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**Datasheet for the decision  
of 24 July 2012**

**Case Number:** T 0591/09 - 3.3.08

**Application Number:** 96932771.7

**Publication Number:** 853668

**IPC:** C12N 15/12

**Language of the proceedings:** EN

**Title of invention:**

Regulated genes and uses thereof

**Patentee:**

VEGENICS PTY LTD

**Headword:**

c-Fos Induced Growth Factor/VEGENICS

**Relevant legal provisions:**

EPC Art. 123(2)

RPBA Art. 12(4)

**Keyword:**

"Admissibility of the opposition (not decided)"

"Main Request - added subject-matter (yes)"

"Admissibility of Auxiliary Request I (no)"

**Decisions cited:**

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**Catchword:**

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Case Number: T 0591/09 - 3.3.08

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.08  
of 24 July 2012

**Appellant:** VEGENICS PTY LTD  
(Patent Proprietor) Level 1  
10 Wallace Avenue  
Toorak, VIC 3142 (AU)

**Representative:** Stephen, Robert John  
Olswang LLP  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
on 7 January 2009 concerning maintenance of the  
European patent No. 853668 in amended form.

**Composition of the Board:**

**Chairman:** M. Wieser  
**Members:** P. Julià  
C. Heath

## Summary of Facts and Submissions

- I. Both the patentee and the opponent lodged an appeal against the decision of the opposition division of 7 January 2009, whereby European patent Nr. 0 853 668, based on European patent application 96 932 771.7 and published as International patent application WO 97/12972 (hereinafter "*the application as filed*"), was maintained on the basis of a first Auxiliary Request filed on 15 July 2008 at the oral proceedings before the opposition division. The opposition division considered that the opposition was admissible and that the Main Request (claims as granted) did not fulfil the requirements of Article 123(2) EPC/Article 100(c) EPC.
- II. Statements setting out their grounds of appeal were filed by the parties on 12 May 2009 and 7 May 2009. With its statement, the patentee filed Auxiliary Requests I and II, the latter identical to the request on which the opposition division decided to maintain the patent, and submitted arguments against the admissibility of the opposition. As its Main Request, the patentee requested the maintenance of the patent as granted.
- III. With letters dated 19 November 2009 and 30 November 2009, the parties replied to their respective statements of grounds of appeal. The opponent filed further submissions with letter dated 1 September 2010.
- IV. With letter dated 9 December 2011, the opponent withdrew its appeal.

- V. With letter dated 15 December 2011, the patentee informed the board that the contested patent had been assigned to the opponent. Thereby, the opponent took over the procedural position of the patentee and became the sole remaining appellant in the appeal proceedings.
- VI. Summons to oral proceedings were issued by the board on 26 March 2012 and, in a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed thereto, the board expressed its preliminary, non-binding opinion on some of the procedural and substantive issues of the appeal, *inter alia*, the requests on file, in particular the admissibility of the opposition, the admissibility of Auxiliary Request I into the appeal proceedings (Article 12(4) RPBA) and the relevance of several objections raised under Article 100(c) EPC/Article 123(2) EPC against the subject-matter of the Main Request.
- VII. With letter of 21 June 2012, the sole remaining appellant informed the board of its intention not to attend the oral proceedings and referred to the arguments filed by the patentee in its grounds of appeal of 12 May 2009 and the reply of 19 November 2009, requesting the board to issue a decision on the basis of these submissions.
- VIII. Oral proceedings were held on 24 July 2012 in the absence of the sole remaining appellant.
- IX. Claims 1 and 2 of the **Main Request** (claims as granted) read as follows:

"1. A nucleotide molecule with at least 80% homology to the nucleotide sequence recited between nt. 283 and nt. 1356 of Figure 1, said nucleotide molecule encoding a protein with mitogenic activity, or a fragment of said nucleotide molecule, which fragment encodes a protein with mitogenic activity."

"2. A nucleotide molecule with at least 80% homology to the nucleotide sequence recited between nt. 242 and nt. 1303 of Figure 2, said nucleotide molecule encoding a protein with mitogenic activity, or a fragment of said nucleotide molecule, which fragment encodes a protein with mitogenic activity."

X. Claims 1 and 2 of the **Auxiliary Request I** were identical to claims 1 and 2 of the Main Request, except for the degree of homology that was defined in Auxiliary Request I as "at least 90% homology".

XI. With letter dated 21 June 2012, the sole remaining appellant referred to the arguments filed by the patentee with the grounds of appeal of 12 May 2009 and the reply of 19 November 2009. As far as these arguments are relevant to the present decision, they may be summarized as follows:

*Main Request*

*Article 100(c) EPC/Article 123(2) EPC*

From page 4, third paragraph of the application as filed, it was evident that the protein and fragments thereof were encoded by the nucleotide sequences shown in Figures 1 and 2. These Figures showed not only nucleotide sequences but also the open reading frames

(ORFs) encoded by them and therefore, the proteins and fragments thereof were unambiguously disclosed. The nucleotide sequences shown in these Figures were further characterized as being similar to genes of a family of growth factors characterized by the Platelet Growth Factor (PDGF) family signature. The relationship between the nucleotide sequences of Figures 1 and 2 and the encoded proteins was also highlighted in the third paragraph of page 10 of the application as filed, wherein it was said that the protein encoded by the sequence in Figure 2 was the human homologue of a mouse protein encoded by the nucleotide sequence of Figure 1.

Figure 2(I) showed the nucleotides from position 181 to 300 and, in addition to the coding and the complementary nucleotide strand, it showed the amino acid sequences in all three possible ORFs. The longest ORF, highlighted by a box, was the one in the middle. Unambiguously, this ORF was the one which was considered by the skilled person to be relevant, since the two other ORFs comprised several stop codons and coded only for short peptide stretches. The legal question to be answered in the present case was whether the skilled person, in the light of the common general knowledge, would have directly and unambiguously understood that the relevant protein started at nucleotide 218 (coding for serine) or at position 242, where the triplet ATG encoding a methionine was highlighted by a box. The general prior art on file, including a textbook, showed that the skilled person knew that mRNA translation started with the first AUG codon in nearly all eukaryotes and that any exception to this general rule had to be evidenced and specified. In the first paragraph of page 8 of the application as

filed, it was said that the first amino acid at the N-terminus of the encoded protein was a methionine encoded by the start codon ATG. Thus, it was very unlikely that the skilled person considered the serine encoded by nucleotide 218 as a start position for the translated protein. This was further supported by the presence of an adenine (A) at position -3 which, according to the well-known "Korzac rule", was statistically the most significant, highly conserved purine in all eukaryotic mRNAs. For this reason, the skilled person would not have considered the second and third ATG codons as start codons, since they did not comply with this rule.

When reading paragraph on page 4, lines 16 to 24 together with the last paragraph on page 4, lines 31 to 38, the skilled person would immediately have understood that the homology at the protein level required on the one hand that the activity was maintained and that the homology was at least 80% of the protein or fragments thereof encoded by the nucleotide sequences shown in Figures 1 or 2 or fragments thereof.

XII. As far as they are relevant to the present decision, the submissions of the opponent, made before withdrawing its appeal and becoming patentee/appellant by assignment, may be summarized as follows:

*Main Request*

*Article 100(c) EPC/Article 123(2) EPC*

The application as filed contained no indications that the fragment specified in granted claim 2 was a

preferred embodiment of a fragment to which the homology disclosure on page 4 of the application as filed could apply. Indeed, the patentee itself claimed a different fragment in its initial claims (claims with "International Preliminary Examination Report", IPER), namely nucleotides 218 to 1302, which was changed to 242 to 1303 in the granted claims. This change was caused by subsequent disclosures of the correct Vascular Endothelial Growth Factor D (VEGF-D) sequence. Thus, even the inventors were not sure of the correct ORF when the application was filed. Therefore, the ORF starting at nucleotide 242 was not directly and unambiguously derivable from the application as filed. What is more, even if it was considered to be derived from Figure 2 as one of several possibilities, the combination of 80% homology with this specific fragment was not directly and unambiguously derivable from the application as filed.

*Admissibility of Auxiliary Request I*

Auxiliary Request I was the same as Auxiliary Request II considered during the oral proceedings before the opposition division. According to page 9, third paragraph of the "Minutes of the oral proceedings before the Opposition Division" (hereinafter the "*Minutes*"), the patentee maintained the Main Request and Auxiliary Request I but not Auxiliary Request II (Annex 2 to the Minutes). Therefore, this set of claims was not maintained in opposition proceedings and it could not be revived in appeal proceedings.

XIII. In its letter of 21 June 2012, the sole appellant requested, as a Main Request, the maintenance of the



patent as granted or, in the alternative, the maintenance of the patent on the basis of the Auxiliary Requests I or II filed on 12 May 2009 with the patentee's statement of grounds of appeal.

## **Reasons for the Decision**

### *Procedural issues; requests on file*

1. Apart from a precautionary request for oral proceedings, the patentee in its statement of grounds of appeal and in its letter of 19 November 2009 requested that the opposition was not admissible.
2. In view of the fact that the contested patent has been assigned to the former opponent, the board considers that the opponent has taken over the procedural position of the patentee and thereby, the appeal filed by the latter. Thus, the opponent - now by assignment, owner of the patent - is the sole remaining appellant in the present appeal proceedings (cf. Section V, *supra*).
3. In a communication pursuant to Article 15(1) RPBA, the board stated that, since the requests originally made by the patentee had been taken over, by assignment, by the sole remaining appellant, in the board's view, it was difficult for the sole remaining appellant to argue that the opposition was not admissible. Thus, in the last sentence of point 8 of its communication, the board explicitly pointed to the necessity of clarifying the actual requests of the sole remaining appellant.

4. In its reply to the board's communication on 21 June 2012, the sole remaining appellant referred to the submissions filed by the patentee in its grounds of appeal of 12 May 2009 and the reply of 19 November 2009. The board was asked to issue a decision on the basis of these submissions. As its Main Request, the sole remaining appellant requested the board to maintain the patent as granted or, in the alternative, on the basis of Auxiliary Requests I or II. No request was made as regards the admissibility of the opposition.
5. In view of this factual situation, the board sees no reason to review the decision of the first instance on the admissibility of the opposition at filing.

*Main Request*

*Article 100(c) EPC/Article 123(2) EPC*

6. All the objections raised in the opposition proceedings under Article 100(c) EPC/Article 123(2) EPC were considered not to be relevant by the opposition division (cf. page 7 to page 13, point 5 of the decision under appeal), except for the objection concerning the combination of the feature "*at least 80% homology*" with the feature relating to the specific nucleic acid molecule of claims 1 and 2. This combination was considered not to be directly and unambiguously derivable from the application as filed, in particular not from page 4, lines 16 to 24 in combination with Figures 1 and 2 (cf. page 13, point 5.1.15 of the decision under appeal). Although for different reasons, this decision of the opposition division was originally contested in appeal proceedings by both the patentee and the opponent.

7. In its communication pursuant to Article 15(1) RPBA, the board stated that, contrary to the opposition division, it was its preliminary, non-binding opinion that at least the following issues were of relevance and contentious, requiring further discussion at the summoned oral proceedings: i) the presence in the claims as granted of a mitogenic activity in general, not limited to the exemplified mitogenic activity on fibroblasts; ii) the combination of the specific nucleotide sequence recited in claim 2 as granted, in particular **nt. 242**, with the specific percentage of homology; and iii) fragments of the nucleic acid sequences with at least 80% homology to the specific nucleotide sequences recited in claims 1 and 2 which retain a mitogenic activity. The board further stated that for the issues ii) and iii), the same reasoning used for the combination of features not acknowledged by the opposition division also applied for these issues.
  
8. It has not been contested during both the opposition and the appeal proceedings that the references on page 4 of the application as filed to the particular degree of homology of the sequences shown in Figures 1 or 2 or fragments thereof are of a general character and they do not define any specific fragment of these sequences. The wording of these references is similar to that found in original claim 2 of the application as filed which refers to sequences having "*at least 80% homology to the protein or fragment thereof, encoded by the sequences shown in Figure 1 or 2*". No specific fragment is defined or characterized in any other part

of the description or in the original claims of the application as filed.

9. It may be argued that the skilled person would immediately consider as preferred embodiments of the invention those fragments encoding the full-length sequences of Figures 1 or 2 and, more particularly, fragments of the nucleotide sequences shown in these Figures encoding the full-length amino acid sequences of the mouse (F0401) protein of Figure 1 and of the human homologue (HF175) protein of Figure 2. According to this argument, these full-length fragments would be directly and unambiguously recognized by the skilled person as preferred embodiments of the invention and thus, to be directly and unambiguously derivable from the application as filed (cf. Section XI, *supra*).
  
10. Whereas it may be open for discussion whether or not this argument applies to the nucleotide and amino acid sequences of the mouse F0401 shown in Figure 1 of the application as filed, the board, in the light of the application as a whole, does not consider it to apply to the sequences of the human homologue HF175 shown in Figure 2. The following considerations are relevant for the board to reach this conclusion:
  - 10.1 According to the application as filed, Figure 2 shows the "*DNA sequence of Fos regulated gene HF175 (human homologue of F0401), showing the encoded protein*" (cf. page 17, lines 18 to 20 of the application). There is no other information in the application as filed explaining or commenting the sequences shown in Figure 2. The skilled person has to rely on the information depicted in this Figure 2, together with

the common general knowledge, for interpreting the disclosure of the application as regards the human HF175 protein.

- 10.2 There are three different amino acid sequences shown in Figure 2, each amino acid sequence corresponding to one of the three possible ORFs of the nucleotide sequence disclosed in this Figure. Although not stated in the application, starts depicted in the amino acid sequences correspond to nucleotide triplets coding for stop codons. The longest amino acid sequence is the sequence in the middle, which is highlighted by a box that starts with a serine (Figure 2(I), nucleotide position 218) and ends with a proline (Figure 2(VIII), nucleotide position 1303). In the nucleotide sequence itself, a first box is found at positions 242-244 for a triplet encoding methionine and then a second box at positions 275-280 for triplets encoding two consecutive methionines. In absence of any further information, it is questionable whether a skilled person would identify the first box as the start codon of the HF175 coding sequence or else the second box would also have been identified as possible start codons or alternative start codons. Although reference was made to the relevance of the first ATG start codon and of its context in the nucleotide sequence (Korzac rule) (cf. Section XI, *supra*), in the board's view and taken the actual information of Figure 2 at face value, a skilled person could not have excluded the presence of possible potential alternative start codons in the HF175 nucleotide sequence shown in Figure 2. They might well encode HF175 variants of different length (short and long) and physiological relevance. There is no information in the application as filed stating which

of the three boxes identified in Figure 2 may be a major or a minor transcription start site, if at all.

10.3 In fact, the box highlighting the middle amino acid sequence does not start at any of these three boxed or highlighted ATG start codons but at position 218 with a triplet encoding a serine. No matter how unusual or exceptional the presence of a serine at the N-terminus of an eukaryotic protein may be, the actual fact is that, in the absence of any information in the application, the possible significance and/or relevance of the box's starting point indicated in Figure 2 is, taken again at face value, completely open to interpretation. Indeed, it might well be interpreted as indicating the possible presence of a long signal peptide, such as that for a preproprotein, proprotein, etc. Again, they might represent different post-transcriptional forms of the same protein with different length (shorter or longer) and physiological relevance. As a matter of fact, the presence of a signal peptide at the N-terminus of the predicted sequence of the mouse F0401 protein is acknowledged in the application as filed (cf. page 23, lines 11 to 13 of the application), and there is nothing in the application to exclude with certainty the presence of a possible longer signal peptide in the human homologue HF175 sequence.

10.4 It follows from the above that all these possible variants and posttranscriptional forms may well be considered to be of relevance by a skilled person. However, in the absence of any further information, it is arguable whether all, some or only a few of them may actually represent preferred embodiments of the

invention. The very particular selection of a specific single HF715 protein among all possible HF175 proteins, namely of the one starting at nucleotide position 242, cannot be directly and unambiguously derived from Figure 2 of the application as filed.

- 10.5 This deficiency cannot be remedied by references to the similarities of the disclosed F0401 and HF175 sequences to the family of growth factors characterised by the PDGF family signature and the more related Vascular Endothelial Growth Factor (VEGF) (cf. *inter alia* page 10, lines 7 to 12, page 17, lines 22 to 26 and page 22, line 26 to page 23, line 7). There is no information in the application as filed regarding the presence of variants and/or posttranscriptional forms of members of this family. It is not clearly derivable from the application as filed whether these variants and forms are normal or rare, found in all, some or only a few members of this family. Suffice it to say that if these variants and/or forms are present in a single member of this family, the skilled person would immediately have doubts on their possible presence in the human homologue HF175 protein. These doubts could not be dispelled by merely referring to the prior art. In the board's view, it is rather a question of obviousness than of formal support in the application as filed, while the former is not a criterium for assessing the requirements of Article 123(2) EPC (cf. "Case Law of the Boards of Appeal of the EPO", 6th edition 2010, A.7.1, page 347).

11. Therefore, the fragment cited in claim 2 of the Main Request is considered not to be directly and unambiguously derivable from the application as filed,

let alone in combination with the specific degree of homology indicated in this claim and thus, the Main Request does not fulfil the requirements of Article 123(2) EPC.

*Admissibility of Auxiliary Request I*

12. In its communication pursuant to Article 15(1) RPBA, the board referred to Article 12(4) RPBA and to the purpose of an appeal proceedings as established by the case law (cf. "Case Law", *supra*, VII.E.1 and VII.E.16, pages 821 and 888, respectively) for questioning the admissibility of Auxiliary Request I into the appeal proceedings. In this communication, the board further noted that Auxiliary Request II was identical to the claim request on which the opposition division decided to maintain the contested patent and, since the appeal filed by the opponent was withdrawn, it could, in principle, not be examined by the board.
  
13. According to the appealed decision, various Auxiliary Requests were filed during the oral proceedings before the opposition division and eventually only Auxiliary Request I (Annex 3 in the decision) was maintained (cf. page 3, point 1.14 of the decision under appeal). Indeed, there are four annexes to the Minutes with four different Auxiliary Requests. Annex 1 contains the Auxiliary Request I on which the opposition division decided to maintain the patent and Annex 2 contains an Auxiliary Request II identical to Auxiliary Request I filed in appeal proceedings by the patentee with its grounds of appeal. According to the Minutes, this Auxiliary Request was not maintained at the end of the oral proceedings before the opposition division (cf.



page 9, third paragraph of the Minutes). No reasons have been given for the reintroduction of this Auxiliary Request now in the appeal proceedings.

14. Since the opposition division acknowledged that the patentee's Auxiliary Request I fulfilled all the requirements of the EPC, there was no reason for the patentee to maintain Auxiliary Request II in the opposition proceedings. Indeed, if the patentee had decided to maintain Auxiliary Request II, the decision of the opposition division would not have been different from the appealed decision since, by maintaining the patent on the basis of Auxiliary Request I, there was no reason for the opposition division to examine and decide on Auxiliary Request II.
  
15. It is, however, in appeal proceedings that the patentee has decided to change the order of these two Auxiliary Requests, so that its previous - and withdrawn - Auxiliary Request II in opposition proceedings has become its Auxiliary Request I in appeal proceedings and its previous Auxiliary Request I in opposition proceedings is now Auxiliary Request II in appeal proceedings. No reasons have been provided to justify this change of order of these Auxiliary Requests now in appeal proceedings. However, as a result of this procedural change at this very late stage of the proceedings, the board, for the first time in these proceedings, would have to decide on a claim request which, if presented in the first instance proceedings at the same hierarchic level as in the appeal proceedings, could already have been decided there.

16. It is noted in addition that the reasons under Article 123(2) EPC/Article 100(c) EPC given above for the Main Request apply to, and are also of relevance, for the subject-matter of Auxiliary Request I in appeal proceedings, since the sole amendment introduced into this Auxiliary Request is a change in the degree of homology, which instead of reading "at least 80% homology" (Main Request) reads "at least 90% homology" (Auxiliary Request I) (cf. Sections IX and X, *supra*).
17. In view of these circumstances, the board, exercising its discretion pursuant to Article 12(4) RPBA which allows the board to hold inadmissible requests that could have been presented in the first instance proceedings, decides not to admit Auxiliary Request I into the appeal proceedings.

## **Order**

### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

A. Wolinski

M. Wieser