

**Internal distribution code:**

- (A) [ - ] Publication in OJ
- (B) [ - ] To Chairmen and Members
- (C) [ - ] To Chairmen
- (D) [ X ] No distribution

**Datasheet for the decision  
of 10 July 2018**

**Case Number:** T 1389/13 - 3.3.04

**Application Number:** 06706064.0

**Publication Number:** 1856153

**IPC:** C07K16/18, A61K39/395,  
A61P35/00, A61P35/04,  
A61P29/00, A61P1/16, A61K38/08,  
A61K38/10, A61P37/00,  
A61K39/00, C07K14/47

**Language of the proceedings:** EN

**Title of invention:**  
YKL-40 monoclonal antibodies

**Patent Proprietors:**  
BIO-Y A/S  
Regents of the University of California

**Opponent:**  
Bayer Pharma Aktiengesellschaft

**Headword:**  
YKL-40 monoclonal antibodies/BIO-Y

**Relevant legal provisions:**

EPC Art. 83, 104, 116(1), 123(3)

EPC R. 115(2)

RPBA Art. 13(1), 15(1), 15(3), 16, 17

**Keyword:**

Admissibility of appeal (yes)

Main request, AR1-6 - sufficiency of disclosure (no)

AR7,9 - admission into proceedings (no)

AR8 - extended scope (yes)

Apportionment of costs (no)

**Decisions cited:**

T 2285/09

**Catchword:**

-



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0  
Fax +49 (0)89 2399-4465

Case Number: T 1389/13 - 3.3.04

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.04**  
**of 10 July 2018**

**Appellant I:** BIO-Y A/S  
(Patent Proprietors) Strandgade 95  
3000 Helsingør (DK)

Regents of the University of California  
1111 Franklin Street, 12th Floor  
Oakland, CA 94607 (US)

**Representative:** Høiberg P/S  
Adelgade 12  
1304 Copenhagen K (DK)

**Appellant II:** Bayer Pharma Aktiengesellschaft  
(Opponent) Müllerstrasse 178  
13353 Berlin (DE)

**Representative:** BIP Patents  
C/o Bayer Intellectual Property GmbH  
Creative Campus Monheim  
Alfred-Nobel-Straße 10  
40789 Monheim (DE)

**Decision under appeal:** **Interlocutory decision of the Opposition**  
**Division of the European Patent Office posted on**  
**8 April 2013 concerning maintenance of the**  
**European Patent No. 1856153 in amended form**

**Composition of the Board:**

**Chairwoman**            G. Alt  
**Members:**             B. Claes  
                             M. Blasi

## Summary of Facts and Submissions

- I. These appeal proceedings relate to European patent No. 1 856 153. The title of the patent is "*YKL-40 monoclonal antibodies*".

Claim 1 of the patent as granted read:

"1. An antibody, antigen binding fragment or recombinant protein thereof, which is specific for human YKL-40 (SEQ ID NO: 1), said antibody, binding fragment or recombinant protein thereof capable of inhibiting growth of a cell upon binding to an epitope on YKL-40, wherein the cell is an YKL-40 expressing cancer cell."

- II. Both the patent proprietor and the opponent filed appeals against the interlocutory decision of the opposition division holding that the patent in amended form on the basis of a third auxiliary request complied with the requirements of the EPC. The opposition division had decided in relation to claim 1 of the patent as granted (main request), that it did not relate to added subject-matter (Article 123(2) EPC, Article 100(c) EPC), but that the patent did not sufficiently disclose the invention as claimed (Article 83 EPC, Article 100(b) EPC).

Claim 1 of the third auxiliary request was identical to claim 1 as granted but for the insertion of the wording "wherein the cell is selected from the group consisting of U87, MG63 and U2OS, and wherein the antibody is a monoclonal antibody" at the end of the claim.

- III. With their statement of grounds of appeal, the patent proprietor (hereinafter "appellant I") requested the

board to set aside the decision under appeal and maintain the patent as granted (main request) or, alternatively, to maintain the patent in amended form based on the sets of claims of one of newly submitted first to fourth auxiliary requests, in which the third auxiliary request was identical to the third auxiliary request considered by the opposition division. They submitted, *inter alia*, arguments in relation to sufficiency of disclosure and two new documents.

- IV. With its statement of grounds of appeal, the opponent (hereinafter "appellant II") requested the board to set aside the decision under appeal and to revoke the patent. It therefore submitted supporting arguments in relation to the provisions under Articles 56, 83, 84 and 123(2) EPC. The submissions in relation to sufficiency of disclosure included the argument that the patent did not enable the skilled person to arrive at an anti-YKL-40 antibody which inhibits growth of a cell as it did not provide an assay assessing this functional feature. Appellant II also submitted a new document.
- V. With its reply to the statement of grounds of appeal of appellant II, appellant I requested the board to reject appellant II's appeal as inadmissible and to admit not the document newly filed by appellant II into the appeal proceedings. Arguments were submitted in reply to the statement of grounds of appeal of appellant II including, *inter alia*, the submission that for the skilled person the terms "inhibiting growth of a cell" and "having growth repressive effect" were interchangeable and that the patent in examples 1 and 2 provided methods for assessing inhibition of cancer cell growth.

Appellant I furthermore replaced the new first, second and third auxiliary requests as earlier filed - which included obvious errors in certain claims other than claim 1 - with sets of claims of new, corrected first, second and fourth auxiliary requests. Claim 1 of the first and second auxiliary requests was identical to claim 1 as granted but for the insertion of the wording "wherein the antibody is a monoclonal antibody" at the end of the claim. Claim 1 of the fourth auxiliary requests was identical to claim 1 of the third auxiliary request (see section II).

- VI. In its reply to the statement of grounds of appeal of appellant I, appellant II submitted arguments to the effect that the main request failed to meet the requirements of *inter alia* sufficiency of disclosure. The arguments were essentially based on the same facts as submitted with the statement of grounds in relation to the third auxiliary request (see section IV). This finding also applied to the first to fourth auxiliary request. Appellant II filed a further new document.
- VII. By letter dated 31 January 2014, appellant II requested a correction of the indication on page 2 of the statement of grounds of appeal from "Bayer Schering Pharma AG" to "Bayer Pharma AG", accompanied by a notarial certificate.
- VIII. In a communication dated 10 December 2014 setting a two-month time limit for comments, the board indicated its preliminary opinion that there had never been any doubt as to appellant II being Bayer Pharma Aktiengesellschaft and that the requested correction appeared allowable. No reply was received from the parties within the set time limit.

- IX. In the further course of the appeal proceedings, a transfer of the patent was recorded in the European Patent Register, and the Regents of the University of California were registered as co-proprietors of the patent.
- X. In a letter dated 9 May 2018 filed in response to the summons to oral proceedings, appellant I requested the board not to admit the further new documents filed by appellant II into the appeal proceedings and submitted sets of claims of three further auxiliary requests as well as arguments in response to the reply of appellant II to their appeal. Claim 1 of the fifth and sixth auxiliary requests were identical to claim 1 of the third auxiliary request (see section II).

Claim 1 of the seventh auxiliary request read:

"1. An antibody, antigen binding fragment or recombinant protein thereof, which is specific for human YKL-40 (SEQ ID NO: 1), wherein said antibody, binding fragment or recombinant protein thereof is capable of specifically recognizing and binding to an epitope comprising residues 210-220 of SEQ ID NO: 1."

- XI. On 20 June 2018, appellant II informed the board that it would not attend the oral proceedings.
- XII. Via a registered letter dated 26 June 2018, the board informed appellant I of this information.
- XIII. On 4 July 2018, appellant I contacted the registry of the board by telephone and asked whether the board would grant one of the requests on file; this to avoid being present at the hearing on 10 July 2018. In response to the enquiry, appellant I was send a copy of



the information of 20 June 2018 by facsimile on the same day and informed by telephone on 5 July 2018 by the registrar that the board's "current work schedule does not allow the board at present to come to an early opinion on the case as requested".

XIV. During the oral proceedings, from which appellant II was absent, appellant I submitted sets of claims of a new 7th and 9th auxiliary request. Claim 1 of the new 7th auxiliary request (originally labelled "8th auxiliary request") was identical to claim 1 as granted but for the insertion of the wording "wherein the inhibition of growth is measured by MTT assay" at the end of the claim. The earlier filed seventh auxiliary request (see section X) was renumbered as the 8th auxiliary request.

Claim 1 of the 9th auxiliary request read:

"1. An antibody, ~~antigen binding fragment or recombinant protein thereof~~, which is specific for human YKL-40 (SEQ ID NO: 1), wherein said antibody, ~~binding fragment or recombinant protein thereof~~ is capable of specifically recognizing and binding to an epitope comprising residues 210-220 of SEQ ID NO: 1." (strike-through by the board indicates changes over claim 1 of the 8th auxiliary request)

Appellant I requested that the board ordered a different apportionment of costs pursuant to Article 16 RPBA.

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

XV. The arguments of appellant I, in so far as they are relevant for the present decision, can be summarised as follows:

*Admissibility of the appeal of the opponent  
(Article 108 EPC)*

The appeal of the opponent was inadmissible because no statement of grounds of appeal was filed on behalf of Bayer Pharma Aktiengesellschaft. A statement of grounds of appeal was filed by a different legal person as shown on the second page of the letter on which "Appellant/Opponent: Bayer Schering Pharma AG" was indicated. Hence, no statement of grounds of the opponent was filed on time.

*Main request - claim 1  
Sufficiency of disclosure (Article 100(b) EPC)*

In the context of cell biology in general and the patent in particular, the skilled person understood that the terms "inhibiting cell growth" (as used in the claim) and "having growth repressive effect" (as used in example 1) were interchangeable, and this general understanding was also reflected in the patent.

In the art, the term "growth of a cell" referred to an increase in the number of cells in a population, and "inhibiting growth of a cell" concerned reduced numbers of cells as compared to the start. It was clear from the first sentence in paragraph [0204] of the patent that the "repressive effect" of an antibody on the growth of cells was, in the patent, "reflected by a reduced number of cells in treated wells (with antibody) compared to control wells".

The patent provided two specific examples of methods useful for assessing inhibition of cancer cell growth. The *in vitro* MTT assay disclosed in example 1 (see paragraphs [0202] to [0206]) was stated to allow to distinguish between living and dead cells in culture. The assay thus allowed determining the number of cells in a population and hence also determining the inhibition of growth of a cancer cell which meant "*inhibiting an increase in the number of cells in a population*". Example 2 disclosed an *in vivo* method for determining inhibition of cancer cell growth by anti-human YKL-40 monoclonal antibodies by which tumour size was daily measured.

Paragraph [0206] of the description of the patent did not lead to the claimed invention being insufficiently disclosed. The skilled person reading the patent with a mind willing to understand had no problem in carrying out the invention. It would not have incited the skilled person - upon reading the patent - to draw an artificial distinction between the terms "inhibiting cell growth" and "having growth repressive effect".

The last sentence of paragraph [0206] of the patent was ambiguous and unclear. Whereas "apoptosis" was different from "inhibition of growth", both terms were not the same; however, they were not mutually excluding each other.

*First to sixth auxiliary request - claim 1  
Sufficiency of disclosure (Article 83 EPC)*

If the board came to the conclusion that the patent did not sufficiently disclose the invention as defined in claim 1 of the main request, then this applied equally to the invention defined in these claims.

*7th auxiliary requests - admission into the proceedings*

The request was filed only at this point of the oral proceedings as it was a reaction to the opinion of the board on the issue of sufficiency of disclosure, which had come as a complete surprise because the board had not issued a communication informing of its preliminary opinion in the written proceedings. Accordingly, the appellant had a right to react to this new development.

The insertion of the feature in claim 1 specifying which assay was used to measure of the inhibition of growth remedied the lack of sufficiency of disclosure found for the invention as defined in claim 1 of the main request. Although a theoretical possibility may exist that the MTT assay measured apoptosis, what was measured in reality was the cell growth inhibition as required by the claim.

The set of claims of the 7th auxiliary request should therefore be admitted into the proceedings.

*8th auxiliary request - claim 1 - Article 123(3) EPC*

Paragraph [0214] of the patent stated that antibody 201F9 recognised the epitope referred to in claim 1, and the last sentence disclosed that "*[o]ccupation of these residues by the antibody inhibits biological activity of YKL-40 and therefore leads to the inhibition of growth of cancer cells*". Any antibody binding to the same epitope would react in the same way.

Therefore, although claim 1 no longer explicitly stated that the antibody was "capable of inhibiting growth of

a cell upon binding to an epitope on YKL-40" (see claim 1 of the main request), it now specified that the antibody was "capable of specifically recognizing and binding to an epitope comprising residues 210-229 of SEQ ID NO: 1" leaving it beyond doubt that the so-defined antibody was capable of inhibiting growth of a cell. Accordingly, claim 1 complied with the requirements of Article 123(3) EPC.

*9th auxiliary request - admission into the proceedings*

This request was based on the 8th auxiliary request, in which the claims were restricted to antibodies. The board's concerns under Article 123(3) could therefore no longer exist.

*Request on apportionment of costs (Article 16 RPBA)*

Appellant II could have informed appellant I of their non-attendance earlier. Moreover, appellant II's letter was forwarded by the EPO with a substantial delay and, as it was sent by ordinary mail, was received even later. Only afterwards and very shortly before the oral proceedings could appellant I contact the board to find out whether the oral proceedings would take place, but then the board's working schedule did not allow the board to give an indication on the allowability of the requests on file.

The EPO had not provided appellant I with a written communication setting out the board's preliminary opinion on the issues of the case. Appellant I was a small company with limited financial resources. It would therefore have preferred for the case to be concluded without having to appear at oral proceedings.

The fact that the board had not issued a preliminary opinion had prevented appellant I from maintaining cost efficiency.

Had a communication been issued, then appellant I would, for example, have known that the issue of sufficiency of disclosure in relation to the MTT assay was considered so crucial.

It was unfair that appellant I was heard on requests without knowing the opinion of the board, because there was no time to prepare and react to the new arguments. Admittedly, all new arguments were on late-filed requests.

XVI. The arguments submitted in writing by appellant II, in so far as they are relevant for the present decision, can be summarised as follows:

*Admissibility of the appeal of the opponent  
(Article 108 EPC)*

The opponent (appellant II) had lodged an admissible appeal. The notice of appeal and the statement of grounds of appeal were both filed on behalf of Bayer Pharma Aktiengesellschaft, who, as party to the opposition proceedings, was entitled to appeal. The statement of grounds of appeal referred to the correct number of the appeal case and opposed patent, the name of the patent proprietor was correct, and specific reference was made to the notice of appeal filed on 13 June 2013. The indication of "Bayer Schering Pharma AG" on the second page was an obvious error. By mistake, the wrong name - in fact the opponent's former name "Bayer Schering Pharma AG" - had been used. As confirmed by the submitted evidence, the name change

had occurred in 2011, i.e. before opposition was filed. Accordingly, a correction of this obvious error according to Rule 139 EPC was allowable.

*Main request - claim 1*

*Sufficiency of disclosure (Article 100(b) EPC)*

Claim 1 was for a compound such as an antibody which was "*capable of inhibiting growth of a cell upon binding to an epitope on YKL-40*".

Throughout the description, the patent differentiated between possible modes of action of the antibodies of the invention, such as "inhibition of growth" and "growth repressive effect" (see in particular paragraphs [001], [0113] and [0114]).

The patent was, however, silent on how to assess the functional feature "*capable of inhibiting growth of a cell upon binding to an epitope on YKL-40*".

Whereas in paragraphs [0202] to [0206] the patent disclosed the so-called MTT assay - reportedly allowing to distinguish between living and dead cells in a culture - such assay neither provided any data on cell growth nor gave any information on the inhibition of the cell growth. Indeed, the patent itself disclosed in example 1 that using such MTT assay could not distinguish whether the observed effect was due to inhibition of cell growth and survival or induction of apoptosis, or due to both (see paragraph [0206] where, in particular, the obtained experimental results of example 1 were stated as demonstrating a "growth repressive effect" for monoclonal antibodies 116F9 and 201F9 and that this (growth repressive) "*effect may be*

*due to inhibition of cell growth and survival or induction of apoptosis, or due to both").*

The patent accordingly failed to provide a single analytical measuring method allowing the person skilled in the art to carry out the invention as claimed, i.e. to arrive at an anti-YKL-40 antibody which inhibits growth of a cell.

*First to fourth auxiliary requests - claim 1  
Sufficiency of disclosure (Article 83 EPC)*

The arguments submitted in relation to sufficiency of disclosure of the main request applied *mutatis mutandis* to the patent in relation to the invention defined in claim 1 of the first to fourth auxiliary requests.

XVII. The final requests of the parties were:

Appellant I requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, that it be maintained in amended form on the basis of the sets of claims of the first or second auxiliary request as filed on 2 January 2014, further alternatively, that appellant II's appeal be dismissed, i.e. the patent be maintained as considered allowable by the opposition division or, further alternatively, that the patent be maintained in amended form on the basis of the sets of claims of the fourth to sixth auxiliary requests, of which the fourth auxiliary request as filed with letter dated 2 January 2014 and the fifth and sixth auxiliary requests as filed with letter dated 9 May 2018 or, further alternatively, on the basis of the sets of claims of a 7th auxiliary request filed during the oral proceedings and labelled "8th auxiliary request", or of



the 8th auxiliary request filed with letter dated 9 May 2018 as "seventh auxiliary request", or of a 9th auxiliary request filed during the oral proceedings. Furthermore, it was requested that a different apportionment of costs pursuant to Article 16 RPBA be ordered.

Appellant II requested the board in writing to set aside the decision under appeal and to revoke the patent.

### **Reasons for the Decision**

1. The appeals of both appellants are admissible. Each of them complies with the requirements pursuant to Articles 106 to 108 and Rule 99 EPC.
2. Admissibility of the opponent's (appellant II's) appeal had been contested by appellant I based on the argument that no statement of grounds of appeal pursuant to Article 108, third sentence, EPC had been filed by the opponent, and the statement of grounds of appeal in question had been filed by a different legal person.
3. Notice of appeal dated 13 June 2013 was duly filed by the opponent Bayer Pharma Aktiengesellschaft and the appeal fee was duly paid. The notice of appeal comprises, in addition to the details required pursuant to Rule 99(1) EPC, the party's internal reference number.
4. The statement of grounds of appeal that was subsequently received was signed by the same representative who had signed the notice of appeal and the notice of opposition. The appeal case number, the number of the patent in suit, the name of the (then

sole) patent proprietor and the internal reference number mentioned in the document corresponded to the indications provided in the notice of appeal. Explicit reference was made to the "appeal of opponent filed on 13 June 2013".

5. The fact that "Bayer Schering Pharma AG", the opponent's former name, as proven by the documentary evidence, was indicated on the second page of the statement of grounds of appeal as the legal person on behalf of which the document was submitted, points to the fact that it was indeed on behalf of the opponent and not on behalf of a third party.
6. Also, considering that there is no indication on file that a legal person called "Bayer Schering Pharma AG" existed at the point in time when the statement of grounds was filed, the mentioning of "Bayer Schering Pharma AG" in the statement of grounds of appeal is an obvious error and it is evident that it should read "Bayer Pharma AG" (or "Bayer Pharma Aktiengesellschaft").
7. Thus, the board has no doubt that the statement of grounds of appeal in question was indeed filed on behalf of the opponent, i.e. the party referred to as appellant II in these appeal proceedings.
8. Furthermore, there is no doubt, and this has not been contested, that the four-month time limit under Article 108, third sentence, EPC has been met.
9. Accordingly, appellant II has duly submitted a statement of grounds of appeal, and its appeal is thus admissible.

10. Appellant II was duly summoned but did not attend the oral proceedings, in accordance with its announcement to the board on 20 June 2018. The oral proceedings took place as scheduled in accordance with Article 116(1) EPC, first half-sentence, and Rule 115(2) EPC. Appellant II was treated as relying on their written case in accordance with Article 15(3) RPBA.

*Main request - claim 1*

*Sufficiency of disclosure (Article 100(b) EPC)*

11. The invention defined in the claim is an antibody, antigen binding fragment or recombinant protein thereof, which is specific for human YKL-40 and which is "capable of inhibiting growth of a cell upon binding to an epitope on YKL-40, wherein the cell is an YKL-40 expressing cancer cell" (emphasis added by the board).
12. Both examples 1 and 2 relate according to their title to the inhibition of cancer cell growth by anti-human YKL-40 monoclonal antibodies, the former *in vitro* and the latter *in vivo*.
13. The *in vitro* experiments of example 1 relate to various YKL-40 expressing cancer cell lines which are treated with various antibodies specific for human YKL-40. The results of the experiments are determined by the so-called MTT assay - which is described in paragraphs [0202] and [0203] - and are summarised in paragraphs [0204] to [0206] and Figures 1 and 2. The paragraphs in the description read in particular:

"[0202] *MTT-assay (allows to distinguish between living and dead cells in the culture) was performed according to Mossmann T. J Immunol Methods 65:55-63, 1983.*

[0203] 40  $\mu$ l MTT was added to each well (2 mg/ml stock solution) and the plates were incubated for 1 hour at 37°C in a normoxic incubator. Afterwards the media was discarded and 100  $\mu$ l DMSO added to each well. Plates were shaken for 10 sec and the OD (optical density) values were read at 570 nm (with the background correction on 690 nm). Results are given as an average [sic] of OD in 6 wells +/- standard deviation [sic].

[0204] As it can be seen from Figure 1 monoclonal antibodies (MAb) 116F9 and 201 F9 have a repressive effect on growth of U87 glioblastoma cells reflected by a reduced number of cells in treated wells (with antibody) compared to control wells (without antibody named "Kontrol" in Figure 1 and "Negative" in Figure 2) after 72 hours of treatment independently of the presence FCS in the culture media. Monoclonal Ab 115F9 and polyclonal Ab R667 (not shown) did not inhibit the growth of tested cancer cells. MAb116F9 was further tested in cultures of two human osteosarcoma cell lines MG63 and U2OS and one human malignant melanoma cell line SK-MEL-28.

[0205] The results shown in Figure 2 demonstrate that MAb 116F9 has a growth repressive effect in both osteosarcoma cells, but not in melanoma SK-MEL-28 cells. The two tested osteosarcoma cell lines are characterized by a high expression level of YKL-40, whereas SK-MEL-28 cells line has a very low expression level, if any.

[0206] These results demonstrate that monoclonal antibodies against YKL-40 (MAb 116F9 and 201 F9) have the growth repressive effect in YKL-40 expressing cancer cells. The effect may be due to inhibition of

cell growth and survival or induction of apoptosis, or due to both." (emphasis added by the board)

14. The board emphasises that paragraph [0206] of the description explicitly states that the results obtained with the MTT assay demonstrate a growth repressive effect on cancer cells, which effect may be due to inhibition of cell growth and survival or induction of apoptosis, or due to both.
15. The board thus concludes on the basis of evidence from the patent itself, that the MTT assay disclosed in the patent in suit is, as such, not suitable to distinguish at least between cancer cell growth repressive effects due to the inhibition of the growth of cells (as required for the invention defined in claim 1) or due to induction of apoptosis, i.e. the induction of cell death.
16. Appellant I argued that in the context of cell biology in general and the patent in particular, the skilled person considered the terms "inhibiting cell growth" (as used in the claim) and "having growth repressive effect" (as used in example 1) as interchangeable.
17. In support of its argument, appellant I referred in particular to the title of examples 1 and 2 of the patent in suit in which it was explicitly stated that these were related to the "inhibition of cancer cell growth" (see point 12 above). They further referred to the first sentence in paragraph [0204] of the patent (see point 13 above), which stated that the "*repressive effect on growth*" of cancer cells of an antibody in the patent was "*reflected by a reduced number of cells in treated wells (with antibody) compared to control*

wells". Since the term "growth of a cell" referred to an increase in the number of cells in a population and "inhibiting growth of a cell" meant reduced numbers of cells as compared to the start, the paragraph [0204] reflected the general understanding by the skilled person of the equivalence of the terminologies.

18. Appellant I furthermore submitted that, in view of the general understanding of the equivalence of the meaning of the terms "inhibiting cell growth" and "having growth repressive effect", the last sentence of paragraph [0206] of the patent may be ambiguous and unclear. Whereas "apoptosis" was different from "inhibition of growth", i.e. both terms did not describe the same situation, they were however not mutually excluding each other, i.e. inhibition of growth could be due to apoptosis and apoptosis could lead to an inhibition of growth. However, given the general understanding of the skilled person and the remainder of the teaching in the patent, the passage would not have incited the skilled person upon reading the patent with a mind willing to understand to draw an artificial distinction between the terms "inhibiting cell growth" and "having growth repressive effect". The MTT assay was therefore perfectly suitable for identifying the compounds as defined by the functional feature in the claim.
  
19. The board notes, however, that a number of passages throughout the description of the patent in suit emphasise and distinguish different possible biological activities of the compounds of the invention, including the inhibition of growth of cells (which is the functional feature comprised in the claim), induction of apoptosis of cells, and a "growth repressive effect".

Indeed, paragraph [0001] reads:

*"The present invention relates to monoclonal anti-human YKL-40 antibodies, which are capable to inhibit the growth and/or inducing apoptosis of cells, in particular cancer cells, pharmaceutical compositions comprising said antibodies and uses said antibodies and/or pharmaceutical compositions for treatment of a disease wherein inhibition of cell growth, cell differentiation, remodelling of extracellular matrix, metastasis and/or induction of cell death due to apoptosis is a prerequisite for successful curing." (emphasis added by the board);*

paragraph [0113] reads:

*"According to the invention antibodies 115F9, 116F9 and 201F9 are capable of binding to an epitope as defined above and thereby inhibiting the function of YKL-40 in connection with cell growth and survival by inhibiting at least one biological activity of YKL-40 protein described herein." (emphasis added by the board); and*

paragraph [0114] reads, under the heading "Functionally active antibody":

*"Thus, the present invention relates to an antibody, an antigen binding fragment, or recombinant protein thereof, which is capable of recognising an epitope [...] said antibody, antigen binding fragment or recombinant protein being capable of modulating at least one biological activity of human YKL-40 or an YKL-40 functional homolog, or a functional fragment thereof said activity being associated with i) cell growth ii) cell survival, iii) cell differentiation iv) extracellular matrix remodeling, v) development of*

*liver fibrosis, vi) development of tissue fibrosis, vii) development of organ fibrosis, viii) development of angiogenesis, ix) development of rheumatoid arthritis, x) development of inflammation, and/or xi) development of metastasis."* (emphasis added by the board)

20. Thus, on the basis of the patent, the board cannot concur with appellant I that the general understanding of the meaning of the terms "inhibiting cell growth" and "having growth repressive effect" was that they were equivalent and that this would be derivable from the patent. The board also cannot concur that a distinction between the meaning of the terms "inhibiting cell growth" and "having growth repressive effect" is artificial.
21. Therefore, the board is not persuaded by appellant I's arguments that the MTT assay is suitable for identifying the compounds as defined by the functional feature in the claim.
22. Appellant I has further argued that the patent in suit discloses besides the MTT assay, another method for measuring the growth of cancer cells, namely the *in vivo* method described in example 2 of the patent relying on the visual measurement of the tumour size in the experimental mice treated with antibodies of the invention.
23. However, the board considers, and the contrary has not been argued by appellant I, that this method suffers from the same drawback as the MTT assay, as here a growth repressive effect on the numbers of cells is determined in a way - size of the tumour - which fails



to distinguish between inhibition of the growth of cells and the induction of apoptosis.

24. Finally, the board notes that appellant I has not argued that the skilled person was aware of any method which was capable of distinguishing between inhibition of the growth of cells and induction of apoptosis either.
25. Accordingly, the board concludes that the patent in suit does not provide the skilled person with suitable methods for obtaining the compounds of the claim, i.e. such compounds which are capable of inhibiting growth of a cell. The patent therefore does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

*First to sixth auxiliary requests - claim 1  
Sufficiency of disclosure (Article 83 EPC)*

26. Claim 1 of each of these requests, like claim 1 of the main request, requires the claimed compounds to be "capable of inhibiting growth of a cell upon binding to an epitope on YKL-40".
27. Appellant I concurred with the board that if the patent was found to not sufficiently disclose the invention as defined in claim 1 of the main request, then this applied *mutatis mutandis* to the invention defined in these claims.

*7th auxiliary request - admission into the proceedings*

28. Claim 1 is identical to claim 1 as granted but for the insertion of the wording "wherein the inhibition of

growth is measured by MTT assay" at the end of the claim.

29. Pursuant to Article 13(1) RPBA, an amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion.
30. The request was filed during the oral proceedings after the board had announced its opinion that, in relation to the invention as defined in claim 1 of the main request and of the first to sixth auxiliary requests, the patent lacked sufficiency of disclosure.
31. Appellant I argued that this negative opinion had come as a complete surprise because the board had not issued a communication informing the parties of its preliminary opinion in the written proceedings. Moreover, the insertion of the specific assay used to measure the inhibition of growth in claim 1 remedied the lack of sufficiency of disclosure of the invention as defined in claim 1 of the main request. The set of claims of this request should therefore be admitted into the proceedings.
32. The board notes that the line of argument that the MTT assay was not suitable to determine whether any of the compounds referred to in the claims was capable of inhibiting growth upon binding to an epitope on YKL-40 had been on file since appellant II had submitted it with its statement of grounds of appeal in relation to the amended version of the patent considered allowable by the opposition division. The line of argument had again been presented in relation to appellant I's main request and auxiliary requests then on file in the reply of appellant II to the appeal of appellant I (see

section VI). Appellant I, being aware of this line of argument, could thus have anticipated that one of the possible outcomes of the appeal was that the issue would be decided in the negative for them and they therefore could have reacted to it, even without a preliminary opinion of the board in the written proceedings.

33. Furthermore, the board considers it not *prima facie* apparent how the amendment in claim 1 consisting solely of the insertion of the very method for the measurement of a particular parameter in a claim, here inhibition of growth of a cell, which was earlier held by the board to fail to distinguish this parameter from another parameter, here induction of apoptosis, can remedy the lack of sufficiency of disclosure found in relation to the invention defined in claim 1 of the main request.
34. Accordingly, the board, exercising its discretion under Article 13(1) RPBA, decided not to admit the request into the appeal proceedings.

*8th auxiliary request - claim 1 - Article 123(3) EPC*

35. Appellant I filed this request with the reply to the statement of grounds of appeal of appellant II and it was renumbered as the 8th auxiliary request during the oral proceedings (see section XI).
36. Compared with claim 1 of the patent as granted the claim no longer requires that the "antibody, antigen binding fragment or recombinant protein thereof" is "capable of inhibiting the growth of a cell upon binding to an epitope on YKL-40". Instead, the "antibody, antigen binding fragment or recombinant

protein thereof" as now claimed is specified to be "capable of specifically recognizing and binding to an epitope comprising residues 210-220 of SEQ ID NO: 1".

37. Appellant I argued that paragraph [0214] of the patent stated that the antibody 201F9 - which recognises the epitope now referred to in the claim, "an epitope comprising residues 210-220 of SEQ ID NO: 1" - inhibited the biological activity of YKL-40 which therefore lead to the inhibition of the growth of cancer cells. It was beyond doubt that the antibody 201F9 was capable of inhibiting growth of cancer cells.
38. Appellant I alleged that, generally, any antibody binding to the same epitope as another antibody necessarily had the same functionality as that antibody. Therefore, any antibody binding to the epitope to which the antibody 201F9 binds will necessarily have the same biological activity as the antibody 201F9 to inhibit the growth of cancer cells, and this was in fact so regarding all compounds referred to claim 1 since they were all "capable of specifically recognizing and binding to an epitope comprising residues 210-220 of SEQ ID NO: 1".
39. The board is not convinced by appellant I's allegation that the compounds referred to in claim 1 - "antibody, antigen binding fragment or recombinant protein thereof" - and defined to be "capable of specifically recognising and binding" to a particular epitope all necessarily exhibit the same functionalities as a reference compound, here the antibody 201F9 which also binds to this epitope. By way of example, the board refers to the substantial variability in the size and nature of the compounds subsumed under the terms "the antibody, antigen binding fragment or recombinant

protein thereof" in claim 1 which leads, already from the simple point of view of steric hindrance, to a variety of different impacts on the interaction of ligand partners and their consequential functionalities, thereby rendering it not conceivable to the board that claim 1 after amendment encompasses compounds having mandatorily at least the property referred to in claim 1 as granted by way of a functional feature, i.e. those being "capable of inhibiting growth of a cell upon binding to an epitope on YKL-40". In other words, the board is not convinced that the claim does not extend the protection conferred vis-à-vis the claims as granted.

40. In the absence of relevant provisions in the EPC, the case law of the boards of appeal, in the context of the principle concerning the allocation of the burden of proof, has established that each party bears the burden of proof for the facts it alleges (Case Law of the Boards of Appeal, 8th edition 2016, hereafter "CLBA", III.G.5). This principle also applies within the context of the requirements of Article 123(3) EPC (see e.g. decision T 2285/09 of 20 January 2011).
41. In view of the above considerations, the board accordingly concludes that in relation to claim 1 the requirements of Article 123(3) EPC are not met.

*9th auxiliary request - admission into the proceedings*

42. Compared with claim 1 of the 8th auxiliary request, claim 1 of the 9th auxiliary request was not directed to products which were an "antibody, antigen binding fragment or recombinant protein thereof", but to products which were antibodies (see section XIV).

43. The auxiliary request was filed during oral proceedings in response to the finding of the board that claim 1 of the 8th auxiliary request did not comply with the requirements of Article 123(3) EPC. Appellant I argued that, because the claims were now restricted to antibodies, the board's concerns under Article 123(3) EPC could no longer apply.
44. The board notes that the findings on claim 1 of the 8th auxiliary request were neither related nor restricted to particular classes of compounds covered by the claims (see points 26 to 28). Therefore, the reasoning applies to the present claim 1 and is thus considered as not complying with the requirements of Article 123(3) EPC.
45. Hence, the submitted 9th auxiliary request was not clearly allowable.
46. The board, exercising its discretion under Article 13(1) RPBA, therefore decided to not admit the request into the appeal proceedings.

*Request on apportionment of costs (Article 104 EPC and Article 16 RPBA)*

47. Pursuant to Article 104(1) EPC, each party to the opposition proceedings bears the costs it has incurred, unless, for reasons of equity, a different apportionment of costs is ordered. Article 16 RPBA specifies that the board may order a different apportionment of costs upon request and gives examples of situations in which a different apportionment may be justified.

48. Generally, the boards of appeal have stated that ordering a different apportionment of costs is justified if the conduct of a party or parties is not in keeping with the care required and thus is disadvantageous for the other party or parties (see CLBA, IV.C.6.2).
49. In the context of its request for a different apportionment of costs, appellant I submitted two main lines of argument.
50. In the first line, appellant I submitted that appellant II should have announced their intention not to attend the oral proceedings earlier. Appellant I considers that, had there been an earlier notification by appellant II of its non-attendance, they would then have had an opportunity to obtain the opinion of the board on their pending claim requests at some point before the oral proceedings, noting that no written communication setting out the board's preliminary opinion had been issued up to then. As a consequence, then, the oral proceedings could have been cancelled or the attendance of appellant I at the oral proceedings could have been avoided. Either option would have saved costs for appellant I, it being a small company.
51. In the second line of argument appellant I pointed to deficiencies in the procedure on the part of the EPO which allegedly put them at a disadvantage: i) the delay in forwarding appellant II's letter announcing its non-attendance at the oral proceedings to appellant I, with the consequence that appellant I had even less time to react; and ii) the fact that the board had not issued a written preliminary opinion, which prevented appellant I from reacting before the oral proceedings took place, so as to possibly avoid

them, and from finding out, before the oral proceedings, the crucial issue in relation to sufficiency of disclosure.

52. The board notes that the latter line of argument on the perceived misconduct on the part of the EPO (the board dealing with the case) has no bearing on the board's decision about a different apportionment of costs under Article 104 EPC since the EPO is not a party to the proceedings, nor is it conceivable that the delay in forwarding the communication or the non-issuance of a written preliminary opinion can be ascribed to appellant II. Hence, these submissions need not be dealt with.
53. In view of the circumstances of the present case, the question to be answered to decide about a different apportionment of costs is thus whether or not the oral proceedings, or at least the attendance of appellant I at these oral proceedings, could have been avoided, had appellant II announced earlier about their intention not to attend the oral proceedings earlier (see point 50).
54. Both appellant I and II had requested oral proceedings. Therefore, oral proceedings were scheduled and the parties were summoned by the board. The board notes that even if appellant II's information that they did not intend to appear at the oral proceedings was considered to be the equivalent to a withdrawal of appellant II's request for oral proceedings, appellant I's request for oral proceedings was still pending. Accordingly, in all circumstances, the oral proceedings had to be held.



55. Thus, the board concludes that the perceived misconduct on the part of appellant II, i.e. that they should have filed the notification of its non-attendance at the oral proceedings earlier, was not the cause for appellant I attending the oral proceedings. Accordingly, the board comes to the conclusion that appellant II's conduct was not disadvantageous for appellant I.

56. In view of the above considerations the board decided to reject appellant I's request for a different apportionment of costs.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.
3. The request for apportionment of costs is rejected.

The Registrar:

The Chair:



S. Lichtenvort

G. Alt

Decision electronically authenticated