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**Datasheet for the decision
of 13 September 2018**

Case Number: T 2321/13 - 3.3.04

Application Number: 02712879.2

Publication Number: 1355658

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A61K39/395, G01N33/68,
A61P35/00, A61P29/00

Language of the proceedings: EN

Title of invention:

Anti HER3 antibody for diagnosis, prevention and treatment of hyperproliferative diseases

Patent Proprietor:

Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V.

Opponents:

F. Hoffmann-La Roche AG(CH) / Genentech, Inc.(US)
MedImmune LLC
Ablynx N.V.
Glaxo Group Limited
Merck Patent GmbH

Headword:

Hyperproliferative diseases/MAX-PLANCK-GESELLSCHAFT

Relevant legal provisions:

EPC Art. 84

EPC R. 115(2)

RPBA Art. 12(4), 15(3)

Keyword:

Main request - clarity (no)

Auxiliary requests 1 to 7 - admitted (no)

Decisions cited:

G 0003/14, T 0241/95, T 1811/13

Catchword:



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Case Number: T 2321/13 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 13 September 2018

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 18 October 2013
revoking European patent No. 1355658 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chair B. Claes
Members: R. Morawetz
L. Bühler

Summary of Facts and Submissions

I. The appeal of the patent proprietor (hereinafter "appellant") lies against the decision of the opposition division revoking European patent No. 1 355 658. The patent is entitled "*Anti HER3 antibody for diagnosis, prevention and treatment of hyperproliferative diseases*".

Independent claim 1 of the patent as granted reads as follows:

"1. Use of a HER3 inhibitor for the manufacture of a medicament for the diagnosis, prevention or treatment of a hyperproliferative disease associated with HER3 mediated phosphorylation, wherein the inhibitor is an anti HER3 antibody or a fragment thereof."

II. Five oppositions were filed to the patent. The patent was opposed as a whole under Article 100(a) EPC, on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Article 100(b) EPC and Article 100(c) EPC. In reply to the notices of opposition, the appellant filed the set of claims as granted as a main request and sets of claims of auxiliary requests 1 to 5. In a communication issued together with the summons to oral proceedings, the opposition division held that the feature "*hyperproliferative disease associated with HER3 mediated phosphorylation*", present in claim 1 of the main request and each of auxiliary requests 1 to 5, had no basis in the application as filed and therefore constituted added subject-matter. During the oral proceedings before the opposition division, the appellant filed a set of claims of auxiliary request 6.

III. In the decision under appeal, the opposition division held that the subject-matter of the claims as granted (main request) did not fulfil the requirements of Article 100(c) EPC, that the subject-matter of claim 1 of each of auxiliary requests 1, 2, 4 and 5 did not fulfil the requirements of Article 123(2) EPC and that claim 1 of auxiliary request 6 did not fulfil the requirements of Article 84 EPC and revoked the patent. As to why claim 1 of auxiliary request 6 lacked clarity, the opposition division stated that it *"fails to see how the skilled person could recognize such disorders ['HER3 related' hyperproliferative diseases] encompassed in the claims when no suitable diagnostic means existed at the date of filing of the patent in suit, especially considering that the disorders claimed are "associated with" MAPK pathway/HER3 and PYK2 but the specific way in which they are associated is never clarified in the opposed patent"* (see decision under appeal, Reasons, point 10).

IV. With the statement of grounds of appeal, the appellant resubmitted the claims of auxiliary request 6 as the main request, submitted sets of claims as first to fifth auxiliary requests as well as arguments *inter alia* to the effect that the claims complied with the requirements of Article 84 EPC.

Claim 1 of the main request reads as follows:

"1. Use of an inhibitor of HER3 kinase activity for the manufacture of a medicament for the diagnosis, prevention or treatment of **a MAP kinase pathway associated hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2**, wherein the inhibitor is an anti HER3 antibody or a fragment thereof, said anti HER3 antibody or a fragment

thereof being capable of inhibiting HER3 kinase activity." [emphasis added by the board]

V. In reply to the statement of grounds of appeal, opponent 01 to opponent 05 (hereinafter "respondent I" to "respondent V", respectively, or "the respondents") filed arguments regarding *inter alia* the lack of clarity of claim 1 of all of the claim requests filed with the statement of grounds of appeal.

VI. In response to the replies of the respondents, the appellant submitted new sets of claims in the form of first to seventh auxiliary requests.

Claim 1 of the first auxiliary request is the same as claim 1 of the main request (see section IV).

Claim 1 of the second auxiliary request reads as follows:

"1. Use of an inhibitor of HER3 kinase activity for the manufacture of a medicament for the diagnosis, prevention or treatment of **a MAP kinase pathway associated hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2**, wherein the inhibitor is an anti HER3 antibody or a fragment thereof, said anti HER3 antibody or a fragment thereof being capable of inhibiting HER3 kinase activity directly phosphorylating PYK2." [emphasis added by the board]

Claim 1 of the third auxiliary request reads as follows:

"1. Use of an inhibitor of HER3 kinase activity for the manufacture of a medicament for the diagnosis,

prevention or treatment of **a MAP kinase pathway associated hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2**, wherein said hyperproliferative disease is selected from inflammatory processes, tumors and tumor invasion particularly in gliomas, and wherein the inhibitor is an anti HER3 antibody or a fragment thereof, said anti HER3 antibody or a fragment thereof being capable of inhibiting HER3 kinase activity directly phosphorylating PYK2." [emphasis added by the board]

Claim 1 of the fourth auxiliary request reads as follows:

"1. Use of an inhibitor of HER3 kinase activity for the manufacture of a medicament for the diagnosis, prevention or treatment of **a MAP kinase pathway associated hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2**, wherein said hyperproliferative disease is selected from breast cancer, acute myeloid leukemia, glioma and tumor invasion in gliomas, and wherein the inhibitor is an anti HER3 antibody or a fragment thereof, said anti HER3 antibody or a fragment thereof being capable of inhibiting HER3 kinase activity directly phosphorylating PYK2." [emphasis added by the board]

Claim 1 of the fifth auxiliary request reads as follows:

"1. Use of an inhibitor of HER3 kinase activity for the manufacture of a medicament for the diagnosis, prevention or treatment of **a MAP kinase pathway associated hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2**, wherein the inhibitor is an anti HER3 antibody or a

fragment thereof, said anti HER3 antibody or a fragment thereof being capable of inhibiting HER3 kinase activity directly phosphorylating PYK2, wherein inhibition of HER3 kinase activity directly phosphorylating PYK2 leads to an inhibition of the MAP kinase pathway." [emphasis added by the board]

Claim 1 of the sixth auxiliary request reads as follows:

"1. Use of an inhibitor of HER3 kinase activity for the manufacture of a medicament for the diagnosis, prevention or treatment of **a MAP kinase pathway associated hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2**, wherein said hyperproliferative disease is selected from inflammatory processes, tumors and tumor invasion particularly in gliomas, and wherein the inhibitor is an anti HER3 antibody or a fragment thereof, said anti HER3 antibody or a fragment thereof being capable of inhibiting HER3 kinase activity directly phosphorylating PYK2, wherein inhibition of HER3 kinase activity directly phosphorylating PYK2 leads to an inhibition of the MAP kinase pathway." [emphasis added by the board]

Claim 1 of the seventh auxiliary request reads as follows:

"1. Use of an inhibitor of HER3 kinase activity for the manufacture of a medicament for the diagnosis, prevention or treatment of **a MAP kinase pathway associated hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2**, wherein said hyperproliferative disease is selected from breast cancer, acute myeloid leukemia, glioma and

tumor invasion in gliomas, and wherein the inhibitor is an anti HER3 antibody or a fragment thereof, said anti HER3 antibody or a fragment thereof being capable of inhibiting HER3 kinase activity directly phosphorylating PYK2, wherein inhibition of HER3 kinase activity directly phosphorylating PYK2 leads to an inhibition of the MAP kinase pathway." [emphasis added by the board]

- VII. Respondent V filed arguments regarding *inter alia* the lack of clarity of claim 1 of all of the pending requests.
- VIII. The board issued a summons to oral proceedings accompanied by a communication pursuant to Article 15(1) RPBA informing the parties of its preliminary opinion on the case.
- IX. In response to the summons, the appellant filed *inter alia* arguments in favour of the admissibility of the claim requests and the clarity of the claims.
- X. Oral proceedings were held on 13 September 2018. The respondents were neither present nor represented, as announced beforehand in writing. At the end of the oral proceedings, the chair announced the board's decision.
- XI. The following documents are referred to in this decision:

D1 US 5,837,815 (1998)

D4 WO 97/35885 (1997)

D7 R.J. Fiddes et al., *Oncogene* (1998), vol. 16, pages 2803 to 2813

D30 Prescribing information of Herceptin® (2010)

D34 C. Widmann et al., *Physiological Reviews* (1999),
vol. 79, pages 143 to 180

XII. The appellant's arguments may be summarised as follows:

Main request

Admissibility into the proceedings

The opposition division had exercised its discretion correctly in admitting the main request, filed as auxiliary request 6 during the oral proceedings before them, into the proceedings.

Clarity (Article 84 EPC) - claim 1

Only those features that were not present in the claims as granted were open to objections under Article 84 EPC. Thus, the expression "*MAP kinase pathway associated*" and the feature "*HER3 kinase activity directly phosphorylating PYK2*" could be considered under Article 84 EPC.

In the patent, a new signalling pathway from HER3 to the MAP kinase was described, i.e. it was disclosed for the first time that HER3 showed kinase activity, that PYK2 could be directly phosphorylated and that said pathway could be inhibited by the inhibition of HER3 kinase. The terms "MAP kinase pathway", "HER3", and "PYK2" used in the claims in this context had a clearly defined meaning (see documents D7, D4 and D1).

The skilled person had a detailed knowledge of the well-characterised MAP kinase pathway, its components,

the involvement of the pathway in HER3 signalling and would also know that the stimulation of the MAP kinase pathway could trigger a hyperproliferative disease (see documents D7 and D34).

The term "*MAP kinase pathway associated hyperproliferative disease*" had a clearly defined meaning, i.e. it indicated that the therapy induced the inhibition of the MAP kinase pathway. The skilled person could determine whether a given disease was associated with the MAP kinase pathway or not.

In the context of the invention, HER3-PYK2 signalling was the diagnostic criterion to be applied by the skilled person. The examples of the patent clearly demonstrated HER3 kinase activity phosphorylating PYK2 and its involvement in tumor invasion, determined by biochemical methods. Based on this information, an assay could be provided for diagnosing the involvement of HER3-PYK2 signalling in a MAP kinase pathway associated hyperproliferative disease.

An example in the prior art of such a diagnostic and therapeutic strategy were hyperproliferative diseases which were associated with an overexpression of HER2. An antibody against HER2, trastuzumab (Herceptin[®]), was known and document D30 disclosed that a disorder characterised by the overexpression of HER2 could be identified by a suitable diagnostic method.

The question of delimiting of the hyperproliferative disease from other, previously known hyperproliferative diseases was not relevant to the clarity of the claim, but to the novelty and inventive step of the claimed subject-matter.

First to seventh auxiliary request

Admissibility into the appeal proceedings

The first to seventh auxiliary requests were filed in response to the arguments of the opposition division for revoking the patent and in response to the submissions by the respondents replying to the statement of grounds of appeal.

As the opposition division found the main request not to be allowable due to lack of clarity, new auxiliary requests were filed with the grounds of appeal, and modified after receiving the replies of the respondents.

The requests were a serious attempt to overcome the objections raised by the opposition division regarding Articles 123(2) and 84 EPC and should be admitted at this stage of the proceedings.

Clarity (Article 84 EPC) - claim 1

The arguments submitted for claim 1 of the main request also applied to claim 1 of the first and second auxiliary requests as the medical indication in these claims was the same.

Claim 1 of the third auxiliary request differed from claim 1 of the main request by features which were the subject of claims 5 and 6 as granted and which were thus not open to objection under Article 84 EPC. The skilled person would have known that the specific diseases recited in the claim could be associated with the MAP kinase pathway and would be able to determine if a tumour was associated with the HER3 kinase

activity. Guidance for detecting HER3 kinase activity was provided in the examples of the patent.

Claim 1 of the fourth auxiliary request differed from claim 1 of the main request in that the hyperproliferative disease was selected from breast cancer, acute myeloid leukemia, glioma and tumor invasion in gliomas as disclosed on page 7, lines 17 to 26 of the application. Breast cancer and acute myeloid leukemia would have a clear meaning to the skilled person, who would also know that these specific diseases could be associated with the MAP kinase pathway.

The fifth, sixth and seventh auxiliary requests were based on the second, third and fourth auxiliary request, respectively, and also included in claim 1 the feature "*wherein inhibition of HER3 kinase activity directly phosphorylating PYK2 leads to an inhibition of the MAP kinase pathway*".

XIII. The respondents' arguments submitted in writing may be summarised as follows:

Main request

Admissibility into the appeal proceedings

The main request, filed as auxiliary request 6 during the oral proceedings before the opposition division, addressed objections which had been raised earlier in the written proceedings. It was thus filed late in the opposition proceedings and should not have been admitted into the proceedings by the opposition division.

Clarity (Article 84 EPC) - claim 1

The purpose of Article 84 EPC is to ensure that third parties can determine with reasonable certainty what does and does not fall within the scope of the claims. Claim 1 was a medical use claim and had to allow the skilled person to determine whether a disease fell within the ambit of the claim.

It was not clear to the skilled person which disease was a "hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2" or how to differentiate such a hyperproliferative disease from a hyperproliferative disease associated with HER3 kinase activity indirectly phosphorylating PYK2. The MAP kinase pathway was just one of many possible pathways which might cause a hyperproliferative disease. Since a given hyperproliferative disease could be the result of a number of different pathways, including the MAP kinase pathway, it was not clear under what circumstances the disease could then be designated as "associated" with the MAP kinase pathway. It was not clear whether it was merely sufficient for the MAP kinase pathway to be active. A situation could arise in which the MAP kinase pathway was originally active but the hyperproliferative disease was subsequently driven by processes upstream or downstream of the MAP kinase pathway. The patent provided no guidance on these issues.

The patent provided neither teaching, e.g. in the form of an assay, to determine whether a given hyperproliferative disease was a "MAP kinase pathway associated" hyperproliferative disease, nor teaching on how to determine whether any given MAP kinase pathway associated hyperproliferative disease was "associated

with HER3 kinase activity directly phosphorylating PYK2". In particular, no assay was provided for measuring HER3 kinase activity in respect of directly phosphorylating PYK2. HER3 was believed to lack the ability to act as a kinase in its own right, and merely to allow phosphorylation of downstream targets by virtue of its ability to form a heterodimer with the HER2 protein. The HER3 kinase activity directly phosphorylating PYK2 represented a finding of the patent. Thus, common general knowledge did not provide the skilled person with a test for this functional feature either.

The patent failed to identify testable criteria for recognising which conditions fell within the functional definition of the claimed medical use (see decision T 241/95, Reasons, point 3.1.1). The skilled person would be unable to determine whether or not they were working within the "forbidden area" of the claims.

Compliance with Article 84 EPC not only requires that the individual terms of the claim are understood, but also that the claim as a whole is clear to the skilled person. In claim 1, the disease to be treated was not clearly defined (see e.g. decisions T 1048/98 and T 830/08).

The term "*MAP kinase pathway*" was not clear to the skilled person, as many signalling factors were associated with MAP kinase (see Table 1 of document D34 and the text beginning on page 156 under the heading "mammalian MAP kinase pathways").

Claim 1 was not directed toward conditions where HER3 was over-expressed and the patent did not disclose which diagnostic assay could be performed to identify a

hyperproliferative disease associated with HER 3 kinase activity directly phosphorylating PYK2. The comparison with trastuzumab, which was suitable for treating a disorder characterised by the overexpression of HER2, was thus not relevant.

The appellant's reasoning was circular in that it attempted to define the disease in terms of the means by which it could be treated.

First to seventh auxiliary requests

Admissibility into the appeal proceedings

The first to seventh auxiliary requests were presented for the first time before the board of appeal but could clearly have been presented during the proceedings before the opposition division. They should be dismissed as late-filed under Article 12(4) RPBA.

Clarity (Article 84 EPC) - claim 1

The claims lacked clarity because the patent did not disclose which diagnostic assay could be performed to identify a hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2.

The skilled person could only guess which disease was being referred to in the claims and would be unable to establish whether they were working within the "forbidden area" of the claims or not.

- XIV. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request filed with the statement of grounds of appeal

or, alternatively, of one of the first to seventh auxiliary requests, all filed with the letter dated 22 December 2015.

- XV. The respondents each requested in writing that the appeal be dismissed. Respondent III requested that none of the claim requests filed with the statement of grounds of appeal be admitted into the appeal proceedings. Respondents IV and V requested that the first to fifth auxiliary requests filed with the statement of grounds of appeal should not be admitted into the appeal proceedings. Respondent V further requested that the first to seventh auxiliary requests, all filed with the letter dated 22 December 2015, should not be admitted into the appeal proceedings.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is therefore admissible.
2. The duly summoned respondents were neither present nor represented at the oral proceedings. The board decided to continue the proceedings without the respondents in accordance with Rule 115(2) EPC and treated them as relying on their written case in accordance with Article 15(3) RPBA.

Main request

3. The main request corresponds to auxiliary request 6 considered in the decision under appeal. This request was filed during the oral proceedings and admitted into the proceedings by the opposition division.
4. Although admittance of this set of claims was contested by respondent III, there is no need to give reasons for

the admittance and substantive assessment of the appellant's main request by the board, since, for the reasons given below, this request could not be allowed.

Clarity (Article 84 EPC) - claim 1

5. The claim has been amended vis-à-vis claim 1 as granted and it is not disputed that the features "*a MAP kinase pathway associated*" and "*kinase activity directly phosphorylating PYK2*" derive from the description of the application as filed and may thus be examined for compliance with the requirements of Article 84 EPC (see also decision G 3/14, OJ EPO 2015, 102, Reasons, point 87).
6. Article 84, second sentence, EPC requires the claims to be clear, which serves the purpose of ensuring that the public is not left in any doubt as to the subject-matter covered by a claim. From this principle of legal certainty, it follows that there is a lack of clarity if a claim does not allow this distinction to be made. In this respect the board thus agrees with the finding of decision T 1811/13 of 8 November 2016 (see Reasons, point 5.1) that the definition of the "forbidden area" of a claim should be considered in relation to Article 84 EPC, and not to Article 54 EPC or Article 56 EPC as suggested by the appellant.
7. The claim is a second medical use claim which defines the condition to be treated as "*a MAP kinase pathway associated hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2*" (see section IV). Thus, the condition to be treated is not defined in terms of a specifically defined disease, but in functional terms with two requirements, namely that the hyperproliferative disorder is associated with

(i) the MAP kinase pathway and (ii) HER3 kinase activity directly phosphorylating PYK2. The question is thus whether or not the skilled person would be in a position to determine without any doubt which disease or group of diseases falls within this functional definition and which do not.

8. As regards requirement (i), the board notes that the appellant does not dispute that the MAP kinase pathway is one of many possible pathways which may cause a hyperproliferative disease. Therefore, in order to determine whether or not a hyperproliferative disease is such a disease as cited in the claim the skilled person needs to know or be taught under what circumstances the hyperproliferative disease is to be considered "associated" with the MAP kinase pathway or not.
9. The board notes that the term "associated" itself provides no guidance in this respect. Also the specification of the patent does not provide any instructions regarding circumstances in which a particular hyperproliferative disease is to be considered "associated" with the MAP kinase pathway or how the skilled person can determine whether or not a particular hyperproliferative disease is "associated" with the MAP kinase pathway. It is thus uncertain whether, for example, a hyperproliferative disease in which the MAP kinase pathway was active but where the hyperproliferative disease is then driven by processes outside the MAP kinase pathway, is to be considered "associated" with the MAP kinase pathway or not.
10. Furthermore, a diagnostic assay which would allow a skilled person to discriminate hyperproliferative diseases that are "associated" with the MAP kinase

pathway from those that are not is not disclosed in the patent either.

11. In this context, the appellant's argument that the skilled person would have a detailed knowledge of the well-characterised MAP kinase pathway is not persuasive. It ignores in fact that this knowledge does not help the skilled person to understand which hyperproliferative diseases are to be considered "associated" with the MAP kinase signalling pathway, and which are not.
12. Also the appellant's further argument that the term "MAP kinase pathway associated hyperproliferative disease" has a clear meaning in that it indicates that "the therapy includes the inhibition of the MAP kinase pathway", fails in the opinion of the board as it amounts to an attempt to define the hyperproliferative diseases in terms of the means by which they can be treated, i.e. uses a circular definition.
13. Regarding requirement (ii) (see point 7), and similar to the situation for the first requirement, neither the claim nor the specification of the patent provide any guidance for the skilled person as to which assay can be used to determine whether any given MAP kinase pathway associated hyperproliferative disease is also associated with HER3 "kinase activity directly phosphorylating PYK2".
14. The board has furthermore not seen any evidence that the skilled person, as a matter of common general knowledge, would know which hyperproliferative diseases are "associated" with the MAP kinase pathway and associated with HER3 "kinase activity directly phosphorylating PYK2" or any assays that could be used

to verify this. Indeed, the signaling pathway leading from HER3 kinase activity to the MAP kinase pathway was not known in the prior art and it would appear that it is in fact the patent which is the first disclosure of HER3 showing kinase activity and that native HER3 protein is capable of directly phosphorylating PYK2 and thereby stimulating the mitogenic activity mediated by the MAP kinase pathway (see paragraph [0024] of the patent).

15. The board notes that in the relevant example of the patent, HER2 and HER3 were over-expressed in HEK293 fibroblasts and stimulated with heregulin. Receptor-immunocomplexes were then subjected to *in vitro* kinase assays using a GST-fusion protein of the C-terminal region of PYK2 (GST-PYK2-CT) as substrate (see paragraph [0052], Figure 4c). However, in the board's opinion, the biochemical *in vitro* kinase assays used in the patent for determining that HER3 directly phosphorylates PYK2 are manifestly unsuitable for use as diagnostic assays for measuring HER3 kinase activity directly phosphorylating PYK2, in e.g. a tissue sample where PYK2 is subject to phosphorylation by several kinases - not only HER3. The appellant has also not argued otherwise. Moreover, the patent also fails to provide instructions on how to design an assay that would allow the skilled person to discriminate, in such a tissue sample, between HER3 directly phosphorylating PYK2 from HER3 indirectly phosphorylating PYK2 and any other kinase phosphorylating PYK2, e.g. HER2 phosphorylating PYK2.
16. Therefore, as the patent provides no guidance to the skilled person to specifically assay for HER3 directly phosphorylating PYK2, the appellant's arguments, which rely on "HER3-PYK2 signalling" as the diagnostic

criterion to be applied by the skilled person for determining whether or not a hyperproliferative disease was a MAP kinase pathway associated hyperproliferative disease, must also fail.

17. The board concludes from the above that the use of the term "associated" in the functional definition of the hyperproliferative diseases in relation to the MAP kinase pathway and the lack of any guidance in the form of experimental tests or any testable criteria, in the patent documents and the common general knowledge, which would allow the skilled person to recognise which conditions fall within the functional definition and accordingly within the scope of the claim, leads to a lack of clarity of the claim. The board notes that this finding is in line with the established jurisprudence of the Boards of Appeal (see decision T 241/95, OJ EPO 2001, 103, Reasons, point 3.1.1).
18. The board also notes that the board's finding that the lack of clarity of the claim arises from the use of the term "associated" and the lack of guidance regarding an assay which makes it possible to determine unambiguously whether or not a hyperproliferative disease falls within the functional definition of the claim or not, would also apply when taking into account the appellant's argument that the terms "MAP kinase pathway", "HER3" and "PYK2" had a clearly defined meaning for the skilled person.
19. Consequently, the amendments in claim 1 of the main request result in a lack of clarity (Article 84 EPC).

First to seventh auxiliary requests

Admissibility into the appeal proceedings

20. The first to seventh auxiliary requests were filed in response to the respondents' replies to the appellant's statement of grounds of appeal (see section VI). The appellant claimed that filing these requests at that point in the proceedings was a serious attempt to overcome the objections raised under Articles 123(2) and 84 EPC.
21. However, the board notes that the objections to added subject-matter (Article 100(c) EPC) had been in the proceedings since the beginning of the opposition proceedings (see section II). Accordingly, in the board's opinion, the appropriate time to address these objections would have been when replying to the notices of opposition or, at the latest, when responding to the communication of the opposition division (see section II).
22. Furthermore, the main request was filed as auxiliary request 6 in the oral proceedings before the opposition division, after all higher-ranking claim requests had been found not to meet the requirements of Article 100(c) or 123(2) EPC. The opposition division decided that claim 1 of auxiliary request 6 lacked clarity. In the board's opinion, however, this decision of the opposition division cannot justify filing even more claim requests for the purpose of addressing objections - here added subject-matter - which had been in the proceedings from the beginning.
23. The board concludes that the first to seventh auxiliary requests could thus have been presented earlier and, therefore, the board has the discretion not to admit

these requests into the appeal proceedings for this reason alone (Article 12(4) RPBA).

24. The first to seventh auxiliary requests comprise in their respective claim 1 the same functional definition of the disease - "a MAP kinase pathway associated hyperproliferative disease associated with HER3 kinase activity directly phosphorylating PYK2" - as in claim 1 of the main request (see sections IV and VI and point 7 above). Therefore, the considerations regarding lack of clarity given above for claim 1 of the main request apply equally to claim 1 of the first to seventh auxiliary requests.

25. This assessment is not changed by the fact that in claim 1 of the third and sixth auxiliary request, the hyperproliferative diseases has been further specified to be selected "from inflammatory processes, tumors and tumor invasion particularly in gliomas", while in claim 1 of the fourth and seventh auxiliary requests, the hyperproliferative diseases have been further specified to be selected "from breast cancer, acute myeloid leukemia, glioma and tumor invasion in gliomas", because the selected hyperproliferative diseases are further limited by the preceding unclear functional definition. Indeed, the inflammatory process still has to be a MAP kinase pathway "associated" inflammatory process and the breast cancer still has to be a MAP kinase pathway "associated" breast cancer.

26. Accordingly, for the same reasons as for claim 1 of the main request, claim 1 of the first to seventh auxiliary requests does not comply with the requirements of Article 84 EPC. Thus, the first to seventh auxiliary requests do not overcome the issue of lack of clarity and, for this reason alone, are clearly not allowable.

The admission of said requests into the appeal proceedings would thus be contrary to the need for procedural economy.

27. Accordingly, the board, exercising its discretion pursuant to Article 12(4) RPBA, decided not to admit the first to seventh auxiliary requests into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



S. Lichtenvort

B. Claes

Decision electronically authenticated