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**Datasheet for the decision
of 14 November 2013**

Case Number: T 1150/09 - 3.3.04

Application Number: 01943357.2

Publication Number: 1297016

IPC: C07K 16/22

Language of the proceedings: EN

Title of invention:

Use of inhibitors of placental growth factor for the treatment of pathological angiogenesis, pathological arteriogenesis, inflammation, tumour formation and/or vascular leakage

Patent Proprietor:

Vlaams Interuniversitair Instituut voor
Biotechnologie vzw.
D. Collen Research Foundation vzw.

Opponent:

STRAWMAN LIMITED

Headword:

-

Relevant legal provisions:

EPC Art. 83, 123(2)
RPBA Art. 13(1), 13(3)

Keyword:

"Main request, auxiliary requests 1 to 5 - sufficiency of disclosure (no)"
"Auxiliary requests 7 and 8 - admitted (no)"

Decisions cited:

G 0005/83, R 0002/08, R 0012/09, R 0015/10, R 0013/11,
T 0019/90, T 0609/02, T 0801/06, T 0183/09

Catchword:

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Case Number: T 1150/09 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 14 November 2013

Appellant: STRAWMAN LIMITED
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted
on 27 March 2009 concerning maintenance of
European patent No. 1297016 in amended form.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: R. Morawetz
B. Claes

Summary of Facts and Submissions

- I. The appeal of the opponent (hereafter "appellant") lies against the decision of the opposition division posted on 27 March 2009, whereby European patent No. EP 1297016 was maintained in amended form on the basis of auxiliary request 1 filed on 28 November 2008.
- II. The patent at issue has the title "Use of inhibitors of placental growth factor for the treatment of pathological angiogenesis, pathological arteriogenesis, inflammation, tumour formation and/or vascular leakage". It was granted on European application No. 01943357.2 which originated from international application PCT/EP2001/005478 published as WO 2001/085796 (hereinafter "application as filed").
- III. The patent was opposed under Article 100(a) EPC 1973 on the grounds of lack of novelty (Article 54 EPC 1973) and lack of inventive step (Article 56 EPC 1973), under Article 100(b) EPC 1973 and under Article 100(c) EPC 1973.
- IV. The opposition division decided that the claims of the auxiliary request 1 (which corresponds to the present main request) fulfilled the requirements of the EPC.
- V. The appellant filed its statement of grounds of appeal on 6 August 2009 including substantial arguments why the claims upheld by the opposition division *inter alia* failed to meet the requirements of Article 83 EPC.
- VI. In response the proprietors (hereafter "respondents") filed a reply on 22 January 2010, submitting the claims

allowed by the opposition division as their main request and filing five auxiliary requests.

Claim 1 of the main request reads as follows:

"1. Use of an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to placental growth factor for the preparation of a medicament for the treatment of **cancer**, pulmonary hypertension, inflammation, oedema, retinopathy of prematurity, diabetic retinopathy, choroidal and other intraocular disorders, and retinal ischemic diseases." (Emphasis added).

Claim 1 of auxiliary request 1 reads as follows:

"1. Use of an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to placental growth factor for the preparation of a medicament for the treatment of **cancer**, pulmonary hypertension, inflammation, oedema, retinopathy of prematurity, diabetic retinopathy, choroidal and other intraocular disorders, and retinal ischemic diseases, with the proviso that said angiogenesis inhibitor is not for use as a medicament in combination with a molecule specifically binding to VEGF." (Emphasis added).

Claim 1 of auxiliary request 2 reads as follows:

"1. Use of an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to placental growth factor for the preparation of a medicament for the treatment of **cancer**, pulmonary

hypertension, oedema, retinopathy of prematurity, diabetic retinopathy, choroidal and other intraocular disorders, and retinal ischemic diseases." (Emphasis added).

Claim 1 of auxiliary request 3 reads as follows:

"1. Use of an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to placental growth factor for the preparation of a medicament for the treatment of **cancer**, pulmonary hypertension, inflammation, and oedema." (Emphasis added).

Claim 1 of auxiliary request 4 reads as follows:

"1. Use of an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to placental growth factor for the preparation of a medicament for the treatment of **cancer**, pulmonary hypertension, and oedema." (Emphasis added).

Claim 1 of auxiliary request 5 reads as follows:

"1. Use of an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to placental growth factor for the preparation of a medicament for the treatment of **cancer**." (Emphasis added).

VII. By a communication of 16 January 2013 the parties were summoned to oral proceedings to be held on 14 November 2013.

VIII. In its letter of 8 October 2013 the appellant announced that it would not attend the oral proceedings scheduled for 14 November 2013.

IX. Oral proceedings before the board were held on 14 November 2013 in the absence of the appellant. At the request of the respondents the board expressed its view on the objection raised by the appellant with respect to the issue of sufficiency of disclosure. Thereafter the respondents provided their arguments. After the board expressed its view that the disclosure was insufficient as regards the treatment of cancer and that this view affected all pending requests the respondents filed auxiliary requests 6 and 7. The board expressed its surprise at the proposed amendments and questioned the likelihood of overcoming the objection under Article 100(b) EPC which prompted the respondents to withdraw auxiliary request 6. The board heard the respondents on the admissibility of auxiliary request 7 and decided not to admit auxiliary request 7. The respondents then filed auxiliary request 8. The board heard the respondents on the admissibility of auxiliary request 8 and decided not to admit it. After the board announced its decision not to admit auxiliary request 8 in the proceedings, the respondents requested an adjournment of the oral proceedings. After resumption of the oral proceedings the respondents stated that there had been a procedural defect. The respondents submitted that the board should have admitted auxiliary request 8 because, in accordance with decision T 183/09, a request which addressed an issue raised during oral proceedings should be allowed. The respondents had been expected to address an issue during oral proceedings which required more preparation and which was not

anticipated on their own reading of the appellant's argument. They were considering a petition for review on the ground that their right to be heard had been violated (cf. minutes).

Claim 1 of auxiliary request 7 reads as follows:

"1. Use of an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to placental growth factor for the preparation of a medicament for the treatment of **carcinomas, sarcomas, carcinosarcoma, tumours of nerve tissues, melanoma,** pulmonary hypertension, inflammation, oedema, retinopathy of prematurity, diabetic retinopathy of prematurity, choroidal and other intraocular disorders, and retinal ischemic diseases." (Emphasis added).

Claim 1 of auxiliary request 8 reads as follows:

"1. Use of an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to placental growth factor for the preparation of a medicament for the treatment of pulmonary hypertension, inflammation, oedema, retinopathy of prematurity, diabetic retinopathy, choroidal and other intraocular disorders, and retinal ischemic diseases."

X. Documents referred to in this decision:

(D7) Tumour angiogenesis, R. Bicknell, C.E. Lewis, and N. Ferrara editors, pages 1-18 (1997)

(D10) Nomura M. et al., J. Neuro-Oncology, vol. 40, pages 123-130 (1998)

- (D15) Ryan A.M. et al., *Toxicologic Pathology*, vol. 27, pages 78-86 (1999)
- (D16) Experimental data filed by letter dated 24 March 2005
- (D21) Carmeliet P., *Verhandelingen*, vol. 62, pages 31-68 (2000)

XI. The relevant arguments of the appellant in writing can be summarised as follows:

Main request

Amendments (Article 100(c) EPC) - claim 1

The term "consisting of" as applied to the angiogenesis inhibitor added subject-matter. There was no direct and unambiguous disclosure of the angiogenesis inhibitor being specifically limited to consisting of an antibody or a fragment thereof. Indeed the application as filed allowed for the possibility of additional components within the angiogenesis inhibitor (page 6, lines 23 to 24).

Sufficiency of disclosure (Articles 100(b) and 83 EPC)

Decisions T 792/00, T 187/93 and T 609/02 were highly pertinent to the present case. There was in the patent not one example of inhibition of PlGF using an antibody to inhibit angiogenesis in a valid disease model for any of the diseases as claimed. In the experiments disclosed in the patent, the lesion studied was introduced or induced in the mice after knock-out of the PlGF genes and this was in contrast to any pathological situation in which the lesion already

existed and where PlGF was already present in the system.

The disclosure in the patent provided no more than the beginnings of a research program of uncertain outcome and for the skilled person, to be able to carry out the invention as claimed, would require the exercise of an undue burden of experimentation. The patent disclosure itself should put the skilled person in possession of at least one way of putting the claimed invention into practice, as well as provide a sufficient disclosure across the whole scope of the claims.

There was no definition of "cancer" in the specification and therefore claim 1 appeared to cover all cancers. In fact, no evidence was provided that PlGF was involved in all cancers. Treatment of tumour formation was addressed in the specification to the extent that a generic list of various types of tumours was provided (page 6, paragraphs [0016] and [0017]), however no indication was given regarding which of the tumours were suitable for treatment using anti-PlGF antibodies and indeed if PlGF was actually involved in the formation of any of these tumours. It was well known in the art at the priority date of the application that PlGF was not expressed in all tumours, for example see document (D10). Indeed it was known that the involvement of PlGF might be dependent on the origin of the tumour. The patent provided no teaching of which tumours would be suitable for treatment with a PlGF inhibitor or how the skilled person should identify such a tumour. The skilled person was expected to predict which cancers might be suitable for the anti-PlGF treatment without guidance from the

specification. An undue burden was placed on the skilled person to perform extensive experimentation to clarify which cancers were suitable for treatment with an anti-PlGF antibody in order to perform the invention as claimed in claim 1. Thus the disclosure was insufficient for the skilled person to be able to carry out the whole subject-matter defined in the claims without undue burden.

XII. The relevant arguments of the respondents can be summarised as follows:

Main request

Amendments (Article 100(c) EPC) - claim 1

The application as filed provided a basis for "consisting of" on page 5, lines 1 to 14, on page 3, lines 23 to 31, the example section as a whole and claim 6.

Sufficiency of disclosure (Articles 100(b) and 83 EPC)

In the written procedure the respondents argued that it was well established by the EPO case law that an opponent carried the burden of proving insufficiency, see decision T 19/90 (reasons, point 3.3), and the Case Law of the Boards of Appeal of the EPO (5th edition, page 179, third paragraph). The appellant had failed to provide any evidence ("verifiable facts") to support its sufficiency objections and therefore it had failed to discharge its burden of proof. The application as filed contained ample experimental evidence supporting the utility (*sic*) of anti-PlGF antibodies in the inhibition of pathological angiogenesis. The utility

(sic) of the present invention was also confirmed by post-filed data, notably document (D16).

During the oral proceedings the respondent argued that the experiment described in the patent rendered the claimed therapeutic effect of inhibiting PlGF plausible and document (D16) confirmed it. There was no indication in the prior art that removal of PlGF was sufficient to treat cancer. The patent indicated that PlGF produced by the tissue surrounding the tumour played a role in the growth of the tumour and this irrespective of whether or not the tumour itself produced PlGF. It was irrelevant that not all tumours produced PlGF because PlGF affected the response of cells to VEGF. Therefore removal of PlGF had an effect regardless of whether or not the tumour expressed PlGF. Documents (D7), (D15) and (D21) confirmed that VEGF played a role in a variety of solid tumours.

Auxiliary requests 1 to 5

Sufficiency of disclosure (Article 100(b) and 83 EPC)

No further arguments were provided.

Auxiliary request 7

Admissibility

The request should be admitted because it addressed the objection discussed during oral proceedings. Claim 1 has now been restricted to cancers known to be VEGF dependent.

Auxiliary request 8

Admissibility

The request should be admitted because it addressed the objection raised by the appellant by deleting any reference to cancer. It was admittedly filed at a late stage but it had not been envisaged that the board would agree with the appellant as to lack of sufficiency regarding the treatment of cancer.

XIII. The appellant requested in writing that the decision under appeal be set aside and that the patent be revoked. The respondents request that the appeal be dismissed or that the decision under appeal be set aside and that the patent be maintained on the basis of one of their auxiliary requests 1 to 5 filed with their reply to the statement of grounds of appeal or auxiliary requests 7 and 8 filed during the oral proceedings.

Reasons for the Decision

Main request

Amendments (Article 100(c) EPC) - claim 1

1. The board is satisfied that the application as filed provides a basis for the feature "consisting of" on page 5, lines 1 to 14, on page 3, lines 23 to 31, in the example section as a whole and in claim 6. In view of the decision on sufficiency of disclosure, see below, the board considers it unnecessary to provide a detailed reasoning for its finding.

Sufficiency of disclosure (Articles 100(b) and 83 EPC)

2. Claim 1 is drafted in the so-called Swiss-type format and relates to the use of an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to placental growth factor (PlGF) for the preparation of a medicament for the treatment of *inter alia* cancer (see section VI above for the complete wording of claim 1).

3. As a first line of argument the appellant submitted that there was no exemplification of inhibition of PlGF to inhibit angiogenesis using an antibody to achieve any technical effect in any valid model relevant to the treatment of cancer because in the experiment disclosed in the patent the lesion studied was induced in mice after knock-out of the PlGF genes, i.e. in the absence of PlGF.

4. The board notes that it is established jurisprudence of the Boards of Appeal that where, as in the present case, a therapeutic application is claimed in the form allowed by the Enlarged Board of Appeal in decision G 5/83 (OJ EPO 1985, 64), i.e. in the form of the use of a substance or composition for the manufacture of a medicament for a defined therapeutic application, attaining the claimed therapeutic effect is a functional technical feature of the claim. As a consequence, under Article 83 EPC, unless this is already known to the skilled person at the priority date, the application must disclose the suitability of the product to be manufactured for the claimed therapeutic application. It has been established by the case law relating to sufficiency of disclosure with

- regard to claims to a second medical use, that a claimed therapeutic effect may be proven by any kind of data as long as they directly and unambiguously reflect the therapeutic application (*cf.* Case Law of the Boards of Appeal of the European Patent Office, 7th edition 2013, section II.C.6.2, and decisions T 609/02 of 27 October 2004, reasons, point 9 and T 801/06 of 4 March 2009, reasons, point 28).
5. Therefore, in the board's judgement the mere fact that the experiments were carried out in knock-out mice does not in itself suffice to deny sufficiency of disclosure. Rather, the question to be addressed is whether or not the data provided in the patent in suit reflect the claimed therapeutic application.
 6. Example 1 of the patent in suit (*cf.* paragraph [0025]) entitled "Impaired pathological angiogenesis in PlGF^{-/-} mice" is the relevant example. In this example, the growth and angiogenesis of embryonic stem (ES) cell-derived tumours, known to be mediated by VEGF, were studied in nu/nu PlGF^{-/-} mice and shown to be also dependent on PlGF. Indeed, PlGF^{+/+} ES cell-derived tumours, obtained within four weeks after subcutaneous inoculation in nu/nu PlGF^{+/+} mice, weighed 4 ± 1 g (n=8) and appeared haemorrhagic and bled profusely (7 of 8 tumours). In contrast, PlGF^{-/-} tumours in nu/nu PlGF^{-/-} hosts only weighed 1.0 ± 0.3 g (n=8) and were homogeneously white with minimal bleeding (5 of 7 tumours). Growth and vascularization in PlGF^{-/-} tumours were reduced to the same degree as in VEGF^{-/-} tumours. PlGF^{+/+} and PlGF^{-/-} tumours contained comparable vascular densities of endothelial cords and capillaries. However, compared to PlGF^{+/+} tumours, PlGF^{-/-} tumours contained

fewer medium-sized or large vessels. Angiogenesis of PlGF^{+/+} tumours in nu/nu PlGF^{-/-} mice or of PlGF^{-/-} tumours in nu/nu PlGF^{+/+} mice was comparable to that of PlGF^{+/+} tumours in nu/nu PlGF^{+/+} mice, indicating that production of PlGF either by tumour or by host-derived tissue could rescue the phenotype.

7. The board is satisfied that example 1 demonstrates that the absence of PlGF has an effect on the growth and vascularisation of ES cell-derived tumours (which are known to be VEGF dependent). That tumour growth was assessed in mice where the PlGF genes had been knocked-out before inducing the tumour can not detract from the fact that absence of PlGF has been shown to have an effect that reflects a therapeutic application. In the board's judgement the results obtained in the knock-out mice render the therapeutic application of inhibiting angiogenesis by using an antibody which binds to PlGF in the context studied, i.e. growth and angiogenesis of ES cell-derived tumours, known to be mediated by VEGF, and wherein either the tumour or the surrounding tissue is known to produce PlGF, at least plausible for the skilled person. The board notes however that there is no evidence on file that this context reflects a mechanism which would be common to all cancers. Finally, document (D16), a post-filed document, confirms that in the four solid tumour models tested, injection of monoclonal anti-PlGF antibody resulted in a significant reduction of tumor volume and size.

8. In a further line of argument the appellant argued that the disclosure was insufficient for the skilled person to carry out the claimed invention without undue burden. The skilled person had to perform extensive

- experimentation to clarify which cancers were suitable for the treatment with an anti-PlGF antibody in order to perform the invention as claimed, and this constituted an undue burden.
9. It is established jurisprudence of the Boards of Appeal that the requirement of sufficiency of disclosure is met only if the invention as defined in the claims can be performed by a person skilled in the art over the whole range claimed without undue burden, using common general knowledge and having regard to the information provided in the patent. This principle applies to any invention irrespective of the way in which it is defined and is a question of fact to be decided on a case-by-case basis (cf Case Law of the Boards of Appeal of the European Patent Office, 7th edition 2013, sections II.C.4.1., 4.2. and 4.4).
 10. The appellant argued, and this has not been contested by the respondents, that there is no definition of "cancer" in the specification. Therefore claim 1 embraces the treatment of any and all cancers and is not restricted to the treatment of tumours for which an involvement of PlGF on tumour formation is known to the skilled person. Furthermore, from document (D10) it was known in the art at the relevant date that PlGF is not expressed in all tumours and that the involvement of PlGF might be dependent on the origin of the tumour.
 11. Indeed, document (D10) investigates the expression of PlGF in brain tumours and discloses that PlGF was found to be expressed in 25 out of 39 brain tumours. While PlGF mRNA is expressed in all the hypervascular brain tumors, PlGF mRNA is not common in hypovascular tumors

and no PlGF mRNA was detected in the metastatic hypervascular brain tumors tested. The authors conclude that the involvement of PlGF in tumor angiogenesis may depend on the origin of the tumors (cf abstract and paragraph bridging pages 128 and 129).

12. In the board's judgement document (D10) provides evidence that PlGF is not involved in the angiogenesis of all cancers. For the invention underlying claim 1 to be sufficiently disclosed, the skilled person must therefore be able to select without undue burden those cancers that are treatable by using an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to PlGF.

13. The patent in suit does not indicate which criteria the skilled person should apply for identifying a cancer which can be treated with an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to PlGF. The specification of the patent merely addresses the treatment of tumour formation in the general part of the description to the extent that a generic list of various types of tumours is provided (cf paragraphs [0016] and [0017]) however no indication is given regarding which of the tumours are actually suitable for treatment using anti-PlGF antibodies in accordance with the invention and whether or not PlGF is actually involved in the formation of any of these tumours. Thus, the skilled person wanting to perform the claimed invention is expected to predict which cancers might be suitable for the anti-PlGF treatment without guidance from the specification. Moreover, there is no evidence on file that the skilled person is able to select cancers amenable to the

- claimed treatment on the basis of his/her common general knowledge. This has not been contested by the respondents.
14. The board concludes from the above that the skilled person was not in a position to predict, on the basis of the information contained in the specification and taking into account the relevant common general knowledge, which cancers can be treated in accordance with the invention. Accordingly, such cancers have to be identified by carrying out further tests for which the patent also provides no guidance. Therefore the skilled person is in a position where he/she has to carry out a research program to clarify which cancers are suitable for the treatment with an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to PlGF in order to perform the invention as claimed in claim 1. The board judges that in the present case this amounts to an undue burden for the skilled person. Accordingly, the claimed invention suffers from insufficiency of disclosure.
15. As a first line of argument in defence the respondents relied on decision T 19/90 (OJ EPO 1990, 476, reasons, point 3.3) and submitted that the appellant had failed to provide any evidence ("verifiable facts") to support its sufficiency objections and had therefore failed to discharge its burden of proof.
16. The board notes that decision T 19/90, *supra*, reads at the relevant passage relied on by the respondents as follows: "*Only if there are serious doubts, substantiated by verifiable facts, may an application*

be objected to for lack of sufficient disclosure". The board understands this passage to mean that verifiable facts are required to substantiate an objection as to lack of sufficiency of disclosure. In the board's judgement it is a verifiable fact that claim 1 is directed to the treatment of any and all cancers while the patent is silent as to which cancers are amenable to treatment with an antibody that binds to PlGF. It is also a verifiable fact that the patent provides no guidance as to how the skilled person should identify those cancers that are amenable to treatment. It is a further verifiable fact that not all cancers express PlGF. The evidence which supports these verifiable facts is on the one hand the patent specification of the patent in suit and on the other hand document (D10). The board therefore considers it established by the appellant that not all cancers are treatable with an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to PlGF. The board concludes that the appellant has discharged its burden of proof for arguing lack of sufficiency of disclosure of the invention in claim 1 in its broadest form. Accordingly, it is for the respondents to present refuting facts and/or arguments.

17. The respondents have not provided any refuting facts or arguments in the written appeal proceedings other than that (i) the application as filed contained ample experimental evidence supporting the utility of anti-PlGF antibodies in the inhibition of pathological angiogenesis and (ii) that the utility of the present invention was also confirmed by post-filed data, notably document (D16).

18. In the board's judgement these arguments advanced by the respondents address merely the first issue raised by the appellant (see point 3, above), but do not begin to address the second one (see point 8, above), namely that the skilled person faces an undue burden when trying to work the invention across the whole scope of claim 1. The evidential value of the data disclosed in the patent in suit and in document (D16) has already been discussed above (see points 4 to 7, above).

19. During the oral proceedings the respondents argued that it was irrelevant that not all tumours expressed PlGF because PlGF affected the response of tumour cells to VEGF. The example in the patent demonstrated that PlGF produced by the tissue surrounding the tumour played a role in the growth of the tumour and this irrespective of whether or not the tumour itself produced PlGF. Therefore removal of PlGF had an effect regardless of whether or not the tumour expressed PlGF. Document (D7) at page 2, left hand column, lines 16 to 14 from bottom; document (D15) at page 78, left hand column, first paragraph; and document (D21) at page 37, first full paragraph were referred to in order to provide evidence that VEGF played a role in a variety of solid tumours.

20. The board does not consider this line of reasoning persuasive. Firstly, it is a fact that the term "cancer" is not synonymous with solid tumours but embraces any and all cancers including cancers of the blood-forming tissues, such as leukemias and lymphomas (see paragraph [0017] of the patent in suit). In fact, no evidence is on file that angiogenesis, VEGF or PlGF is involved at all in these types of cancers, neither in the patent *in suit* nor in the prior art relied on by

the respondents. From the prior art (see document (D10), page 123 LHC, first paragraph) it would appear that it was speculated that angiogenesis might contribute to the growth, progression and metastasis of several types of solid tumours but the prior art referred to by the respondents is silent on the role of any of PlGF or VEGF on any other type of cancers such as for example cancers of the blood-forming tissues.

21. Secondly, the argument by the respondents that PlGF might also be produced by the surrounding tissue fails to address the problem that the skilled person is given no guidance in the patent as to which cancers can be treated in the first place. Even if PlGF were to be produced by the surrounding tissue and not by the cancer itself, the patent in suit does not identify these tissues and in the absence of any relevant common general knowledge the skilled person still has to test for the presence of PlGF in the surrounding tissue in order to identify whether or not a cancer is amenable to the treatment with an angiogenesis inhibitor consisting of an antibody or a fragment thereof specifically binding to PlGF. The skilled person would thus be in a similar situation as with the cancer itself, i.e. he/she would have to carry out further tests without any guidance. Therefore the respondents' arguments fail.

22. In conclusion, the board, having regard to the facts and arguments presented to it, decides that the disclosure of the contested patent does not allow the skilled person to perform the invention across the whole scope claimed without undue burden so that there

is insufficiency of disclosure.

Auxiliary requests 1 to 5

Sufficiency of disclosure (Articles 100(b) and 83 EPC)

23. Auxiliary requests 1 to 4 include and auxiliary request 5 is limited to the treatment of cancer. The respondents submitted no further arguments for these requests and conceded that the objections that applied to the main request also applied to these requests. Accordingly these requests fail the requirement of sufficiency of disclosure for the same reasons as indicated above (cf. points 7 to 14) for the main request.

Auxiliary request 7

Admissibility

24. This request was filed during the oral proceedings after the board expressed its view that claim 1 of all requests on file failed the requirements of sufficiency of disclosure. Auxiliary request 7 is based on the main request and differs therefrom in that in claim 1 the term "*cancer*" is replaced by the terms "*carcinomas, sarcomas, carcinosarcoma, tumours of nerve tissues, melanoma*" (see section VI above for the complete wording of claim 1). The respondents submitted that the request should be admitted because it addressed the objection discussed during oral proceedings by limiting the claim to cancers known to be VEGF dependent. The request was admittedly late filed but the respondents argued in their defence that they had not envisaged that the board would agree with the appellant as to

lack of sufficiency regarding the treatment of cancer.

25. The board notes that the appellant had raised the objection as to lack of sufficiency of disclosure already in its notice of opposition and had maintained its objection on appeal. The respondents were aware of this objection upon the receipt of the statement of the grounds of appeal of the appellant. In their reply to the statement of grounds of appeal, the respondents maintained the request underlying the decision under appeal as main request and filed five auxiliary requests. All these requests included the treatment of cancer and auxiliary request 5 had been limited to cancer as the sole disease to be treated.

26. It is for the respondents to defend their case as they see fit. This includes the timely submission of their fall back positions in the form of auxiliary requests (Article 12(2) RPBA). That the respondents considered the case made by the appellant as not persuasive can be no justification for addressing the objection as to lack of sufficiency of disclosure at such a late stage of the proceedings. In addition, the board notes that in this request features from the description were incorporated into the claims which were not present in any of the claims of any of the requests on file. This type of amendment was not foreseeable either for the appellant or the board and came as a surprise. Therefore the board decided not to admit auxiliary request 7 in the proceedings (Articles 13(1) and (3) RPBA).

Auxiliary request 8

Admissibility

27. This request was also filed during the oral proceedings. It is based on the main request and differs therefrom in that the term "cancer" has been deleted from claim 1. The respondents submitted that the request should be admitted because it addressed the objection discussed. The respondents conceded that the request was late filed but reiterated that they had not envisaged that the board would agree with the appellant as to lack of sufficiency of disclosure regarding the treatment of cancer.

28. As set out above (see point 25), the respondents were aware of the objection since the receipt of the statement of the grounds of appeal of the appellant. Therefore, this request could have been filed earlier and was thus late-filed. That the respondents considered the case made by the appellant as not persuasive and awaited the view of the board before filing auxiliary request 8 can be no justification for addressing the objection as to lack of sufficiency of disclosure at such a late stage of the proceedings. Auxiliary request 8 is based on the main request but removes for the first time the most preferred embodiment which was present in all requests filed pursuant to Article 12(2) RPBA and to which auxiliary request 5 indeed had been limited. With this amendment the respondent shifted the subject-matter claimed in an unexpected manner in a different direction. It is established jurisprudence of the Boards of Appeal that the very late filing of diverging auxiliary requests runs counter the need for procedural economy (cf Case

Law of the Boards of Appeal of the European Patent Office, 7th edition 2013, section VII.E.4.4.4).

Therefore the board decided not to admit auxiliary request 8 in the proceedings because it was late filed, it could have been filed earlier and admitting the request into the proceedings would run counter to the need for procedural economy and to the principle of procedural fairness (Articles 13(1) and (3) RPBA).

29. After the board had announced its decision on the admissibility of their auxiliary request 8 filed during the oral proceedings, the respondents submitted (see section IX above) that the board should have admitted that request because, in accordance with decision T 183/09 of 9 September 2010, a request which addressed an issue raised during oral proceedings should be admitted. This was however the first occasion on which the respondents made that submission and by that point in time the board had, after hearing the respondents on the admissibility of that request, made and announced its decision.

30. The respondents also submitted at this point (again, see section IX above) that they had been expected to address an issue during oral proceedings which required more preparation and which was not anticipated on their own reading of the appellant's argument. While the board accepts that the respondents did not expect the appellant's argument on insufficiency to succeed, that argument was clearly set out in the statement of grounds of appeal. In their reply the respondents elected to deal with the issue of insufficiency only by relying on the argument that the appellant had not provided evidence (see section XII above). At the oral

proceedings the respondents indeed appeared less than fully prepared to deal with the issue but, however unfortunate, that was the result of their appraisal of the issue or, as they said in their own submission, their reading of the appellant's argument. As mentioned above (see point 26) in the context of the admissibility of the respondents' requests, it was for the respondents to defend their case as they saw fit. They were responsible for the conduct of their case and it was for them to submit the necessary arguments to support their case on their own initiative and at the appropriate time (see R 2/08 of 11 September 2008, reasons, points 8.5 and 9.10). If the respondents were surprised by the result, such surprise may be an understandable subjective reaction but such subjective surprise cannot change the fact that they knew the issue would be raised and had an opportunity to prepare their position and to present that position both in writing and at the oral proceedings (see R 12/09 of 15 January 2010, reasons, point 13; R 15/10 of 25 November 2010, reasons, point 11; and R 13/11 of 20 April 2012, reasons, point 18).

31. The board concludes that all admissible requests fail the requirements of Article 83 EPC. Accordingly, the patent cannot be maintained on any of these requests and, in the absence of another, allowable claim request, the patent has to be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

P. Cremona

C. Rennie-Smith