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D E C I S I O N
of 11 May 2005

Case Number: T 0870/04 - 3.3.8

Application Number: 97930715.4

Publication Number: 0914452

IPC: C12N 15/54

Language of the proceedings: EN

Title of invention:
Novel PTP20, PCP-2, BDP1, CLK and SIRP proteins and related products and methods

Applicant:
Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V.

Opponent:
-

Headword:
BDP1 Phosphatase/MAX-PLANCK

Relevant legal provisions:
EPC Art. 52(1), 57
EPC R. 23e(3), 27(1)(f)

Keyword:
"Main request and auxiliary request - industrial application (no)"

Decisions cited:
T 0144/83, T 0338/00

Catchword:

(1) Merely because a substance (here: a polypeptide) could be produced in some ways does not necessarily mean that the requirements of Article 57 EPC are fulfilled, unless there is also some profitable use for which the substance can be employed (cf. point 4 of the reasons).

(2) For the purposes of Article 57 EPC, the whole burden cannot be left to the reader to guess or find a way to exploit an invention in industry by carrying out work in search for some practical application geared to financial gain without any confidence that any practical application exists (cf. point 19 of the reasons). A vague and speculative indication of possible objectives that might or might not be achievable by carrying out further research with the tool as described is not sufficient for fulfilment of the requirement of industrial applicability. The purpose of granting a patent is not to reserve an unexplored field of research for an applicant (cf. point 21 of the reasons).

(3) In cases where a substance, naturally occurring in the human body, is identified, and possibly also structurally characterised and made available through some method, but either its function is not known or it is complex and incompletely understood, and no disease or condition has yet been identified as being attributable to an excess or deficiency of the substance, and no other practical use is suggested for the substance, then industrial applicability cannot be acknowledged. Even though research results may be a scientific achievement of considerable merit, they are not necessarily an invention which can be applied industrially. (cf. point 6 of the reasons).

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0870/04 - 3.3.8

D E C I S I O N
of the Technical Board of Appeal 3.3.8
of 11 May 2005

Appellant: Max-Planck-Gesellschaft zur Förderung
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 19 February 2004 refusing European application No. 97930715.4 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: L. Galligani
Members: P. Julià
S. C. Perryman

Summary of Facts and Submissions

I. The applicant (appellant) lodged an appeal against the decision of the examining division whereby the European patent application No. 97 930 715.4 filed on 17 June 1997 (published as WO 97/48723) with the title "Novel PTP20, PCP-2, BDP1, CLK and SIRP proteins and related products and methods" was refused pursuant to Article 97(1) EPC. The decision under appeal was based on a set of 24 claims filed on 4 March 2003. The reasons for the rejection were objections in relation to added subject-matter (Article 123(2) EPC), lack of support (Article 84 EPC), insufficient disclosure (Article 83 EPC), lack of novelty (Article 54(3)(4) EPC), lack of inventive step (Article 56 EPC) and lack of industrial application (Article 57 EPC).

II. With the statement of grounds of appeal filed on 16 June 2004, the appellant submitted a new set of 16 claims (main request).

III. The board sent a communication pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal (RPBA) indicating its preliminary non-binding opinion on all the pending issues. The appellant's attention was drawn to the review article D12 (see Section VIII infra).

IV. Submissions in reply to the board's communication were filed on 11 April 2005 together with an auxiliary request.

V. Oral proceedings took place on 11 May 2005.

VI. Claims 1, 13-14 and 16 of the **main request** read as follows:

"1. An isolated, enriched or purified BDP1 polypeptide comprising at least 200 contiguous amino acids of the amino acid sequence of Figure 3."

"13. A method of identifying a compound capable of activating or inhibiting BDP1 protein phosphorylation activity, wherein said method comprises:
(a) adding a compound to a mixture containing the polypeptide of any of claims 1 to 3 and a substrate for said polypeptide; and
(b) detecting a change in phosphorylation of said substrate."

"14. A method of identifying compounds useful for diagnosis or treatment of an abnormal condition in an organism, wherein said abnormal condition is associated with an aberration in a signal transduction pathway characterized by an interaction between the polypeptide of any of claims 1 to 3 and a natural binding partner, the method comprising:
(a) adding a compound to cells; and
(b) detecting whether the compound promotes or disrupts said interaction between the polypeptide and a natural binding partner."

"16. A pharmaceutical composition comprising the polypeptide of any of claims 1 to 3."

Claims 2 to 3 were directed to further embodiments of claim 1. Claims 4 to 6 related to BDP1 nucleic acid molecules encoding the polypeptide of claims 1 to 3,

whereas claims 7, 8 and 9 related, respectively, to a nucleic acid vector, a recombinant nucleic acid molecule and a recombinant host cell or tissue comprising the BDP1 nucleic acid molecule. Claims 10 and 11 related, respectively, to antibodies or fragments thereof having binding affinity to BDP1 and to hybridomas producing them. Claim 12 was concerned with a method of detecting a compound capable of binding to the polypeptide of any of claims 1 to 3. Claim 15 was directed to a pharmaceutical composition comprising the antibody of claim 11.

VII. The **auxiliary request** differed from the main request by the deletion of claims 10, 11, 14 and 15 and the deletion of the wording "*isolated, enriched or purified*" in claims 1, 3, 4 and 6 of the main request.

VIII. The following documents are cited in the present decision:

D1: Q. Yang et al., J. Biol. Chem., 25 March 1993, Vol. 268(9), pages 6622 to 6628;

D3: H. Saito and M. Streuli, Cell Growth & Differentiation, January 1991, Vol. 2, pages 59 to 65;

D11: M. Gensler et al., J. Biol. Chem., 26 March 2004, Vol. 279(13), pages 12110 to 12116;

D12: D.A. Pot and J.E. Dixon, Biochim. et Biophys. Acta, 1992, Vol. 1136, pages 35 to 43.

IX. The appellant's arguments in writing and during oral proceedings may be summarised as follows:

Articles 52(1) and 57 EPC, Rules 23e(3) and 27(1)(f) EPC

The present application related to the general field of phosphatases, in particular protein tyrosine phosphatases (PTPases), and among them it was concerned with the specific non-transmembrane (cytosolic) PTPase BDP1 ("Brain Derived Phosphatase 1"). PTPases and tyrosine kinases (TKs) were known in the prior art to be involved in cellular signal transduction pathways. At the priority date of the present application, the compounds involved in these signal cascade pathways were not yet fully characterized. Scientific studies were carried out to determine them and to elucidate a complete signal transduction pathway. In this context, progress in the understanding of the function and role of the TKs (and the resulting phosphorylation events) in cellular pathways was extensive, including the identification of several TKs in tumour cell growth (cancer), such as the TK activity of the EGF receptor HER2 in colon cancer. However, the situation was different for the PTPases which were considered to have a more general function by affecting only in a non-specific and indirect manner the effects of these TKs. The technical contribution of the present application had to be assessed in the context of this general prior art. Since there was a very limited number of available PTPases, in particular non-transmembrane PTPases, having a well characterized biological function, the disclosure of a biological

role for these enzymes represented an important technical contribution to this prior art.

In this respect, the application disclosed the molecular characterization of a newly identified PTPase (BDP1) and revealed specific features that enabled the elucidation of its cellular function. BDP1 was shown to belong to the PTPase-PEST family of PTPases, a family characterized by the occurrence of PEST sequences (rich in Pro, Glu/Asp, and Ser/Thr) which were believed to provide a mechanism for rapid cellular turnover. The location of the PEST motifs at the C-terminal of the catalytic domain and the lack of other conserved sequence motifs distinguished these enzymes from other PTPases. Importantly, BDP1 could be distinguished from other known members of the PTP-PEST family by several parameters, namely: (i) a much lower molecular weight, (ii) a much higher average hydrophobicity, and (iii) the absence in its C-terminal tail (residues 295-459) of any nuclear localization signals or Ser-phosphorylation sites found in other family members and which normally were key determinants for the intracellular localization and the substrate specificity of these enzymes. Interestingly, the N-terminal region of BDP1 (residues 1-25) was found to be homologous to the yeast and human CAP proteins which were known to be linked to Ras-signalling and appeared to be essential for cell growth. Thus, from the **structural** features of BDP1 it was readily apparent that BDP1 had some specific functions in the cell and/or was located in discrete cellular targets/compartments.

Furthermore, BDP1 exhibited a restricted gene expression profile which also suggested a specific cellular function. High levels of BDP1 mRNA were found in several cancer cell lines, whereas basic expression was detected in brain, colon, and the human epithelial cell line Caki-1. No BDP1-specific signal could be detected in any other tissues and cell lines tested. The expression of the BDP1 gene was in general much higher in tumour cell lines than in normal cells and tissues. BDP1 was shown to dephosphorylate several TKs *in vivo* in a substrate-specific manner. In particular, co-transfection of a cell with BDP1 led to virtually complete dephosphorylation of auto-phosphorylated EGF (HER), PDGF and c-kit, whereas there was only a partial effect on insulin receptor (EIR). This was the first demonstration of substrate selectivity *in vivo* for a non-transmembrane PTPase, showing that the function of BDP1 in cell growth and proliferation (cancer) was not - as assumed in the prior art - general and unspecific but, on the contrary, specific and restricted only to a few substrates. These (**functional**) results lent support to the suggestion made in the prior art as regards an anti-cell proliferation activity of PTPases, i.e. acting as tumour suppressor agents, that reversed the effects of unrestricted or deregulated expression of specific TKs.

BDP1 was the first non-transmembrane PTPase for which this combination of distinct **structural** and **functional** features was disclosed, making this PTPase a promising target for the manufacture of anti-cancer drugs and for the elucidation of the molecular mechanisms underlying cancer development. Post-published evidence was also provided demonstrating the correctness of the

conclusions arrived at in the application with regard to the cellular function and therapeutic potential of BDP1.

In the biotechnological field and more particularly in genetic engineering, it was common to accept the elucidation and disclosure of a biological effect or a specific cellular function for a particular compound as a (technical) basis for claims directed to medical applications and to pharmaceutical compositions comprising the said compound, since the development of pharmaceutical compositions was made available to the skilled person once this effect and/or function was disclosed. This was also in line with the established jurisprudence of the boards of appeal, which did not require any practical evidence or experimental support for demonstrating how to carry out an invention as long as the invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The elucidation of such a biological effect and/or cellular function provided a technical contribution that was considered to justify an industrial application, to define the technical problem underlying the application and to allow the assessment of a possible inventive contribution.

In the present case, the experimental results disclosed in the application clearly suggested and identified a role of BDP1 in cancer, namely a tumour-suppressor activity in several specific cancers. Therefore, the non-transmembrane PTPase BDP1 was made readily available to the skilled person as a suitable target for therapy intervention and a promising drug-candidate. Based on this disclosure the skilled person was put in

a position to perform normal and/or standard pharmaceutical-clinical studies that, depending on their outcome, would lead to the development and optimization of the most suitable pharmaceutical compositions.

X. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed on 16 June 2004 or of the auxiliary request filed on 11 April 2005.

Reasons for the Decision

Procedural matters

1. In the present case, a key question for the assessment of compliance with the requirements of the EPC is common to the main request and the auxiliary request, namely whether the invention as disclosed in the application is "susceptible of industrial application". Therefore, it is considered expedient to deal with this key question and to leave aside the issue of compliance of the requests with other articles of the EPC.

Main request and auxiliary request
Articles 52(1) and 57 EPC, Rules 23e(3) and 27(1)(f) EPC

2. According to Article 52(1) EPC for a European patent to be granted an invention has to satisfy *inter alia* the requirement of being "susceptible of industrial application". According to Article 57 EPC, this requirement is fulfilled if the invention "can be made or used in any kind of industry, including agriculture".

In this respect, Rule 27(1)(f) EPC prescribes that the description should "indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry." Rule 23e(3) EPC, which is in relation to biotechnological inventions, similarly requires that "the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application".

3. The case law indicates that the notion of "industry" has to be interpreted broadly to include all manufacturing, extracting and processing activities of enterprises that are carried out continuously, independently and for financial (commercial) gains (cf. e.g. T 144/83 OJ EPO 1986, 301, see point 5 of the reasons).

4. The requirement of Article 57 EPC that **the invention** "can be made or used" in at least one field of industrial activity emphasizes that a "practical" application of the invention has to be disclosed. Merely because a substance (here: a polypeptide) could be produced in some ways does not necessarily mean that this requirement is fulfilled, unless there is also some profitable use for which the substance can be employed.

5. Biotechnological inventions are quite often concerned with substances found in nature (e.g. a protein, a DNA sequence, etc.). In cases where the structure and function of the substance is elucidated and means are provided for extracting it or producing it in large amounts, industrial applicability exists in relation to

the possibility to exploit the information and technical means disclosed in order to manufacture the substance and use it for some function related to its natural one or for some other previously unknown (now disclosed) function or as a starting material for making useful analogs or derivatives with some improved features. If a function is well known to be essential for human health, then the identification of the substance having this function will immediately suggest a practical application in the case of a disease or condition caused by a deficiency, as was the case, for example, for insulin, human growth hormone or erythropoietin. In such cases, an adequate description will ensure in accordance with the requirements of Article 57 EPC that "**the invention** can be made or used in industry" (emphasis added).

6. In cases where a substance, naturally occurring in the human body, is identified, and possibly also structurally characterised and made available through some method, but either its function is not known or it is complex and incompletely understood, and no disease or condition has yet been identified as being attributable to an excess or deficiency of the substance, and no other practical use is suggested for the substance, then industrial applicability cannot be acknowledged. While the jurisprudence has tended to be generous to applicants, there must be a borderline between what can be accepted, and what can only be categorized as an interesting research result which per se does not yet allow a practical industrial application to be identified. Even though research results may be a scientific achievement of considerable

merit, they are not necessarily an invention which can be applied industrially.

7. In the present application, while the claimed BDP1 polypeptide is described as a substance found in the human body and as having unique properties, the question arises whether any disclosure or suggestion has been made as to how these properties of BDP1 might be exploited.

The general disclosure of the application

8. As a general background of the invention, the application refers to prior art concerned with protein kinases and phosphatases and identifies these enzymes as being involved in the balance and regulation of the flow of signals in signal transduction processes. Reference is made to the suggested involvement of protein phosphatases in cellular proliferation and differentiation process. In particular, it is stated that "tyrosine phosphatases can down-regulate the catalytic activity of protein kinases involved in cell proliferation and are therefore thought to be possible candidate anti-cancer proteins" (cf. page 2, lines 24 to 27 of the published application). The application further refers to the need to "identify additional proteins whose inappropriate activity may lead to cancer or other disorders so that pharmaceutical compounds for the treatment of those disorders might also be identified" (cf. page 2, line 35 to page 3, line 2). This general background indicates that the industrial application of the present invention is to be found in the pharmaceutical industry.

9. In line with this purpose, the application identifies and characterizes not only BDP1 but also several other protein phosphatases (PTP20, PCP-2) as well as protein kinases (mCLK2, mCLK3, mCLK4) and substrates thereof (SIRP1 and SIRP4). Notwithstanding a common activity (phosphorylation/dephosphorylation) and a shared general function (cellular signal transduction), the application shows that every product has unique properties (amino acid sequence, structural domains, substrate specificity, cellular location, etc.) that might reflect specific functions, such as a role in cell-cell recognition and adhesion for PCP-2 (cf. page 6, lines 1 to 7 and page 86, example 7), in growth and survival of neurons for PTP20 (cf. page 85, example 6), etc. Moreover, in line with the complexity of cellular signal transduction pathways and the multiple interconnections (network) of these pathways, the specific function of a given product is not limited to a single one. Multiple functions appear also to be a feature of the "Brain Derived Phosphatase 1" (BDP1) identified in the application, which is the subject of the claims at issue.

The specific disclosure in relation to the claimed subject-matter, i.e. BDP1

10. The present application discloses in particular the cloning, isolation and identification of structural properties of the non-transmembrane (cytosolic) protein tyrosine phosphatase BDP1 (cf. pages 71 to 75), which is "expressed in most tissues and cell lines at basal level, but expressed high in epithelium origin cell lines and cancer cell lines", an expression pattern that "suggest a role for BDP-1 in certain cancers" (cf.

page 5, lines 23 to 26 and page 78, line 30 to page 79, line 5). In order to elucidate the function of BDP1, reference is made to studies of the dephosphorylation activity of BDP1 on several receptor-mediated autophosphorylations by co-transfection with chimeric tyrosine kinases into human 293 cells, in particular for the receptors of epidermal growth factor (HER), platelet-derived growth factor (EP), insulin (EIR), kit (EK) as well as for src. It is reported that the results of these studies suggest "that BDP1 PTPase may play a housekeeping role to maintain itself and may have enzymatic specificity to intracellular substrate as well" (cf. page 84, line 15 to page 85, line 18). Therefrom it follows that BDP1 is somehow involved in cellular signal transduction pathways and it might play a possible role in **cellular housekeeping** and in certain types of **cancer**.

11. However, the application does not explicitly disclose the specific nature and the possible significance of these suggested roles for BDP1. Contrary to the assertions of the appellant, the application stops short of suggesting, let alone identifying, an anti-cancer activity for BDP1 or a therapeutic use of BDP1 as a tumour-suppressor agent. There is no evidence as to whether BDP1 plays a passive role (as by-product of certain cancerous processes only) or an active role in cancer and whether, in the latter case, the said role is a positive (promoting and/or supporting tumour growth and/or differentiation) or a negative (tumour-suppressor) one. Moreover, taking into account the fact that both cancer and cellular housekeeping are complex cellular processes which involve a large number of genes and/or proteins with multiple specific

interconnections and finely tuned regulations (reflecting the complexity of the cellular signal transduction pathways), the nature and significance of these roles cannot be inferred from the application itself since the over-expression/under-expression of a single signal (BDP1) may not result in a simple effect but in multiple and unexpected ones (alteration of housekeeping system) within these complex and finely regulated cellular pathways, i.e. the modulation or alteration of one single signal (BDP1) does not take place in a simple black-or-white manner but in a complex network of interconnected pathways.

12. Nor can the identification of BDP1 as a PTP-PEST be taken as any clear identification of its function or use, as the prior art does not attribute clear functions to PTP-PESTs as a class. Thus, document D1 refers to the phosphorylation of tyrosyl residues in proteins as "a key component of the control of many fundamental physiological processes" and reports that *in vivo* this phosphorylation is "a reversible, dynamic process in which the net level of phosphate ... is a reflection of the balance between the competing action of kinases and phosphatases" (cf. page 6622, paragraph bridging left-hand and right-hand columns). The same document discloses the cloning and characterization of a non-transmembrane protein phosphatase PTP-PEST from human skeletal muscle, which is suggested to play a role in long term signalling responses to insulin and in insulin-resistance (cf. page 6622, right-hand column, full paragraph). References are made to other PTP-PEST and related phosphatases (PTP-PEP) and to observations that suggest a "fundamentally important role for PTP-PEST in cellular function" (cf. page 6628,

left-hand column, first full paragraph). Thus, document D1 supports the general involvement of PTPases in fundamental (housekeeping) cellular functions but it is silent on a possible role in abnormal cellular growth or cancer.

13. Document D3 is a review article which refers to PTPases as "a family of diverse, regulated enzymes that may play a key role in signal transduction" (cf. page 59, left-hand column, first paragraph). Reference is made to the presence of two types of PTPases, low molecular weight cytosolic PTPases and high molecular weight membrane-associated PTPases. PTP-1B and TC-PTP are given as examples of the former type of PTPases and studies on PTP-1B suggest "an important role of PTPases in the regulation of insulin action and cell cycle progression" (cf. page 59, right-hand column, second full paragraph). As a conclusion, document D3 states that "the increasing insight into the structure and function of PTPases will help to dissect the role of protein tyrosine phosphorylation in the regulation of cell growth and differentiation" (cf. page 63, left-hand column, full paragraph). Thus, this document does not add anything further to the disclosure of document D1 and shows that identification of BDP1 in the application as a PTP-PEST allowed no clear deduction as to its function or uses to be made.

14. Document D12, a prior art review of the PTPases, refers to the two families of PTPases, the receptor and the non-receptor PTPases, wherein the latter can be further divided into additional subfamilies. Figure 1 discloses the primary structures with the identified domains of several non-receptor PTPases and shows that most

PTPases contain functionally important sequences other than the conserved PTPase domain (cf. page 36). The document refers to initial studies which identified tyrosine phosphorylation in the removal of growth restraints from transformed cells (with oncogenes from tumorigenic viruses) and in the control of cell growth in non-transformed cells (cf. page 35, right-hand column). Thus, the possible action of PTPases as tumour suppressor genes has been considered. However, only cytogenic studies for very specific (receptor) PTPase (PTPγ) are referred to and their results are not conclusive and of no general significance (cf. page 41, paragraph bridging left- and right-hand columns). In fact, reference is also made to other biological studies - using cells transformed with recombinant PTPases - with multiple and varied effects, such as blockage of insulin-like growth factor I receptor autophosphorylation, induction of meiotic cell division, reduction of kidney cell growth rate, reduction of transcriptional activation endowed by AP-1 or CREB transcription factors, reduction of transformed foci, etc. (cf. page 41, right-hand column, first full-paragraph). Document D12 states that "only a few of the PTPases have a well characterized biological function" (cf. page 40, right-hand column, first full paragraph) and it concludes that PTPases is "a diverse and growing family with complex and not yet fully understood functions. It would appear that the proteins will have to be highly regulated, since most likely multiple PTPases will most likely occur in the same cell. The availability of cloned genes, pure proteins, and antibodies to these proteins will give future researchers the tools necessary to continue exploration of this interesting and complex family of regulatory

proteins" (cf. page 42, left-hand column, document D12). The present application provides with the cloning and sequencing of the BDP1 gene a further tool for such scientific exploration, but not an industrial application.

Post-published evidence (cited as expert opinion)

15. Document D11, published some 7 years after filing of the application and submitted by the appellant with its statement of grounds of appeal, refers to the prior art as stating that "since their discovery in 1988..., a tumor suppressor function of PTPs has been postulated based on their potential to counteract oncogenic kinase signalling" but it further adds that "despite extensive investigations, only little evidence has emerged that supports that hypothesis" (cf. paragraph bridging pages 12113 and 12115). Document D11 shows the specificity of BDP1 for a member of the epidermal growth factor receptor (EGFR) family of receptor tyrosine kinases, namely the HER2 (which is also exemplified in the present application; cf. pages 84 and 85 of the published application), and suggests a role of BDP1 as a regulator of HER2 activity involved in HER2 signal attenuation.

16. However, although it is shown that BDP1 down-regulates the phosphorylation of HER2 protein itself as well as downstream signalling events, it is stated that "how this is accomplished by BDP1 remains elusive" and, although "the most obvious explanation would be that BDP1 could be recruited to activated receptor complexes and that phosphorylated HER2 would be a direct substrate for BDP1", it is not excluded that a

downstream effector of HER2 (Gab1), which mediates a positive feedback loop and is itself phosphorylated, might serve itself as a substrate of BDP1 (cf. page 12115, right-hand column, second and third full paragraphs). Document D11 acknowledges that although the results obtained "suggest that BDP1 is responsible for the attenuation of ligand-induced HER2 signal. In vivo, however, the regulation of HER2 can be expected to be much more complex ... it is thus conceivable that rather than BDP1 alone numerous phosphatases act in concert in order to provide a tight and finely tuned regulation of the HER2 signal" (cf. page 12115, left-hand column, at the end of the first full paragraph).

17. Thus, despite the detailed experiments performed and reported in document D11 (more numerous and more elaborated than the ones reported in the present application), the complexity of cellular signal transduction pathways is once more acknowledged to impair or hinder any straightforward and simple conclusion. Therefore, document D11 concludes by stating that "the question whether BDP1 would be able to influence the tumorigenic potential of HER2 in vivo **remains to be addressed by ongoing research**" (cf. page 12115, right-hand column, last paragraph, emphasis added by the board). This is rather far away from an assertion supporting any possible implicit disclosure of a tumour suppressor activity of the BDP1 gene in the present application as even after eight years from the priority date of the application, such an activity did not appear to be completely evident to the inventors themselves.

Is the claimed subject-matter industrially applicable?

18. The claimed "BDP1 polypeptide" is described in the application in terms of its structural features (amino acid sequence of Figure 3) and its enzymatic activity (tyrosine phosphatase). Some homology studies with the PTPase-PEST family have been made. A method and means for making it by recombinant DNA techniques is also described. A possible role in cellular housekeeping and in certain types of cancers has been hypothesized.

19. No doubt exists that a BDP1 polypeptide could be "made and used" as a further tool, in addition to the many already available in the art (cf. document D12), for exploring the complex cellular signal transduction pathways and their implications in the regulation of cellular processes and, possibly, disease states. But the whole burden is left to the reader to guess or find a way to exploit it in industry by carrying out work in search for some practical application geared to financial gain, without any confidence that any practical application exists.

20. No suggestion or indication is given in the application of BDP1 acting as a tumour-suppressor. Due to the high complexity of the cellular signal transduction pathways with finely tuned regulation and a complicated network of interconnections and in view of the fact that each and every phosphatase has unique specific properties (structure, specificity, cellular location, etc.), the board considers that no such suggestion can be derived from the application itself or from the prior art.

21. In the board's judgment, although the present application describes a product (a polypeptide), means and methods for making it, and its prospective use thereof for basic science activities, it identifies no practical way of exploiting it in at least one field of industrial activity. In this respect, it is considered that a vague and speculative indication of possible objectives that might or might not be achievable by carrying out further research with the tool as described is not sufficient for fulfilment of the requirement of industrial applicability. The purpose of granting a patent is not to reserve an unexplored field of research for an applicant.

22. The present case is already on the other side of the borderline to earlier case T 338/00 of 6 November 2002, wherein after similar considerations as regard to whether the then claimed product (heterodimeric receptors between the retinoic acid receptor RXR and other members of the steroid/thyroid hormone receptor hormone superfamily) was a research tool (for studies on cellular development, differentiation and homeostasis) or had a possible industrial application, the board decided that industrial application was present based on the disclosure of several applications, *inter alia* an *in vitro* method to modulate the transcription activation of a gene in an expression system (ibid., points 1 to 3 of the reasons). This suggested exploitation of the properties of what was claimed in that case was applicable to a variety of expression systems, and so could be recognized as an industrial application for the purposes of Article 57 EPC. This contrasts with the present case where the only practicable use suggested is to use what is

claimed to find out more about the natural functions of what is claimed itself. This is not in itself an industrial application, but rather research undertaken either for its own sake or with the mere hope that some useful application will be identified.

23. For these reasons, none of the requests on file (main and auxiliary request) is considered to fulfil the requirements of Articles 52(1) and 57 EPC in combination with Rules 27(1)(f) and 23e(3) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Wolinski L. Galligani