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**Datasheet for the decision
of 4 February 2014**

Case Number: T 2106/10 - 3.3.04

Application Number: 02776926.4

Publication Number: 1416954

IPC: A61K38/39, A61K38/16,
C07K16/18, G01N33/50,
G01N33/574, A61P35/00

Language of the proceedings: EN

Title of invention:

Use of heparin-binding domain of fibronectin for diagnosis and treatment of cancer

Applicant:

Novartis Forschungsstiftung, Zweigniederlassung

Headword:

Tenascin binding to fibronectin/Novartis Forschungsstiftung

Relevant legal provisions:

EPC Art. 84, 111(1), 101(3) (a)

Keyword:

Reimbursement of appeal fee - (no)
Claims - clarity - main request (no) - clarity - auxiliary request (no)

Decisions cited:

G 0010/93, T 0645/11

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 2106/10 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 4 February 2014

Appellant: Novartis Forschungsstiftung, Zweigniederlassung
(Applicant) Friedrich Miescher Institute for
Biomedical Research
Maulbeerstraße 66
4058 Basel (CH)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 6 July 2010
refusing European patent application No.
02776926.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: M. Montrone
R. Morawetz

Summary of Facts and Submissions

- I. This appeal was lodged by the applicant (hereinafter "appellant") against the decision of the examining division to refuse European patent application number 02 776 926 published as WO03/013590 pursuant to Article 97(2) EPC.
- II. The decision under appeal dealt with a main request and auxiliary requests 2 and 4.
- III. The examining division took the view that claims 1 and 5 of the main request related to subject-matter which lacked an inventive step (Article 56 EPC). In particular, the examining division held that the application provided no technical effect for the treatment of the non-cancer diseases as referred to in these claims (see section IV, below). The same applied to the subject-matter of claims 1 and 5 of auxiliary request 2. The subject-matter of auxiliary request 4 was considered to comply with the requirements of the EPC. However, in view of the appellant's request to maintain the higher ranking main and auxiliary request 2, the application was refused. In addition, the examining division considered that no substantial procedural violation had taken place with respect to the missing annexes in its communication according to Rule 71(3) EPC dated 17 September 2009 since, although Rule 126(1) EPC had not been complied with, these annexes were provided online by the EPO in electronic form in Register+ and thus, as admitted by the appellant, available (see appellant's letter submitted on 24 September 2009).
- IV. With the statement of grounds of appeal dated 13 July 2010 the appellant requested that the decision

under appeal be set aside and a patent be granted on the basis of either its main or its auxiliary request. These requests were identical to the main request and auxiliary request 4 which were before the examining division. In addition, the appellant requested the reimbursement of the appeal fee according to Rule 103(1) (a) EPC in view of the numerous substantial procedural violations which it said had taken place either during the examination proceedings and/or within the decision under appeal. Oral proceedings were requested on an auxiliary basis.

Claims 1 to 5 and 11 of the main request read:

- "1. A polypeptide as set forth in SEQ ID NO:1 or a portion thereof, wherein said portion interferes with tenascin binding to fibronectin, for use as a medicament for the treatment or prophylactic treatment of rheumatism, asthma, allergic diseases, autoimmune diseases, thrombosis, atherosclerosis, glioblastoma, breast carcinoma and/or transplant rejection.
2. A polypeptide as claimed in claim 1, comprising said portion, said portion comprising the first five amino acids of the amino acid sequence set forth in SEQ ID NO:3, wherein Xaa is any amino acid.
3. A polypeptide as claimed in claim 1, wherein said portion comprises the amino acid sequence set forth in SEQ ID NO:4 or a fragment thereof, wherein Xaa is any amino acid.
4. A polypeptide as claimed in claim 1, wherein said portion is a polypeptide having the amino acid sequence set forth in SEQ ID NO:2 or a fragment thereof.

5. A composition comprising a polypeptide according to any of claims 1 to 4 for use as a medicament for the treatment or prophylactic treatment of rheumatism, asthma, allergic diseases, autoimmune diseases, thrombosis, atherosclerosis, glioblastoma, breast carcinoma and/or transplant rejection.

11. An *ex vivo* method of diagnosing or prognosing cancer comprising:

- a) analysing a sample obtained from an individual for the presence of accessible FNIII13 or a portion thereof; and
- b) correlating the presence of accessible FNIII13 or a portion thereof with a favourable prognosis or diagnosis."

Claims 1 to 5 and 11 of the auxiliary request read:

"1. A polypeptide as set forth in SEQ ID NO:1 or a portion thereof, wherein said portion interferes with tenascin binding to fibronectin, for use as a medicament for the treatment or prophylactic treatment of glioblastoma and/or breast carcinoma.

2. A polypeptide as claimed in claim 1, comprising said portion, said portion comprising the first five amino acids of the amino acid sequence set forth in SEQ ID NO:3, wherein Xaa is any amino acid.

3. A polypeptide as claimed in claim 1, wherein said portion comprises the amino acid sequence set forth in SEQ ID NO:4 or a fragment thereof, wherein Xaa is any amino acid.

4. A polypeptide as claimed in claim 1, wherein said portion is a polypeptide having the amino acid sequence set forth in SEQ ID NO:2 or a fragment thereof.
5. A composition comprising a polypeptide according to any of claims 1 to 4 for use as a medicament for the treatment or prophylactic treatment of glioblastoma and/or breast carcinoma.
11. An *ex vivo* method of diagnosing or prognosing cancer comprising:
- a) analysing a sample obtained from an individual for the presence of accessible FNIII13 or a portion thereof; and
 - b) correlating the presence of accessible FNIII13 or a portion thereof with a favourable prognosis or diagnosis."
- V. With a letter dated 30 July 2013 the board sent out a summons to oral proceedings scheduled for the 4 February 2014.
- VI. The appellant announced in its letter dated 18 December 2013 that it would not attend or be represented at the oral proceedings scheduled for 4 February 2014.
- VII. The board informed the appellant of its preliminary view in its communication under Article 15 RPBA (Rules of Procedure of the Boards of Appeal; OJ EPO Supplement to Official Journal 1/2013, 39) dated 10 January 2014. The board indicated that it was not inclined to reimburse the appeal fee according to Rule 103(1) (a) EPC. Moreover, it considered that the subject-matter of claims 1 to 5 and 11 of the main request and of the auxiliary request lacked clarity (Article 84 EPC), contrary to the finding of the examining division.

VIII. Oral proceedings before the board were held on 4 February 2014. As announced in its letter of 18 December 2013 the appellant was neither present nor represented. The board rejected the request for reimbursement of the appeal fee according to Rule 103(1) (a) EPC and dismissed the appeal (see minutes).

IX. The appellant's arguments, as far as they are relevant for the present decision, may be summarised as follows:

Reimbursement of the appeal fee

- The first issue raised was directed against the incomplete "Summary of facts and submissions" part of the decision under appeal of the examining division wherein the indication of the official communication dated 2 October 2009 was forgotten. This communication contained the information for the appellant that the previous communication under Rule 71(3) EPC of 17 September 2009 was set aside and that the substantive examination was resumed in view of the appellant's letter of 24 September 2009 in which it explicitly disapproved the text on which the examining division intended to grant a patent.

- A further deficiency directly derived from this "missing" communication of 2 October 2009. According to the appellant this communication did not qualify as such either of Rule 71(3) EPC or Article 94(3) EPC and thus had the legal consequence that the previous communication under Rule 71(3) EPC sent by the examining division on 17 September 2009 was formally withdrawn and therefore never notified to the appellant. In view

of this the appellant considered that the argumentation of the examining division regarding the issue that the appellant's right to be heard has not been violated had to fail (see decision under appeal, point 12).

- A third procedural deficiency was that the examining division only indicated for the first time in its decision that auxiliary request 4 complied with the requirements of the EPC but did not send out a second communication according to Rule 71(3) EPC informing the appellant about its intention to grant a patent on this basis. Instead, the examining division directly sent out a decision to refuse the present application. This procedure deprived the appellant of the possibility to withdraw its higher ranking requests including the main request which would have avoided the filing of the present appeal.
- Further deficiencies encountered during the first instance proceedings were the missing legal basis and the lack of any problem-solution approach in the decision under appeal. Moreover, the communication under Rule 71(3) EPC was silent as to exactly which documents of the application the examining division intended to grant a patent on including any statements relating to the amendments that had been carried out by the examining division in these documents.

Clarity

- The appellant has not replied to any of the clarity objections raised by the board in its

communication under Article 15 RPBA of
10 January 2014.

- X. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of either its main request or its auxiliary request both filed with the statement of grounds of appeal. Moreover, reimbursement of the appeal fee according to Rule 103(1) (a) EPC was requested.

Reasons for the Decision

Patentability requirements under examination in ex parte appeal proceedings

1. In an appeal relating to a decision of an examining division refusing a European patent application, the board of appeal has the power to examine whether the application or the invention to which it relates meets the requirements of the EPC (Art. 111(1) EPC). Hence the board can consider requirements that the examining division did not take into consideration in the examination proceedings or which it regarded as having been met (see decision G 10/93, OJ EPO 1995, 172, Headnote).
2. Thus, the board addresses issues under Article 84 EPC in the present decision which were not raised during the examination proceedings before the department of the first instance.

Reimbursement of the appeal fee

3. The board notes that the appellant has raised several issues with regard to an alleged substantial procedural violation in its statement of grounds of appeal dated

13 July 2010 starting on page 2, fourth paragraph. The board agrees with the appellant that several deficiencies have indeed occurred in the first instance proceedings. However, any reimbursement of the appeal fee has to be equitable and depends on the question whether these procedural deficiencies were (1) substantial and (2) forced the appellant to file the present appeal (see decision T 645/11 of 26 January 2012, point 4 of the reasons). In view of the appellant's request to pursue the present main request, the board is of the opinion that the appellant **had to file the present appeal** irrespective of whether or not substantial procedural violations had taken place during the proceedings and/or in the decision of the examining division. In this respect the board observes that none of the objections raised by the appellant with regard to a substantial procedural violation related specifically to the refusal of the main request in the first instance proceedings (see section IX, above). Hence the board can leave the question relating to whether or not a substantial procedural violation has taken place in the present case unanswered since it will have no bearing on the reimbursement issue because **the appellant pursues the granting of a patent on the basis of the present main request**. Consequently, the board does not accede to the appellant's request for reimbursement of the appeal fee according to Rule 103(1)(a) EPC.

Main Request

Clarity - Article 84 EPC

4. The board observes that the subject-matter of claims 1 and 5 defines the use as "for use as a medicament for the treatment or prophylactic treatment of" while the

appropriate formulation according to Article 54(5) EPC is "product X for use in the treatment...". In the board's judgement, the term "for use as a medicament" renders the scope of these claims unclear because it mixes parts of the "Swiss-type" second medical use formulation ("use of X for the preparation of a medicament for the treatment of") with the formulation according to Article 54(5) EPC (Article 84 EPC).

5. In addition, the preamble of the dependent claims 2 to 4, which are dependent on claim 1, lacks the functional limitation "for use in the treatment". Although these claims are formally dependent on claim 1, which is a "use" claim according to Article 54(5) EPC, the dependent claims 2 to 4 relate to a product which renders it unclear whether or not these claims are in fact "use" claims or rather belong to the category of "product" claims. This deficiency results in unclear claim categories, contrary to the requirements of Article 84 EPC.
6. The board furthermore notes that the subject-matter of claim 11 a) or b) refers solely to the term "a portion thereof" although claim 1 further restricts this term with the functional limitation that the FNIII13 portion has to interfere with the tenascin binding to fibronectin. The board considers that this term therefore lacks clarity because it is no longer clear to the skilled person which portion of the FNIII13 is the suitable marker for the prognosis or diagnosis of cancer (Article 84 EPC).
7. Finally, the board observes that the subject-matter of claim 11 relates in addition to "accessible FNIII13 or a portion thereof". It is not clear from the wording of the claim whether the word "accessible" relates to the

physical accessibility of the fibronectin III 13 polypeptide *per se*, i.e. as a whole or only to a particular structural motif thereof, such as the tenascin binding site. This renders the subject-matter of this claim unclear (Article 84 EPC).

8. For these reasons the board considers that the subject-matter of present claims 1 to 5 and 11 of the main request is unclear and does not comply with the requirements of Article 84 EPC.

Auxiliary Request

Clarity - Article 84 EPC

9. The board notes that the subject-matter of claim 1 of the auxiliary request differs from its corresponding claim of the main request only by restricting the list of diseases claimed to the ones relating to cancer. Otherwise these two claims and claims 2 to 5 and 11 are identical between the two requests (see section IV, above). Accordingly, the reasons outlined above for lack of clarity of the subject-matter of claims 1 to 5 and 11 of the main request (see points 4 to 8) apply *mutatis mutandis* to the auxiliary request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The request for reimbursement of the appeal fee according to Rule 103(1) (a) EPC is rejected.

The Registrar:

The Chairman:



P. Cremona

C. Rennie-Smith

Decision electronically authenticated