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Datasheet for the decision of 16 March 2023

Case Number: T 1742/21 - 3.3.08

Application Number: 13757006.5

Publication Number: 2824181

IPC: C12Q1/6886

Language of the proceedings: EN

Title of invention:
Novel FGFR3 fusion product

Patent Proprietor:
Astellas Pharma Inc.

Opponents:
James Poole Limited
Boult Wade Tennant LLP

Headword:
FGFR3 fusion/ASTELLAS PHARMA

Relevant legal provisions:
EPC Art. 84
RPBA 2020 Art. 12(2), 12(4), 12(6), 13(2)

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It can be changed at any time and without notic

Keyword:
Main request and auxiliary requests 1 to 7 - claims - clarity (no)
Auxiliary requests 8 and 9 - amendement to case - admitted (no)

Decisions cited:
J 0014/19

Catchword:
-

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Case Number: T 1742/21 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 16 March 2023

Appellant: (Patent Proprietor)	Astellas Pharma Inc. 5-1, Nihonbashi-Honcho 2-chome Chuo-ku Tokyo 103-8411 (JP)
Representative:	Finnegan Europe LLP 1 London Bridge London SE1 9BG (GB)
Respondent I: (Opponent 1)	James Poole Limited One Southampton Row London WC1B 5HA (GB)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent II: (Opponent 2)	Boult Wade Tennant LLP Salisbury Square House 8, Salisbury Square London EC4Y 8AP (GB)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 2 August 2021 revoking European patent No. 2824181 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chair	D. Rogers
Members:	B. Claes
	A. Schmitt

Summary of Facts and Submissions

I. The appeal lodged by the patent proprietor (appellant) lies from the decision of the opposition division revoking European patent No. 2 824 181 with the title "*Novel FGFR3 fusion product*". The opposition proceedings were based on the grounds for opposition in Article 100(a) EPC, on novelty (Article 54 EPC) and inventive step (Article 56 EPC), and in Article 100(b) and (c) EPC.

Claims 10 to 12 of the patent as granted (claims 1 to 13) read:

"10. A pharmaceutical composition for use in a method of treating cancer which comprises a substance inhibiting the polypeptide as defined in claim 1, wherein the cancer is positive for either a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of FGFR3 and TACC3.

11. The pharmaceutical composition for use in a method of treating cancer according to Claim 10, wherein the substance inhibiting the polypeptide is Dovitinib, AZD4547 or BGJ398.

12. The pharmaceutical composition for use in a method of treating cancer according to Claims 10 or 11, wherein the cancer is lung cancer or bladder cancer."

II. With the statement of grounds of appeal, the appellant filed sets of claims of a main request and eight auxiliary requests. The main request and auxiliary requests 1 to 7 were identical to requests dealt with in the decision under appeal (see further section VI.).

The appellant submitted arguments that the opposition division had erred in the decision under appeal in its rulings on added subject-matter, sufficiency of disclosure, clarity, inventive step and admittance for the main request and auxiliary requests 1 to 7. The appellant referred to one new document. Subsequently, the appellant submitted a corrected auxiliary request 5 to replace the earlier version.

III. Each opponent (respondent I and respondent II) replied to the appeal.

IV. The board summoned the parties to oral proceedings in line with their requests.

V. The appellant filed a corrected version of the set of claims of auxiliary request 1 to replace the earlier version and submitted a set of claims of auxiliary request 9.

VI. The relevant claims of the claim requests in appeal and the correspondence of these requests with those dealt with in the decision under appeal are as follows.

Claim 10 of the **main request** (claims 1 to 12; identical to the set of claims of the main request in opposition proceedings) reads:

"10. A pharmaceutical composition for use in a method of treating a subject with cancer which comprises a substance inhibiting the polypeptide as defined in claim 1, wherein the substance inhibiting the polypeptide is a low-molecular weight compound having inhibitory activity against FGFR3, and wherein the cancer is positive for either a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein

composed of FGFR3 and TACC3, and wherein the cancer is lung cancer or bladder cancer, and wherein the subject is detected to have a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of a FGFR3 and TACC3." (emphasis added)

Claim 10 of **auxiliary requests 1 to 6** (identical to auxiliary requests 2, 5a, 3, 1, 1a and 4 in opposition proceedings, respectively) is likewise for a pharmaceutical composition for use in a method of treating a subject with cancer and equally includes the features "the substance inhibiting the polypeptide is a low-molecular weight compound having inhibitory activity against FGFR3" and "wherein the subject is detected to have a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of a FGFR3 and TACC3".

Claim 10 of **auxiliary request 7** (claims 1 to 10; identical to auxiliary request 6 in opposition) reads:

"10. A pharmaceutical composition for use in a method of treating a subject with cancer which comprises a substance inhibiting the polypeptide as defined in claim 1, wherein the substance inhibiting the polypeptide is a low-molecular weight compound having inhibitory activity against FGFR3, and wherein the cancer is positive for either a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of FGFR3 and TACC3, and wherein the cancer is lung cancer or bladder cancer, and wherein the subject is detected to have a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of a FGFR3 and TACC3, wherein the fusion gene encodes a fusion protein comprising the polypeptide as defined in claim 1 or claim 2 and wherein the substance inhibiting

the polypeptide is Dovitinib, AZD4547 or BGJ398." (emphasis added)

The set of claims of **auxiliary request 8** is identical to claims 1 to 9 of the main request and the patent as granted.

The set of claims of **auxiliary request 9** is identical to claims 1 to 7 and 10 to 12 of the main request (the latter renumbered as claims 8 to 10).

VII. The board issued a communication pursuant to Article 15(1) RPBA setting out its preliminary opinion that, *inter alia*, contrary to the finding in the decision under appeal, claim 10 of the main request lacked clarity (Article 84 EPC) in view of the feature "low-molecular weight compound". As claim 10 of each of auxiliary requests 1 to 6 included the same feature, these requests equally lacked clarity (Article 84 EPC). The board further held that the subject-matter of claim 10 of auxiliary request 7 lacked novelty (Article 54 EPC) and that auxiliary requests 8 and 9 were unlikely to be admitted in the appeal proceedings.

VIII. On 13 March 2023, in the context of admittance of auxiliary request 8, the appellant requested that a question be referred to the Enlarged Board of Appeal.

IX. The appellant's arguments relevant to the decision are summarised as follows.

Main request and auxiliary requests 1 to 6 - claim 10 - clarity (Article 84 EPC)

The claim was clear.

Auxiliary request 7 - claim 10 - clarity (Article 84 EPC)

The main purpose of the requirement of clarity was to allow the skilled person to determine whether an activity was in or outside the scope of protection.

The claim was formulated in an acceptable format for a second medical use and related to personalised medicine, i.e. to the use of a biomarker to appropriately allocate the treatment of patients in whom the biomarker was detected. The appropriate allocation of treatment identified the patients likely to respond.

In view of the feature "wherein the subject is detected to have a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of a FGFR3 and TACC3", the claim only covered FGFR3 inhibitors when used in conjunction with positive detection of the biomarker. The claim was a purpose-limited product claim and thus did not concern active steps for a method.

The order and timing of the treatment of the subject and the detection of the biomarker was not relevant to the claimed subject-matter. The detection could occur at any time, i.e. before, during or after treatment of the subject.

Request to refer a question to the Enlarged Board of Appeal

The request was occasioned by the statement put forward for the first time in the communication of the board pursuant to Article 15(1) RPBA that the filing of

auxiliary request 8 with the statement of grounds of appeal constituted an amendment in accordance with Article 12(4) RPBA.

Auxiliary request 8 - admittance

This auxiliary request differed from auxiliary request 6, which was admissibly raised in the opposition proceedings, solely by the deletion of claim 10.

The deletion of a claim from an earlier request which was part of the opposition proceedings was not an amendment under Article 12(4) RPBA. It did not change the legal and factual framework of the case. In fact, the remaining claims in the request had been legally and factually considered during the opposition proceedings by all parties and the opposition division. In such circumstances, the board should exercise its discretion to admit this request into the appeal proceedings (see e.g. decisions T 1480/16, T 2638/16, T 0494/18, T 0995/18 and T 1151/18).

In its preliminary opinion, the opposition division considered that the subject-matter of claims 1 to 9 of the patent was novel and inventive, and the decision under appeal included an extensive *obiter dictum* to the same effect.

After the opposition division had announced at the oral proceedings that the subject-matter of claim 10 of auxiliary request 6 (identical to current auxiliary request 7) lacked novelty, the patent proprietor requested to submit an auxiliary request identical to current auxiliary request 8. The division refused to

allow the patent proprietor to submit this request (see minutes, paragraphs 57 and 60).

Claims 1 to 9 had been part of the proceedings throughout the opposition proceedings, and the opponents had ample opportunity to comment on these claims. The deletion of claim 10 addressed the lack of novelty concerns of the opposition division, and the request fulfilled the requirement of "clear-allowability" for an amendment made after the final date set for making written submissions in preparation for the oral proceedings (Rule 116(1) EPC). Therefore, the opposition division had erred and exercised its discretion wrongly when refusing to allow the patent proprietor to submit this request. Therefore, under Article 12(6) RPBA, first sentence, the request should be admitted into the appeal proceedings.

Since the opposition division had refused to allow the patent proprietor to submit this request, the circumstances of the appeal case justified its admittance. The appellant filed this request at the first available opportunity with the statement of grounds of appeal. As the respondents could have expected this request to be filed, the request did not disadvantage the respondents. It also did not raise new issues or change the subject of the appeal compared with the opposition proceedings and in fact restricted the matters to be dealt with. The board should thus admit and consider auxiliary request 8 in the appeal proceedings under Article 12(6) RPBA.

Auxiliary request 9 - admittance

In appeal, the respondents have reiterated their arguments on entitlement to priority of claims 8 and 9

of the patent as granted. Because this aspect was not dealt with in the decision under appeal, it was not necessary to address it in the statement of grounds of appeal. The newly filed request addressed all issues relating to these claims, raised no new matters and thus did not alter the factual or legal framework of the proceedings.

Admitting the request in the appeal proceedings was not contrary to the principles of procedural economy and fair proceedings.

X. The respondents' arguments relevant to the decision are summarised as follows.

Main request and auxiliary requests 1 to 6 - claim 10 - clarity (Article 84 EPC)

The claim lacked clarity.

Auxiliary request 7 - claim 10 - clarity (Article 84 EPC)

The amendment by inserting in the wording of claim 10 as granted the feature that "the subject is detected to have a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of a FGFR3 and TACC3" introduced a lack of clarity.

The claim defined the therapeutic treatment of a subject by a combination of a treatment feature (use of the composition or substance to treat cancer) and a detection feature (the subject is detected to have a fusion gene or a fusion protein composed of a FGFR3 and TACC3). However, the claim did not define the correlation between these two distinct features

defining separate activities, i.e. how the feature that the subject "is detected" to have a fusion gene or protein was part of the therapeutic use of the inhibitor to treat cancer.

If the feature of the detection of the FGFR3-TACC3 fusion biomarker of the claim defined an active, limiting, step of the therapeutic treatment method referred to in the claim - i.e. the FGFR3-TACC3 fusion was to be detected in the subject treated with the substance inhibiting the polypeptide, then the claim wording allowed this detection step to be carried out before treatment of the subject, during treatment as a monitoring tool, or after treatment of the subject, i.e. in a retrospective study.

However, if the detection step could be performed even after the substance inhibiting the polypeptide had been administered to the subject, this could not constitute a technical feature characterising a therapeutic use of the substance to treat cancer. In fact, the party administering the compound could even be different to the party conducting the retrospective analysis of the patients genotypes and may have no knowledge of the patient's genotype when administering the compound.

Accordingly, the detection step was not limiting, and the treatments disclosed in documents D19 and D20 anticipated the claimed subject-matter.

Request to refer a question to the Enlarged Board of Appeal

The objection that the filing of auxiliary request 8 with the statement of grounds of appeal constituted an amendment in accordance with Article 12(4) RPBA had

been raised by the respondents in their replies to the appeal.

The appellant had not justified the request for a referral.

Auxiliary request 8 - admittance

The request was submitted for the first time in the appeal proceedings. It had not formally been submitted during the oral proceedings in opposition and, hence, the opposition division had not decided on the admittance of a claim request limited to claims 1 to 9 of the patent. Article 12(6) RPBA, first sentence thus did not apply.

The request should have been submitted in the opposition proceedings. The opposition division's decision that the subject-matter of claim 10 of former auxiliary request 6 lacked inventive step had been expressed in the preliminary opinion prior to the oral proceedings. Furthermore, the preliminary opinion of the opposition division also indicated that the subject-matter of claims 1 to 9 of the patent was considered novel and to involve an inventive step. The request was thus not presented in the opposition proceedings at the first opportunity and could, and in fact should, have been filed at the latest on the final date set for making written submissions in preparation for the oral proceedings (Rule 116(1) EPC). The request should thus not be admitted and considered under Article 12(6) RPBA, second sentence.

The appellant had not justified presenting this request for the first time in the appeal.

In the oral proceedings in opposition proceedings, the opponents were not heard on the claims of the request on the requirements of novelty and inventive step. The *obiter dictum* in the decision under appeal was not reasoned. Consequently, if the request was admitted and considered in the appeal proceedings, a number of issues would arise for discussion with the board, all for the first time in the absence of a reasoned decision of the opposition division.

Auxiliary request 9 - admittance

The request should have been filed in the opposition proceedings.

XI. The requests of the parties on which this decision is based are as follows.

The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the set of claims of the main request or, alternatively, on the basis of the set of claims of one of auxiliary requests 1 to 9, all requests, with the exception of auxiliary requests 1, 5 and 9, filed with the statement of grounds of appeal; auxiliary requests 1 and 9 filed with the letter dated 21 November 2022 and auxiliary request 5 filed with the letter dated 20 January 2022.

The appellant further requested that auxiliary requests 2, 8 and 9 be admitted and considered in the appeal proceedings. In the context of admittance of auxiliary request 8, the appellant requested that the following question be referred to the Enlarged Board of Appeal: "*Is the deletion of a claim or claims from a request that has already been admitted to the*

proceedings an amendment in accordance with Article 12(4) RPBA?"

Respondents I and II requested that the appeal be dismissed and that auxiliary requests 2, 8 and 9 and the request to refer a question to the Enlarged Board of Appeal not be admitted into the appeal proceedings.

Reasons for the Decision

1. The appeal is allowable.

Auxiliary requests 1 to 7 - clarity (Article 84 EPC)

Auxiliary request 7 - claim 10

2. The claim is for a pharmaceutical composition comprising the FGFR3 inhibitor Dovitinib, AZD4547 or BGJ398 for use in a method of treating a subject with lung cancer or bladder cancer which is positive for either a FGFR3/TACC3 fusion gene or a fusion protein which encoded and/or comprised the polypeptide as defined in claim 1 or claim 2, and wherein the subject is detected to have a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of a FGFR3 and TACC3 (emphasis added).

3. The feature "wherein the subject is detected to have a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of a FGFR3 and TACC3" was added to the wording of the appellant's claim requests with the patent proprietor's reply to the oppositions (see points II.A and II.B). The feature is therefore open to objection under Article 84 EPC and is, in

addition to being in claim 10 of auxiliary request 7, in claim 10 of the main request and each of auxiliary requests 1 to 6 and 9 submitted in the appeal proceedings (see section VI.).

4. The opposition division reasoned that it found "*references in the patent that either perform the detection step before, during or after treatment*" and that the feature had to be "*broadly construed with the limitation that it was technically sensible and reasonable: the fusion detection can be performed as part of starting a personalised treatment, it can be performed during treatment as monitoring tool but also afterwards in retrospective studies*" and concluded that, hence, the claim was clear (see point 39.4. of the decision under appeal in the context of claim 10 of former auxiliary request 6).

5. Because the use of at least one of the FGFR3 inhibitors referred to in the claim was known to treat subjects with xenografted RT112 cancer which had retrospectively been detected to be positive for a FFR3-TACC3 fusion gene equally referred to in the claim, the opposition division subsequently also considered the novelty of the claimed subject-matter (see point 47.5 of the decision under appeal). In this context, the opposition division construed the claim in general to "*cover a known medical use of a known compound, but focusing on patients defined by an allegedly new marker, which however was inherent in at least a part of the known patients. The crux of the matter is whether a new disease marker can be used to identify a new subgroup of patients, thereby providing a new clinical situation*" (emphasis added). The opposition division then decided that the current claim provided such a new

clinical situation (see point 47.5 of the decision under appeal).

6. In appeal, the appellant has defended the clarity of the claim with similar arguments as those of the opposition division (see point 4.). The claim was formulated in a second medical use format in the field of personalised medicine, i.e. the use of a biomarker to appropriately allocate the treatment of subjects in whom the biomarker was detected and who were likely to respond to the treatment. The feature "wherein the subject is detected to have a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of a FGFR3 and TACC3" limited the claim to cover only pharmaceutical compositions comprising FGFR3 inhibitors when used in conjunction with positive detection of the biomarker (fusion gene or polypeptide) in a treated subject.

7. As can be concluded from the decision under appeal and the submissions of the parties, the opposition division and the parties construe the contentious inserted feature "wherein the subject is detected to have a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of a FGFR3 and TACC3" to not limit the treatment referred to in the claim to the effect that the detection can take place prior, during or after the method of treatment. Indeed, as the respondents have submitted, the claim does not define the correlation between distinct features defining separate activities, i.e. how the feature that the subject "is detected" to have a fusion gene or protein is part of the therapeutic use of the inhibitor to treat cancer. The board sees no reason to disagree.

8. Both the opposition division in the decision under appeal and the appellant thus emphasised the relevance of the (new) molecular biomarker referred to in the claim for identifying a subgroup of subjects with lung cancer or bladder cancer for treatment with the FGFR3 inhibitor, namely subjects who are positive for the biomarker. The biomarker, hence, allowed for the identification of a (new) subgroup of patients for personalised treatment with an FGFR3 inhibitor.

9. However, to meet the aim of personalised medicine, the patients for which an envisaged treatment could be useful should be identified by diagnostic marker detection *prior* to the treatment and not later or retrospectively, i.e. after "undetected" patients have been treated. In the case at hand, therefore, the inserted feature as it is formulated casts substantial doubt on whether the treatment method referred to in the claim includes purposive patient selection for the treatment referred to in the claim or not.

10. For this reason alone, it is not clear from the wording of the claim whether the detection referred to is required and whether the claim defines a (new) patient group for the personalised treatment with a FGFR3 inhibitor. The inclusion of the contentious feature thus renders the claim not clear, contrary to Article 84 EPC.

11. Since the feature of the detection of the FGFR3-TACC3 fusion in the claim can be carried out after treatment of the subject, it is not a technical feature characterising the therapeutic use of the substance to treat cancer. In fact, the person administering the compound could even be different to the person

conducting a retrospective analysis of the patient's genotypes.

12. Thus, in view of the unlimited temporal relationship between the therapy feature and the contentious detection feature referred to in the claim, the claim's scope of protection is open ended, and it is, in fact, not possible to determine, when using the compound in therapy, whether patent protection applies or not. Also for this reason, the claim lacks clarity.

Main request and auxiliary requests 1 to 6 - claim 10

13. Claim 10 of the main request and auxiliary requests 1 to 6 all include the feature "wherein the subject is detected to have a fusion gene composed of an FGFR3 gene and a TACC3 gene or a fusion protein composed of a FGFR3 and TACC3" (see section VI.). In their replies to the appeal, the respondents contested the clarity of this feature with reference to claim 10 of the main request.

14. The board considers the reasons for finding claim 10 of auxiliary request 7 unclear (see points 2. to 11. above) to apply *mutatis mutandis* to claim 10 of the main request and auxiliary requests 1 to 6, and these claims consequently equally lack clarity.

15. During the oral proceedings, the board heard the parties first on the issue of clarity of these claims in view of the feature "a low-molecular weight compound having inhibitory activity against FGFR3", in particular whether the "low-molecular weight" qualification clearly defined the inhibitor compound. The board expressed the opinion that the feature rendered the claim to lack clarity (see also

section VII.). However, in view of the board's conclusion in point 14. above, the board sees no reason to address in this decision its opinion on the clarity of the feature "a low-molecular weight compound having inhibitory activity against FGFR3" in claim 10 of these requests.

Auxiliary request 7 - claim 10 - novelty (Article 54 EPC)

16. During the oral proceedings, the board concluded that the subject-matter of claim 10 lacked novelty over the disclosure in two cited documents.

17. However, in view of the board's conclusion that the request is not allowable for lack of clarity (see points 9. to 11. above), the board's conclusion on novelty is not relevant for this decision, and it is therefore not necessary to provide reasons.

Request to refer a question to the Enlarged Board of Appeal

18. The request was submitted by the appellant three days prior to the oral proceedings. Thus, it constitutes an amendment subject to Article 13(2) RPBA and must, as a rule, not be taken into account by the board unless there are exceptional circumstances justified with cogent reasons by the party concerned.

19. The appellant justified the filing of the request by alleging that the board's statement in the communication pursuant to Article 15(1) RPBA that the filing of auxiliary request 8 with the statement of grounds of appeal constituted an amendment in accordance with Article 12(4) RPBA was the first such opinion/objection in the proceedings.

20. However, the objection that the filing of auxiliary request 8 with the statement of grounds of appeal constituted an amendment in accordance with Article 12(4) RPBA had already been raised by the respondents in their replies to the appeal. Accordingly, the appellant has not identified exceptional circumstances justified with cogent reasons why the board should deviate from the general principle established in Article 13(2) RPBA and consider the request to refer a question to the Enlarged Board of Appeal. This request is therefore not considered.

Auxiliary request 8 - admittance

21. Claims 1 to 9 of this request are identical to the same claims in the patent as granted and the same claims of each and every request submitted during the opposition proceedings and the main request and auxiliary requests 1 to 7 submitted in the appeal proceedings.

22. The minutes of the second day of oral proceedings before the opposition division record a discussion between the opposition division and the appellant regarding a *hypothetical* claim request (see paragraphs 57 to 60). This *hypothetical* - and eventually *not* filed - request corresponds to current auxiliary request 8. The request was thus submitted for the first time with the statement of grounds of appeal.

23. It is codified in Article 12(2) RPBA that, in view of the primary object of the appeal proceedings being to review the decision under appeal in a judicial manner, a party's appeal case is to be directed to the issues in dispute (requests, facts, objections, arguments and evidence) on which the decision under appeal was based.

24. Under Article 12(4) RPBA, any part of a party's appeal case which does not meet the requirements in paragraph (2) is to be regarded as an amendment which may be admitted only at the discretion of the board. It is the decision under appeal which is the point of reference for assessing whether a part of the appeal case constitutes an amendment within the meaning of Article 12(4) RPBA (see decision J 14/19).

25. Article 12(4) RPBA also provides that, by way of exception, submissions not dealt with in the decision under appeal cannot be regarded as an amendment if the submitting party demonstrates on appeal that it admissibly raised them and maintained them until the decision was taken in the proceedings leading to the decision under appeal (see also CA/3/19 (supplementary publication 2, OJ EPO 2020), explanatory remarks on Article 12(4) RPBA, third paragraph).

26. The set of claims of auxiliary request 8 was submitted only with the statement of grounds of appeal (see point 22.), and the board concurs with the respondents that, *inter alia,* novelty and inventive step of the subject-matter of claims 1 to 9 were not discussed for any of the claim requests filed in the opposition proceedings during the oral proceedings with the parties.

27. Consequently, the board sees no room for holding that auxiliary request 8 filed with the statement of grounds of appeal had been admissibly raised and maintained in the proceedings leading to the decision under appeal and thus did not amount to an amendment in accordance with Article 12(4) RPBA. In fact, if the board were to admit the request in appeal, the parties would need to be heard for the first time on a number of complex

issues in the absence of a written decision of the opposition division on these issues. Admitting this request in appeal would thus prejudice procedural economy (Article 12(4) RPBA).

28. In accordance with Article 12(6) RPBA, second sentence, the board shall not admit, *inter alia*, requests which should have been submitted in the proceedings leading to the decision under appeal unless the circumstances of the appeal case justify their admittance.

29. Substantive objections against claims 10 to 12 of the patent as granted have been on file throughout the opposition proceedings. Furthermore, based on the (negative) preliminary opinion of the opposition division when summoning the parties to oral proceedings, it was fair to expect that it was unlikely that claims 10 to 12 of any request on file would be allowed. Yet, the appellant did not file a request in which all these claims were deleted, e.g. with the appellant's reply to the preliminary opinion of the opposition division. It was only at the very latest stage of the opposition proceedings during the oral proceedings that the appellant *announced its intention to file* a request corresponding to current auxiliary request 8.

30. The appellant has not argued that new auxiliary request 8 could not have been filed in the opposition proceedings or that it was filed in response to a late turn of events in the opposition proceedings or due to a new reasoning by the opposition division in the decision under appeal to which it had not had time to react. Thus, there appears to be no circumstances that would justify the request's admittance in appeal given that the appellant had both ample opportunity and

significant reasons to file it in the first-instance proceedings and chose not to.

31. The board accordingly holds that this request could and should have been filed during the opposition proceedings. On the basis of the above considerations, auxiliary request 8 is thus not admitted into the appeal proceedings (Article 12(6) RPBA).

Auxiliary request 9 - admittance

32. The claims of this request, submitted after the board had summoned the parties to oral proceedings, are identical to claims 1 to 7 and 10 to 12 of the main request (the latter claims renumbered as claims 8 to 10). Admittance of this claim request is governed by Article 13(2) RPBA.

33. Claim 8 of this request is identical to claim 10 of the main request which the board concluded lacked clarity (see point 14. above).

34. Furthermore, also in the case of claims 8 and 9 of the patent as granted, substantive objections have been on file throughout the opposition proceedings. Nevertheless, the appellant chose not to file a request in which these claims were deleted until after the respondents replied to the appeal. As with auxiliary request 8, there are no circumstances that could justify the request's admittance in appeal.

35. On the basis of these considerations, the request is not admitted into the appeal proceedings (Articles 12(6) and 13(2) RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

L. Malécot-Grob D. Rogers

Decision electronically authenticated