disputed term "*trigger button*", which was extensively discussed during the first-instance proceedings, and this in the sense to specify that the trigger button according to claim 1 is operated by translating it towards the case. This amendment thus clearly addresses the concern of the opposition division which adopted a broader, and as explained above, correct reading for this term in the technical context of claim 1 according to the main request. Regarding the relevant question whether this amendment could have been introduced during the first-

instance proceedings (see Article 12(4) RPBA 2007, first sentence), the Board considers convincing the explanation of the appellant (patent proprietor) that the decisive argument in the reasoning of the opposition division which led to the rejection of the main request for lack of novelty over D1, namely that the reading of the term "*trigger button*" by the appellant (patent proprietor) was based on an "*over-limitation*" not justified by the actual wording of the claim, was set out for the first time in the decision under appeal. The submission of the new auxiliary 1 request with the statement of grounds of appeal can thus be considered a normal reaction, at the earliest possible stage of the appeal proceedings, to the reasoning presented in the decision. In addition, as it will be explained below, the amendment introduced in claim 1 of the auxiliary request 1 clearly addresses and solves the issue raised by the opposition division which led to the rejection of the main request, thereby restoring novelty over D1. Regarding the objection that new issues would arise by this amendment, neither are these issues specified by the respondent (appellant) nor can they be detected by the Board. Regarding the alleged lack of substantiation, the Board notes that in the statement of grounds of appeal the appellant (patent proprietor) has clearly indicated the basis for the amendment and set out the reasons why in their opinion the subject-matter of claim 1 of the auxiliary request 1 was novel and not rendered obvious by the cited prior art (see points 6. to 6.3). Finally, the Board observes that the cited decision T840/93 is well antecedent to the entry into force of the RPBA 2007 and also relates to a case where the new requests dismissed by the competent board, contrary to the present case, had not been filed with the statement of the grounds of appeal, but at a very later stage of the appeal

proceedings. The conclusion of the decision T840/93 do not thus apply to the present case. The Board also notes that the respondent (opponent) did not react to the submissions of the appellant (patent proprietor) dated 24 January 2023 in which arguments in support of the contested admissibility of the new auxiliary requests were provided.

- 2.4 In view of the above the Board does not see any reason to apply the discretion provided by Article 12(4) RPBA 2007 not to admit the auxiliary request 1 which is thus part of the appeal proceedings.

Amendments: Articles 123(2) and 123(3) EPC

3. The auxiliary request 1 meets the requirements of Articles 123(2) and (3) EPC.
- 3.1 Claim 1 of the auxiliary request 1 has been limited with respect to claim 1 of the main request by specifying that actuation of the trigger is allowed "*by the trigger button (13) being translated towards the case*". As explained by the appellant (patent proprietor), this amendment is supported verbatim by the passage on page 3, lines 15-24 of the originally filed PCT application. Compliance with Article 123(2) EPC was not objected by the respondent (opponent) and the Board does not see any reason to raise any objection in this respect. Furthermore, the amendment clearly results in a limitation of the scope of claim 1 as granted and therefore the requirements of Article 123(3) EPC are also met.

Sufficiency of Disclosure: Article 83 EPC

4. The auxiliary request 1 meets the requirements of Article 83 EPC.

4.1 The respondent (opponent) referred to the feature of claim 1 of the main request, which is also present in claim 1 according to auxiliary request 1, reading

"the trigger button is at least initially coupled to the chassis in such a manner that the trigger button emerges from the case when the chassis is being translated towards the case for starting an injection cycle"

and objected that the claim did not include any structural feature linking the emergence of the trigger button to the translation of the chassis, in particular the *"carrier (7)"*, which was presented in the contested patent as a *"key feature"* of the auto-injector according to the present invention (reference was made to paragraph [0066] of the patent disclosure). The respondent (opponent) concluded that the fact that claim 1 missed essential features had the consequence that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carry out across the whole scope of claim 1 by a person skilled in the art.

4.2 The Board does not agree and confirms the conclusion of the opposition division presented in the context of the discussion of the main request which contains the same alleged issue:

4.3 Firstly, the Board points out that according to established case law of the boards of appeal compliance

with Article 83 EPC must be assessed on the basis of the application as a whole, i.e. the description, the claims and the figures. In the present case it is uncontested that the patent specification (see Figures 1A-16B and paragraphs [0062] to [0069]) disclose in detail a quite complex technical solution for at least initially coupling the trigger button to the chassis in such a manner that the trigger button emerges from the case when the chassis is translated towards the case at the beginning of an injection cycle. Regarding the objection of the respondent (opponent) that the disclosed technical solution requires other complex mechanisms and in particular the presence of the carrier (7) which however is not mentioned in claim 1, the Board shares the view of the opposition division that the subject-matter of claim 1 is limited to the solution of the problem stated in paragraph [0018] of the patent specification and relating to the first phase of operation, when it is required to prevent accidental actuation of the auto-injector before the tubular chassis contacts the injection site. The Board agrees with the opposition division that the person skilled in the art realizes that, when limited to this first phase of operation that allows the trigger button to emerge from the case only upon application of the auto-injector on the injection site, only the initial coupling of the trigger button to the chassis and the axial distal translation of the chassis with respect to the case are essential to the definition of the invention. Furthermore, the Board concurs with the opposition division that although the patent specification only presents a solution comprising a carrier connecting the trigger button with the chassis, the skilled person readily understands that this can be also achieved more simply by directly coupling these two elements. Having said that, the Board is convinced

that the person skilled in the art is able, on the basis of their common general knowledge, to realize a direct connection between the chassis and the trigger button that allows the trigger button to emerge from the case when the chassis is being translated towards the case for starting an injection cycle. The contrary has not been demonstrated by the respondent (opponent) who, in the case of the assessment of compliance with Article 83 EPC, carries the burden of proof.

- 4.4 For the reasons above the Board concludes that the auxiliary request 1 meets the requirements of Article 83 EPC.

Novelty: Articles 52(1) and 54 EPC

5. The subject-matter of claim 1 of the auxiliary request 1 is novel within the meaning of Articles 52(1) and 54 EPC.

- 5.1 Lack of novelty was objected by the respondent (opponent) only in view of document D1. It was essentially argued that the person skilled in the art would interpret the term "*translated*" in claim 1 broadly and according to the most commonly used definition. i.e "*moved from one place or condition to another*" as confirmed by the second definition provided by the evidence P4 filed by appellant (patent proprietor). It was also observed that a patent specification could not be read strictly as it would be the case of a physics text, and that the contested patent did not provide any indication that the term "*translated*" was intended to be used in-line with the narrow, literal physics definition alleged by the appellant (patent proprietor) on the basis of the 4th alternative definition provided by P4, i.e "*to cause a*

body to move so that all its parts travel in the same direction, without rotation or change of shape". Furthermore, the respondent (opponent) observed that not even the patent specification used the term "*translated*" according to a strict physics definition adopted by the appellant (patent proprietor) but also, for example, used it to describe the change of shape of an element. The respondent (opponent) concluded that in view of the well justified broader interpretation of the term "*translated*" which did not exclude a rotation component, the actuation of the operating button (40) of the auto-injector according to D1 resulted in the operating button also being translated towards the case, specifically tilted, as required by amended claim 1 of the auxiliary request 1 which thus lacked novelty over D1.

- 5.2 The Board does not agree with the reading of the respondent (opponent) and has no doubt that the person skilled in the art, in a technical context, confers to the term "*translated*" the strict technical meaning that it has in the kinematics/physics, i.e. that an object is moved in a straight direction without rotating. This is not the case of the operating button (40) of the auto-injector according to the embodiment in Figures 1 to 8E of D1 which is tilted/rotated up activation and hence not "*translated*", as convincingly explained by the appellant (patent proprietor). Regarding the embodiment in Figures 9A and 9B the Board shares the view of the appellant (patent proprietor) that, contrary to the assessment of the opposition division presented in the context of the discussion of the main request, the operating button of this alternative embodiment is not initially abutted against the case and does not emerge from the case when the chassis is translated toward the case, as required by features 1-5

and 1-7 of claim 1 respectively.

- 5.3 In conclusion, the technical content of D1 is not prejudicial to novelty of claim 1 of the auxiliary request 1. As no further novelty attacks have been submitted by the respondent (opponent), the subject-matter of claim 1 of the auxiliary request 1 is novel over the cited prior art.

Inventive Step: Articles 52(1) and 56 EPC

6. Inventive step has been assessed by the opposition decision only in respect of the much more restricted auxiliary request XI underlying the decision under appeal on which basis the contested patent was maintained. The question thus arises whether special reasons in the meaning of Article 11 RPBA 2020 are present justifying a remittal of the case to the department of first instance, as was requested in writing by the appellant (patent proprietor). This is not the case for the following reasons:
- 6.1 The Board observes that in their statement of grounds of appeal, the appellant (patent proprietor) presented arguments in support of the inventive step of the subject-matter of claim 1 of the main request, these arguments being based on their incorrect assumption that it was at least implicitly derivable from the wording of claim 1 that the trigger button defined therein was translated toward the case upon operation. As this distinguishing feature is now clearly defined in claim 1 of the auxiliary request 1 (see point 5.2 above), these arguments equally apply to the subject-matter of claim 1 at stake. With their reply the respondent (opponent) also submitted arguments regarding lack of inventive step of the subject-matter

of claim 1 of the auxiliary request 1 starting from the same relevant embodiment in Figures 1 to 8E of D1. The Board, in view of these circumstances and in accordance with Article 111(1) EPC, second sentence, decided not to remit the case.

6.2 There is agreement that document D1 represents the closest prior art as also stated by the opposition division.

6.3 The subject-matter of claim 1 according to the auxiliary request 1 thus differs from the embodiment in Figures 1 to 8E of D1 in that actuation of the trigger button is allowed by translating the trigger button towards the case.

6.4 This results in an alternative activation button operation compared compared to D1.

6.5 The respondent (opponent) observed that no unexpected technical effect was provided by replacing the tilting operating button (40) of the auto-injector of D1 by a well known push button (reference was made to evidence P1 to P3), i.e. by an activation button which was translated toward the case upon activation. The respondent (opponent) also argued that in both cases activation of the tilting button of D1 or of an equivalent push button according to claim 1 led to the identical result of triggering the injection. The respondent (opponent) concluded that the particular selection of one well known type of button over another was nothing more than a routine design choice which could not involve an inventive step.

6.6 The arguments of the respondent (opponent) are not convincing for the following reasons:

In the auto-injector according to document D1 activation of the injector is achieved by tilting the operating button (40). This action determines the breakage of the neck (37) and in turn, first the advancement of the syringe in a forward position and successively delivery of the medicament to the patient. The person skilled in the art thus readily realizes that replacing the tilting operating button of D1 by a push button, which cannot tilt, would also require to completely modify the activating principle underlying the injector of D1 because there is no doubt, as explained by the appellant (patent proprietor), that pressing a push button mounted at the place of the prior art's operating button (40) cannot determine breakage of the neck (37) and thus activation of the injector. Therefore, the person skilled in the art, in view of the major conceptual and constructional changes required in the injector of D1 in order to render its operation compatible with the use of a push button, is not motivated to replace the operating button of D1 by a button which translated toward the case upon activation in the meaning of claim 1.

6.7 As no further inventive step attacks have been submitted by the respondent (opponent), the Board concludes that the subject-matter of claim 1 of the auxiliary request 1 is not rendered obvious by the cited prior art.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent in amended form according to the set of claims of the auxiliary request 1 filed with the statement of grounds of appeal and a description to be adapted.

The Registrar:

The Chairman:



A. Vottner

G. Pricolo

Decision electronically authenticated