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Datasheet for the decision of 27 August 2014

Case Number: T 0879/12 - 3.3.08

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Language of the proceedings: EN

Title of invention:
APO-2 ligand

Applicant:
Genentech, Inc.

Headword:
APO-2 ligand/GENENTECH

Relevant legal provisions:
EPC Art. 125

Keyword:
Double patenting (no) -
scope of swiss type claim and scope of Article 54(5) EPC2000 claim not the same
Remittal to the department of first instance - (yes)

Decisions cited:
G 0005/83, G 0002/88, G 0001/05, G 0001/06, T 1391/07, T 1780/12

Catchword:
see points 10 to 16 of the Reasons

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Case Number: T 0879/12 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 27 August 2014

Appellant: (Applicant)	Genentech, Inc. 1 DNA Way South San Francisco CA 94080-4990 (US)
Representative:	Kiddle, Simon John Mewburn Ellis LLP 33 Gutter Lane London EC2V 8AS (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 30 December 2011 refusing European patent application No. 07022045.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Wieser
Members:	B. Stolz
	C. Heath
	P. Julià
	D. Rogers

Summary of Facts and Submissions

I. The appeal lies against the decision of the examining division to refuse the European patent application No. 07022045.4, which is a divisional application of European patent application No. 06013720.5 which itself is a divisional application of European patent application No. 97903760.3 (hereinafter the grandparent application).

II. The examining division held that claims 1 to 8, filed with letter of 22 October 2009, related to the same subject matter as the claims granted with the grandparent application, and refused the application under Article 97(2) EPC in conjunction with Article 125 EPC.

III. The applicant (appellant) submitted its statement of grounds of appeal and, in a further submission, referred to the identity of the legal issues in the present case and in decision T 1780/12 of 30 January 2014, taken by another board.

IV. Claim 1 of the request before the board, which is identical to the request before the examining division, reads as follows:

"1. An Apo-2 ligand for use in a method for treating cancer, wherein the Apo-2 ligand is:
(a) a polypeptide comprising amino acid residues 41-281 of Figure 1A (SEQ ID NO: 1);
(b) a polypeptide comprising amino acid residues 114-281 of Figure 1A (SEQ ID NO: 1);
(c) a polypeptide consisting of amino acid residues 114-281 of Figure 1A (SEQ ID NO: 1);

(d) a polypeptide consisting of amino acid residues 1-281 of Figure 1A (SEQ ID NO: 1); and
(e) a polypeptide which is a fragment of (a), (b), (c), or (d); and
wherein the cancer is squamous cell carcinoma, small cell lung carcinoma, non-small cell lung carcinoma, neuroblastoma, pancreatic cancer, glioblastoma multiforme, cervical cancer, stomach cancer, bladder cancer, hepatoma, breast cancer, colon carcinoma, head and neck cancer, prostate cancer or ovarian cancer and the Apo-2 ligand induces apoptosis in the cancer cells."

Dependent claims 2 to 8 refer to specific embodiments of the subject matter of claim 1.

V. Claim 1 of the grandparent application as granted reads:

"1. Use of an Apo-2 ligand for the preparation of a medicament for the treatment of cancer, wherein the Apo-2 ligand is:
(a) a polypeptide comprising amino acid residues 41-281 of Figure 1A (SEQ ID NO:1);
(b) a polypeptide comprising amino acid residues 114-281 of Figure 1A (SEQ ID NO:1);
(c) a polypeptide consisting of amino acid residues 114-281 of Figure 1A (SEQ ID NO:1);
(d) a polypeptide consisting of amino acid residues 1-281 of Figure 1A (SEQ ID NO:1); and
(e) a polypeptide which is a fragment of (a), (b), (c), or (d); and
wherein the cancer is squamous cell carcinoma, small cell lung carcinoma, non-small cell lung carcinoma, neuroblastoma, pancreatic cancer, glioblastoma multiforme, cervical cancer, stomach

cancer, bladder cancer, hepatoma, breast cancer, colon carcinoma, head and neck cancer, prostate cancer or ovarian cancer and the Apo-2 ligand induces apoptosis in the cancer cells."

Dependent claims 2 to 8 refer to specific embodiments of the subject matter of claim 1, specifying the same additional features as claims 2 to 8 of the request before the board.

VI. In the decision under appeal, the examining division held that

"1. It is established practice of the EPO first instance departments not to allow that two applications (or a granted patent and an application) from the same applicant claim the same subject-matter. This means not only that the conflicting applications must not contain claims of substantially identical scope, but also that one application must not claim the subject-matter claimed in the other, even in different words. The difference between the claimed subject-matter of the two applications must be clearly distinguishable (Guidelines for Examination, C-VI, 9.1.6 and C-IV, 7.4).

2. A claim directed to a second or further medical use claim under Article 54(5) EPC is considered to be directed to the same subject-matter as a Swiss type claim directed to the same medical use, in the sense that both these claims concern the same invention claimed in a different format.

...

Regarding the arguments based on the (possibly) differing scope of protection accorded to the two formats under national law, it is noted that double

patenting is concerned with the substantial identity of claimed subject-matter and is not related to the (only potential) variance in the scope of protection. For the sake of completeness, it is noted that the EPC legislator considered the two formats discussed here equivalent and clearly stated so in the relevant preparatory documents (OJ EPO, Special edition 4/2007, English version, p. 54).

3. Although the aforementioned passages of the Guidelines make no reference to an EPC provision, in practice double patenting is understood as prohibited under Article 125 EPC.

...

5. The applicant contested that Article 125 EPC be considered as the legal basis in view of T 587/98 (OJ EPO 2000, 497) and T 1423/07 (not published in OJ). The examining division cannot concur with the submitted arguments. While it is noted that individual decisions from the Boards of appeal have no binding effect on the first instance departments beyond the specific case decided therein, the examining division also has the following reasons:

6. The statements concerning the issue of double patenting in T 587/98 were made incidentally and are obiter dicta, not drawing any definitive conclusions with regard to Article 125 EPC. The board only noted that there is no express or implicit provision in the EPC which prohibits the presence in a divisional application of an independent claim which is related to an independent claim in the parent application (or patent if it has already been granted) in such a way that the 'parent' claim includes all the features of

the 'divisional' claim combined with an additional feature (see point 3.7 of the Reasons). The board explicitly pointed out that the question whether there was any legal basis to be found in the law and practice of the Contracting States for the prohibition of "conflicting" claims expressed in the Guidelines did not fall to be decided in that appeal (see point 3.3 of the Reasons).

...

8. Finally, the examining division considers that the prohibition of double patenting is a specific expression of the general principle of legitimate interest in the proceedings (see also point 4 above), which itself is a generally recognised principle of procedural law applicable under Article 125 EPC."

VII. Appellant's arguments can be summarized as follows:

There was no legal basis for raising a double patenting objection except where the claims of a parent and divisional application are identical. The Boards of Appeal and the Enlarged Board of Appeal in decisions G 1/05 (OJ EPO 2008, 271) and G 1/06 (OJ EPO 2008, 307) have recognised that no objection arises where the claims have different scope, even where they might overlap, and/or where the claim of one application includes a feature not present in the other.

The examining division's double patenting objection was based on the premise that Swiss-type claims, referring to a second or further medical use, confer an identical scope of protection as purpose limited product claims that were formulated after the revision of the EPC in the year 2000.

However, the assessment of double patenting turned on the specific question of the wording and scope of the claims in a European patent and a pending application, and in particular whether the claims are identical.

The claims of the grandparent patent referred to a second medical use and were formulated as Swiss-type claims as accepted under the EPC 1973, while the pending claims of the present application were written as purpose limited product claims.

The two claim formats necessarily had a different scope of protection, not least because the Swiss-type claims were use claims directed to the manufacture of a medicament and the purpose limited product claims were directed to a product for use in a method of treating a patient in need of therapy. The examining division, however, disregarded any consideration of the different scope of protection saying that *"double patenting is concerned with the substantial identity of claimed subject-matter and is not related to the (only potential) variance in the scope of protection"* (cf. item VI supra, page 4, point 2 of the decision under appeal).

VIII. The appellant requests that the decision under appeal be set aside and the application be remitted to the department of first instance with the order to grant a patent on the basis of the pending claims 1 to 8 filed with letter of 22 October 2009. Oral proceedings are requested should the board intend to uphold the examining division's decision.

Reasons for the Decision

1. Claims 1 to 8 of the request before the board are identical with claims 1 to 8 of the request before the examining division.

Double patenting

2. The sole ground for refusal of the present patent application was the prohibition of double patenting.

3. Under the EPC 1973 a patent for a further medical application could, pursuant to a line of case law first set out in decision G 5/83 (OJ EPO 1985, 64), be granted for a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified therapeutic application (so called "**Swiss-type claim**") (cf. "Case Law of the Boards of Appeal of the EPO", 7th edition 2013, I.C.6.2.1, 144).

During the course of the revision of the EPC 2000, former Article 54(5) EPC 1973 ("first use in a medical method") was renumbered to become Article 54(4) EPC and a new Article 54(5) EPC was introduced to provide protection for second medical uses. The new Article 54(5) EPC eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits **purpose-restricted product protection** for each further new medical use of a substance or composition already known as a medicine (cf. "Case Law of the Boards of Appeal of the EPO", ibid.).

4. Claim 1 of the present application is in the form of a purpose restricted product claim ("An Apo-2 ligand for use in a method for treating cancer"; cf. item IV above) according to Article 54(5) EPC 2000.

Claim 1 of the grandparent application was granted in the "Swiss-type" format ("Use of an Apo-2 ligand for the preparation of a medicament for the treatment of cancer"; cf. item V above) under the provisions of Article 54(5) EPC 1973.

5. The examining division stated in its decision that a claim directed to a second or further medical use claim under Article 54(5) EPC 2000 was considered to be directed to **the same subject-matter** as a "Swiss-type" claim directed to the same medical use, **in the sense that** both these claims **concerned the same invention** claimed in a different format.

6. The principle of the prohibition of double patenting is based on the idea that the applicant has no legitimate interest in proceedings that give rise to the grant of a second patent in respect of **the same subject-matter** for which he already holds a patent (cf. Reasons 13.4 of decision G 1/05, OJ EPO 2008, 271).

7. The decisive issue is therefore whether the subject matter of claim 1 of the present application is the same as the subject matter of claim 1 of the grandparent application.

8. The present case has much in common with the case underlying decision T 1780/12 of 30 January 2014.

The crucial issue for the main request underlying said decision was also whether the subject matter of a claim directed to a new medical use of a known compound was the same, irrespective of whether the claim was in the "Swiss-type" format or in the format according to Article 54(5) EPC 2000.

Furthermore, the board notes that points 1 and 3 to 8, and, with the exception of a single sentence, all of point 2, of the decision of the examining division underlying the present appeal (see item VI above) can be literally found in points 2 to 10 of the decision of the examining division underlying appeal case T 1780/12 (cf. item VII of decision T 1780/12).

9. Like in the present case, a parent application had been granted with claims in the "Swiss-type" format for the use of a composition comprising a biologically effective amount of an anti-aminophospholipid antibody, or antigen-binding region thereof, in the manufacture of a medicament for the treatment of cancer. A divisional application (underlying T 1780/12) had been filed with a main request comprising purpose-restricted product claims referring to a composition comprising a biologically effective amount of an anti-aminophospholipid antibody, or antigen-binding region thereof, for the treatment of cancer. Further claims, referring to features specifying a mechanism of action, were identical in both types of claims.

The examining division had refused the main request of the divisional application under Article 97(2) EPC in conjunction with Article 125 EPC because, in its view, claim 1 before it related to the same subject matter as granted claims 1, 24 and 25 of the parent application.

10. Regarding the issue of what constitutes the subject matter of a claim, the board in T 1780/12 concluded, by reference to decision G 2/88 (OJ EPO 1990, 93), that the category or type of claim **and** its technical features constitute its subject matter (cf. T 1780/12, Reasons 11 to 13). It was therefore necessary to

establish whether or not the subject matter of the claims as defined by their categories in combination with their technical features was the same.

11. The board stated that Swiss-type claims of the form "Use of X for the manufacture of a medicament for the treatment of Y" are construed as purpose-limited process claims while claims formatted in accordance with Article 54(5) EPC as "X for use in the treatment of Y" are construed as purpose-limited product claims. The categories of the claims are therefore different (cf. T 1780/12, Reasons 16).

Regarding the technical features, the board concluded that both sets of claims defined the same compound and the same therapeutic use, but that the Swiss-type claims comprised in addition the feature of manufacturing a medicament while the claims of the request before it did not (cf. T 1780/12, Reasons 17).

The board therefore decided that the subject matter of the claims of the main request before it was different from the subject matter of the Swiss-type claims of the parent application.

12. The board also dealt with the examining division's argument that "*double patenting is concerned with the substantial identity of claimed subject matter and is not related to the (only potential) variance in granted protection*".

13. In this respect, the board in case T 1780/12, agreed with the finding in decision T 1391/07 of 7 November 2008, that an applicant's lack of legitimate interest in patenting the same subject matter twice, invoked by the Enlarged Board in decision G 1/05 (cf.

point 6, supra) could not be invoked in the case in which the scopes of protection only partially overlapped as there was no objective reason to deny the legitimate interest of an applicant in obtaining a protection different from that of the parent patent already granted (cf. T 1780/12, Reasons 19). Any potential variance in the scope of protection afforded by the claims was therefore crucial to the decision to be taken.

Based on point 3.3 of the Reasons of decision G 2/88, the board concluded that the category of a claim and its technical features constitute its subject matter **and** determine the protection conferred (cf. T 1780/12, Reasons 21). Thus, contrary to the examining division's view, the claimed subject matter and the scope of protection conferred by the claims are intrinsically linked.

Since the purpose limited process claim (Swiss-type claim) and the purpose-restricted product claim according to Article 54(5) EPC 2000 belonged to different categories and differed in at least one technical feature, they differed in the scope of protection afforded (cf. T 1780/12, Reasons 20 to 22).

There was no manifest objective reason to deny the legitimate interest of the appellant in pursuing claims drafted in accordance with Article 54(5) EPC 2000 and thereby obtaining protection different from - albeit partially overlapping - with that of "Swiss-type" claims of the parent application already granted (cf. T 1780/12, Reasons 25).

14. This board agrees with the legal assessment in decision T 1780/12 in that the scope of the claims in both cases

is different, and considers its conclusions to be directly applicable to the present case.

15. In the present case, the claims of the patent application and the grandparent application define the same compound (an Apo-2 ligand defined by features (a) to (e)), and the same therapeutic use (the treatment of the same cancers, as specified in the claims (cf. items IV and V, above). But the subject matter of claim 1 is defined in the format of a purpose-restricted product claim, whereas the subject matter of claim 1 of the grandparent patent is defined in the Swiss-type format.

Since the categories of the claims are different and there is at least one difference in the technical features defining the claimed subject matter (the manufacture of a medicament), the subject matter defined by the claims and the scope of protection conferred by the claims are different.

16. The board therefore decides that granting a patent on the basis of claims 1 to 8 would not lead to double patenting.

17. Since the board does not uphold the decision under appeal, there is no need for oral proceedings (cf. item VIII, above).

18. As the decision under appeal is exclusively concerned with the issue of double patenting (cf. item II above) the Board decides to remit the case to the department of first instance for further prosecution (Article 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution on the basis of

   claims 1 to 8, filed under cover of a letter dated 22 October 2009.

The Registrar: The Chairman:

A. Wolinski M. Wieser

Decision electronically authenticated