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Datasheet for the decision of 30 January 2014

Case Number: T 1780/12 - 3.3.04

Application Number: 04007843.8

Publication Number: 1520588

IPC: A61K39/395, A61K51/10, A61K47/48, A01K67/027, C07K16/00, C07K16/28

Language of the proceedings: EN

Title of invention:
Uses of antibodies to aminophospholipids for cancer treatment

Applicant:
BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM

Headword:
Cancer treatment/BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM

Relevant legal provisions:
EPC Art. 111(1)

Keyword:
Double patenting (no) - not the same subject-matter
Remittal to the department of first instance - (yes)

Decisions cited:
G 0005/83, G 0002/88, G 0001/05, G 0001/06, G 0002/08, T 0250/05, T 0795/06, T 0877/06, T 1391/07, T 1635/09, T 2402/10

Catchword:
See points 16 to 25 of the Reasons

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Case Number: T 1780/12 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 30 January 2014

Appellant: (Applicant)	BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM Office of the General Counsel, 201 West 7th Street Austin, Texas 78701 (US)
Representative:	Walker, Ross Thomson Forresters Skygarden Erika-Mann-Strasse 11 80636 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 27 March 2012 refusing European patent application No. 04007843.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: R. Morawetz
M. Montrone
B. Claes
M.-B. Tardo-Dino

Summary of Facts and Submissions

I. The appeal of the applicant (hereinafter "appellant") lies against the decision of the examining division to refuse the European patent application No. 04007843.8, published as EP 1 520 588 A2 (hereinafter "EP2"). The present application is a divisional application of European patent application No. 99940802.4 which has been granted as EP 1 096 955 B1 (hereinafter "EP1").

II. The examining division held that claim 1 of the main request and of auxiliary request 2 before it related to the same subject-matter as claims 1, 24 and 25 granted for the parent application and that claim 1 of auxiliary request 1 before it related to the same subject-matter as claims 1 and 33 granted for the parent application. It refused the application under Article 97(2) EPC in conjunction with Article 125 EPC.

III. Claims 1, 24, 25 and 33 of EP1 read:

"1. 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 by killing tumor vascular endothelial cells of a vascularised tumor.

24. Use according to any preceding claim, wherein said composition is for use in inducing coagulation in tumor vasculature upon administration to said animal.

25. Use according to any preceding claim, wherein said composition is for use in destroying tumor vasculature upon administration to said animal.

33. Use according to any preceding claim, wherein said composition is for use in combination with a biologically effective amount of a second anti-cancer agent."

IV. Claim 1 of the main request before the examining division (which is identical to claim 1 of the main request before the board) read:

"1. A composition comprising a biologically effective amount of an anti-aminophospholipid antibody, or antigen-binding region thereof, for the treatment of cancer by killing tumor vascular endothelial cells of a vascularised tumor, inducing coagulation in tumor vasculature or destroying tumor vasculature."

V. Claim 1 of auxiliary request 1 before the examining division read:

"1. A composition comprising a biologically effective amount of an anti-aminophospholipid antibody, or antigen-binding region thereof, for the treatment of cancer by killing tumor vascular endothelial cells of a vascularised tumor, inducing coagulation in tumor vasculature or destroying tumor vasculature; wherein said composition is for use in combination with a biologically effective amount of a second anti-cancer agent or for use in combination with radiotherapy."

VI. Claim 1 of auxiliary request 2 before the examining division read:

"1. A composition comprising a biologically effective amount of an anti-aminophospholipid antibody for the treatment of cancer by killing tumor vascular

endothelial cells of a vascularised tumor, inducing coagulation in tumor vasculature or destroying tumor vasculature."

VII. In the decision under appeal the examining division held (see point 2 of the reasons) that: "*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)*". The examining division also noted (see reasons, point 4) that "*Moreover, in G 1/05 and G 1/06 the Enlarged Board of Appeal - albeit in an obiter dictum - accepted that the principle of prohibition of double patenting exists on the basis that an applicant has no legitimate interest in proceedings leading to the grant of a second patent for the same subject-matter if he already possesses one granted patent there for. Therefore, the Enlarged Board found nothing objectionable in the established practice of the EPO that amendments to a divisional application are objected to and refused when the amended divisional application claims the same subject-matter as a pending parent application or a granted parent patent (OJ EPO 2008, 271 and 307 respectively. Reasons 13.4)*". The examining division stated (see reasons, point 9) that: "*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". The examining division also considered (reasons, see point 10) that "*(…) double patenting is concerned with the substantial identity of claimed subject-matter and is not related to the (only potential) variance in the granted 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).*"

VIII. With its statement of grounds of appeal the appellant filed a new main request and new auxiliary requests 1 and 2. Claim 1 of the main request was identical to claim 1 of the main request before the examining division (see section IV above). The preamble of dependent claims 2 to 48 were amended to clarify the claim category but otherwise these claims corresponded to claims 2 to 48 of the main request before the examining division. Two claims, present in auxiliary request 1 before the examining division as claims 49 and 50, were added to the main request as claims 49 and 50. These amendments have no effect on the issues under consideration.

IX. The appellant requested:

- That the decision of the examining division be reversed insofar as it resulted in refusal of this application.

- That the board refer questions posed by the appellant to the Enlarged Board of Appeal so that practitioners were provided with definitive and proper guidance as to

whether a European patent application, or European patent for that matter, could be refused by the European Patent Office because of so called "double-patenting" and, if so, under what circumstances.

- On finding in it's favour, the appellant requested that the board [sic] refund it the appeal fee since this application was refused by the examining division under a non-existent ground of the EPC.

- Oral proceedings in the event that the board was not minded to grant **any** of the above requests. (Emphasis in the letter).

X. By a communication of 15 November 2013 the appellant has been summoned for oral proceedings to be held on 30 January 2014.

XI. In a communication under Article 15(1) RPBA of 6 December 2013 the board informed the appellant of its preliminary view.

XII. In response the appellant submitted new requests with a letter of 2 January 2014.

XIII. In reply the board informed the appellant with a communication dated 17 January 2014 that it considered the requests submitted with its letter of 2 January 2014 unclear.

XIV. With a further letter of 20 January 2014 the appellant filed re-written requests and withdrew its request for referral of questions to the Enlarged Board of Appeal and its request for refund of the appeal fee.

XV. Oral proceedings took place on 30 January 2014 in the absence of the duly summoned appellant.

XVI. The arguments of the appellant may be summarised as follows:

A European application could not be refused for the reasons of double patenting pursuant to Article 97(2) EPC because there was no section in the Convention which expressly dealt with double patenting.

Albeit in *obiter dictum*, the Enlarged Board of Appeal in decisions G 1/05 and G 1/06 accepted the principle of the prohibition of double patenting on the basis that an applicant had no legitimate interest in proceedings leading to the grant of a second patent for the same subject-matter.

The claims of EP1 and EP2 related to different subject-matter. The majority of the case law stated that scope was important, yet the examining division completely overlooked this in their definition of the same subject-matter.

It was evident that on considering whether the parent and divisional claimed the same subject matter, it was clear that the scope of the respective claim sets was relevant. Contextually, what the Guidelines were saying was that to claim the same subject-matter the claims had to be of substantially identical scope.

The claims of EP1 were formatted in accordance with decision G 5/83. It was widely accepted that this format of claim was a purpose-limited process claim. By comparison, the claims of the present application (EP2) were formatted in accordance with Article 54(5) EPC

2000. These claims were purpose-limited product claims, i.e. the product when packaged for that use.

A claim directed towards the second or further therapeutic use of a substance or composition formatted under Article 54(5) EPC and a Swiss-type claim directed towards the same therapeutic use of the same substance or composition were not directed towards the same subject matter. One claim was a purpose-limited process claim whereas the other was a purpose-limited product claim. They might be directed towards the same inventive concept, but they were clearly distinguishable in scope.

The claims in the present application, which were drafted under Article 54(5) EPC 2000 were not of substantially identical scope to the claims of EP1096955 (EP1), i.e., Swiss-type claims. The fact that these claim formats differed in scope was confirmed by the Enlarged Board of Appeal in decision G 2/08 (see Reasons for the decision at section 6.5).

Decisions G 1/05 and G 1/06 referred to the same subject-matter. If the claims were not at least substantially identical in scope, they could not constitute the same subject matter. A process claim and a product claim could not be substantially identical in scope.

For the reasons stated above, the claims were clearly distinguishable in scope and therefore were not directed to the same subject matter.

XVII. The appellant requested in writing that the decision under appeal be set aside and the case be remitted to the department of first instance for further

prosecution on the basis of the main request filed with the statement of grounds of appeal.

Reasons for the Decision

1. The sole ground for refusal of the present application was the prohibition of double patenting. The examining division held (see section VII above) that a claim directed towards the second or further therapeutic use of a substance or composition formatted under Article 54(5) EPC and a Swiss-type claim directed towards the same therapeutic use of the same substance or composition were directed towards the same subject-matter "*in the sense that both these claims concern the same invention claimed in a different format*".

2. It had been established practice under the EPC 1973 that a patent related to a further medical application of a known medicament could only 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"). This practice was based on decision G 5/83 of the Enlarged Board of Appeal (OJ EPO 1985, 64) which had filled a gap in the legal provisions and extended the notional novelty provided for in Article 54(5) EPC 1973 for the first medical use to further medical use claims when drafted in the above format. The law itself (EPC 1973) did not contain any notional acknowledgement of novelty of a claim directed to a further medical use.

3. The provisions of Article 54(5) EPC fill this gap in the former provisions. Article 54(5) EPC now permits purpose-restricted product protection of any substance or composition comprised in the state of the art for any specific use in a method referred to in Article

53(c) EPC (see decision G 2/08 of the Enlarged Board of Appeal, OJ EPO 2010, 456, reasons, points 5.9, 5.10.2, 6.4 and 6.5).

4. The major reason for the amendment of the EPC to allow purpose-limited product claims for further medical use claims was to create greater legal certainty in relation to the patentability of further medical use claims and to overcome doubts as to the validity of the Swiss-type claims (see Travaux Préparatoires, CA/PL 4/00, points 6 to 8; MR/24/00, point 141). As pointed out by the Enlarged Board in decision G 2/08 (*supra*, reasons, point 7.1.3), "*Swiss-type claims could be (and have been) considered objectionable as regards the question as to whether they fulfill the patentability requirements, due to the absence of any functional relationship of the features (belonging to therapy) conferring novelty and inventiveness, if any, and the claimed manufacturing process.*"

5. The examining division based its refusal (see section VII above) on established practice of the EPO departments of first instance (see Guidelines for Examination, C-VI, 9.1.6 and C-IV, 7.4) and decisions G 1/05 and G 1/06 of the Enlarged Board of Appeal (OJ EPO 2008, 271 and 307, respectively).

6. The relevant passages of the Guidelines for Examination (April 2010) in force at the time the decision under appeal was taken read as follows:

"*C-IV, 7.4 Double patenting*
The EPC does not deal explicitly with the case of co-pending European applications of the same effective date. However, it is an accepted principle in most patent systems that two patents cannot be granted to

the same applicant for one invention. It is permissible to allow an applicant to proceed with two applications having the same description where the claims are quite distinct in scope and directed to different inventions. However, in the rare case in which there are two or more European applications from the same applicant definitively designating the same State or States (by confirming the designation through payment of the relevant designation fees) and the claims of those applications have the same filing or priority date and relate to the ***same invention (the claims conflicting in the manner explained in VI, 9.1.6****), the applicant should be told that he must either amend one or more of the applications in such a manner that they no longer claim the same invention, or choose which one of those applications he wishes to proceed to grant. Should two applications of the same effective date be received from two different applicants, each must be allowed to proceed as though the other did not exist.*" (Emphasis added), and

"*C-VI 9.1.6 Claims*
The parent and divisional applications ***may not claim the same subject-matter*** *(see IV, 7.4). This means not only that they 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. As a general rule, however, one application may claim its own subject-matter in combination with that of the other application. In other words, if the parent and divisional applications claim separate and distinct elements A and B respectively which function in*

combination, one of the two applications may also include a claim for A plus B." (Emphasis added).

7. These passages of the Guidelines for Examination thus restrict the prohibition of double patenting to applications claiming the same invention, and more specifically to parent and divisional applications claiming "the same subject-matter". Thus, pursuant to the Guidelines, in order to determine whether or not the same invention is claimed, the claimed subject-matter has to be determined first.

8. The Enlarged Board of Appeal has accepted in decisions G 1/05 and G 1/06 (*supra*, see point 13.4 of the - identical - reasons) in connection with divisional applications that the principle of prohibition of double patenting exists on the basis that an applicant has no legitimate interest in proceedings leading to the grant of a second patent for the same subject-matter if he already possesses one granted patent there for.

9. The board notes that the requirement that the claimed subject-matter must be the same for the double patenting prohibition to apply is generally followed by the Boards of Appeal in more recent decisions, see for instance decisions T 1391/07 of 7 November 2008 (reasons, point 2), T 877/06 of 2 December 2009 (reasons, point 5), and T 2402/10 of 10 May 2012 (reasons, point 8).

10. Therefore, the board finds it appropriate to address first the issue of what constitutes the claimed subject-matter in the case under consideration.

Subject-matter

11. In decision G 2/88 (OJ EPO 1990, 93, see point 2 of the reasons) the Enlarged Board of Appeal was confronted with two points of law concerned with the interpretation and effect of patent claims. The Enlarged Board of Appeal considered (*ibid.*, point 2.6 of the reasons) that: "*(…) the subject-matter of a claimed invention involves two aspects: first, the category or type of the claim, and second, the technical features, which constitute its technical subject-matter.*"

12. The Enlarged Board of Appeal also noted (*ibid.*, see point 3.3 of the reasons) that "*There is a clear distinction between the protection which is conferred and the rights which are conferred by a European patent, however. The protection conferred by a patent is determined by the terms of the claims (Article 69(1) EPC), and in particular by the categories of such claims and their technical features. In this connection, Article 69 EPC and its Protocol are to be applied, both in proceedings before the EPO and in proceedings within the Contracting States, whenever it is necessary to determine the protection which is conferred. In contrast, the rights conferred on the proprietor of a European patent (Article 64(1) EPC) are the legal rights which the law of a designated Contracting State may confer upon the proprietor, for example, as regards what acts of third parties constitute infringement of the patent, and as regards the remedies which are available in respect of any infringement.*"

13. In the board's judgement, it follows from decision G 2/88, *supra*, that the category of a claim and its

technical features constitute its subject-matter and determine the protection conferred. This board is not aware of any different, commonly accepted definition of the term "subject-matter" in the context of a claim. While the board agrees with the examining division that EP1 and the present application relate to the same invention, the board concludes that the approach taken by the examining division when finding that the same invention *eo ipso* had to mean that the same subject-matter was claimed is neither supported by the Guidelines nor by the case law.

14. In the present case, what has to be considered and decided is whether or not the subject-matter of the claims, as defined by their categories in combination with their technical features, is the same for the claims granted for EP1 and pending for the main request.

15. The appellant disputes that the subject-matter of the claims granted for EP1 is the same as that of the main request (see section XVI above).

16. Claims 1, 24 and 25 of EP1 are formatted in accordance with decision G 5/83, *supra*, as so-called Swiss-type claims (see section III above for the complete wording of the claims). These claims take the form "Use of X for the manufacture of a medicament for the treatment of Y", i.e. they are purpose-limited process claims. The claims of the main request are formatted in accordance with Article 54(5) EPC (see section IV above for the complete wording of the claims). These claims take normally the form "X for use in the treatment of Y" and are construed as purpose-limited product claims. Thus, the categories of the claims granted for EP1 and of the claims pending as main request, respectively,

are different.

17. As regards the technical features, both set of claims define the same compound and the same therapeutic use but the claims of EP1 comprise in addition the manufacture of a medicament while the claims of the main request do not (again, see sections III and IV above for the complete wording of the claims). The board concludes that the claimed subject-matter is different between EP1 and the main request.

Scope of protection

18. The examining division further held (see section VII above) that *"double patenting is concerned with the substantial identity of claimed subject-matter and is not related to the (only potential) variance in the granted protection".*

19. As set out above (see points 12 and 13), the claimed subject-matter and the scope of protection conferred by the claims are intrinsically linked. Indeed, as pointed out in decision T 1391/07 (*supra*, reasons, point 2.6) the practice of prohibition of "double patenting" is confined to patents and applications directed to the same invention as defined by the subject-matter of the corresponding claims and is therefore confined to claims conferring notionally the same scope of protection. In particular, in decision T 1391/07 (*supra*, *ibid.*) the then competent board considered that the lack of legitimate interest invoked by the Enlarged Board in decisions G 1/05 and G 1/06, *supra*, could not be invoked in the case in which the scopes of protection conferred by the respective subject-matters overlap only partially with each other as there was no manifest objective reason to deny the legitimate

interest of the applicant in obtaining a protection different from - although partially overlapping with - that of the parent patent already granted. This board agrees with this assessment.

20. The board concludes that, contrary to the position taken by the examining division, the potential variance in the protection afforded by both formats of second or further medical use claims is crucial to the decision to be taken.

21. As set out in decision G 2/88 (*supra*, see reasons, point 3.3) the "(...) *determination of the "extent of the protection conferred" by a patent under Article 69(1) EPC is a determination of what is protected in terms of category plus technical features (...)*".

22. It follows from the above analysis (see points 16 and 17) that the claims under consideration belong to different categories, i.e. purpose-limited process claim vs. purpose-limited product claim and differ in addition in at least one technical feature. It is generally accepted as a principle underlying the EPC that a claim to a particular physical activity (e.g. method, process, use) confers less protection than a claim to the physical entity *per se*, see decision G 2/88 (*supra, r*easons, point 5). It follows that a purpose-limited process claim also confers less protection than a purpose-limited product claim. The scope of protection sought by the invention claimed pursuant the present main request is thus noticeably different from the scope of protection conferred by claims 1, 24 and 25 of EP1, see also decisions T 0795/06 of 18 March 2010 (points 6.3 to 6.4 of the reasons) and T 1635/09 of 27 October 2010 (points 14

and 15.1 of the reasons).

23. As regards the last argument of the examining division, namely that the EPC legislator considered the two claim formats equivalent (see section VII above), the board notes that it was the intention of the legislator to provide a claim format which afforded an equivalent protection, as far as the further medical uses are concerned, to that offered by the Swiss-type claim, see decision G 02/08 of the Enlarged Board (OJ EPO 2010, 456, point 5.10.4 of the reasons) where it refers to preparatory document MR/18/00, point 4 as indicating the intention of the legislator when introducing Article 54(5) EPC as follows: "*The new Article 54(5) EPC eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose—related product protection for each further new medical use of a substance or composition already known as a medicine. This protection is equivalent, as far as the further uses are concerned, to that offered by the 'Swiss type claim'. In contrast to previous Article 54(5), now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) is expressly limited to a specific use.* ***This limitation is intended to match as closely as possible the scope of protection to the scope provided by a 'Swiss type claim'.***" (Emphasis added).

24. That the scope of protection conferred by a Swiss-type claim and a claim pursuant to Article 54(5) EPC is notionally different has been established above (see point 22). Indeed, board 3.3.02 has also held in decision T 250/05 of 4 March 2008 (see reasons, points 3.5 and 3.6) that "*Article 123(3) EPC would not allow*

the change of category of a granted use claim [second medical use claim in Swiss-type claim format] *into a product claim, even if drafted as a purpose-related product claim* [pursuant to Article 54(5) EPC]". In this board's judgement this indicates that that board considered that the scope of protection conferred by a purpose-related product claim was in fact larger than the scope of protection conferred by a Swiss-type claim.

25. It follows from the above analysis that the subject-matter and the scope of protection conferred by claims 1, 24 and 25 granted for EP1 differ from the subject-matter and the scope of protection conferred by claim 1 of the main request. The board is thus satisfied that there is no manifest objective reason to deny the legitimate interest of the applicant in pursuing claims drafted in accordance with Article 54(5) EPC and thereby obtaining protection different from - albeit partially overlapping - with that of the Swiss-type claims of the parent patent already granted.

26. The board concludes that the grant of a patent on the basis of present claim 1 would not lead to double patenting. The appeal is thus allowable.

27. In these circumstances there is no need for the board to address the issue of the legal basis for the prohibition of double patenting in the EPC.

Note by the board

28. For the avoidance of any misunderstandings, the board notes that while for the determination of whether or not the prohibition of double patenting applies in connection with divisional applications, the claimed

subject-matter must be compared, that for the assessment of whether or not the requirements of Article 76(1) EPC are fulfilled, it has to be determined whether the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the earlier application, as a whole. Similarly, for the assessment of whether or not an amendment introduces subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC) and for the assessment of whether or not a claim is entitled to the claimed priority (Article 87 EPC) the whole content of the application as filed, and the previous application, respectively, are to be considered.

Remittal

29. The sole reason for the refusal of the patent application referred to in the decision under appeal is the prohibition of double patenting. The examining division has not indicated whether it considered the requirements of the EPC fulfilled or not. The present main request differs from the main request before the examining division (see section VIII above).

30. Pursuant to Article 111(1) EPC, following the examination as to the allowability of the appeal, the board shall decide on the appeal and, in this respect, it may either exercise any power within the competence of the department which was responsible for the decision or remit the case for further prosecution.

31. In the present case the board considers it appropriate to remit the case to the department of first instance.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the main request filed with the statement of grounds of appeal.

The Registrar: The Chairman:

P. Cremona C. Rennie-Smith

Decision electronically authenticated