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**Datasheet for the decision
of 29 June 2010**

Case Number: T 0699/06 - 3.3.04

Application Number: 92910260.6

Publication Number: 0575555

IPC: A61K 38/17

Language of the proceedings: EN

Title of invention:
Protein-Induced Morphogenesis

Patentee:
Stryker Corporation

Opponent:
Biopharm Gesellschaft zur biotechnologischen Entwicklung von
Pharmaka mbH

Headword:
Morphogenesis/STRYKER

Relevant legal provisions:
EPC Art. 83
RPBA Art. 15

Keyword:
"Change of date of oral proceedings - (no)"
"Sufficiency of disclosure - main request and auxiliary
requests 1-14 - (no)"

Decisions cited:
G 0005/83, G 0002/88, G 0006/88, T 0158/96, T 0609/02,
T 0890/02, T 1102/03, T 0624/04

Catchword:
-



Case Number: T 0699/06 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 29 June 2010

Appellant: Stryker Corporation
(Patent Proprietor) 2825 Airview Boulevard
Kalamazoo
MI 49001 (US)

Representative: Price, Vincent Andrew
Fry Heath & Spence LLP
The Gables
Massetts Road, Horley
Surrey RH6 7DQ (GB)

Respondent: Biopharm Gesellschaft zur biotechnologischen
(Opponent) Entwicklung von Pharmaka mbH
Czernyring 22
D-69115 Heidelberg (DE)

Representative: Böhm, Brigitte
Weickmann & Weickmann
Patentanwälte
Postfach 86 08 20
D-81635 München (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 7 March 2006
revoking European patent No. 0575555 pursuant
to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: C. Rennie-Smith
Members: M. Wieser
B. Claes

Summary of Facts and Submissions

- I. The appeal was lodged by the Patent Proprietor (Appellant) against the decision of the Opposition Division, whereby the European patent No. 575 555 was revoked pursuant to Article 102(1) EPC 1973.

- II. The Opposition Division decided that the main request and second auxiliary request before it did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC). Moreover, it decided that the subject-matter of the claims of the third and fourth auxiliary requests was not novel, contrary to the requirements of Article 54 EPC (the first auxiliary request had been withdrawn at the oral proceedings before the Opposition Division).

- III. In the letter setting out the grounds for appeal, dated 14 July 2006, the Appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request, claims 1 to 17 as granted, or one of auxiliary requests 1 to 14 appended thereto.

The Appellant did not request oral proceedings.

- IV. In response, with letter dated 09 February 2007, the Opponent (Respondent) requested that the appeal be dismissed. Only if this request would not otherwise be granted oral proceedings were requested.

V. The Board expressed its preliminary opinion in a communication dated 15 December 2009 which was annexed to the summons to oral proceedings to be held on 14 April 2010.

In point (8) of this communication the Board expressed its preliminary view that claims which referred to "a morphogen", to a "morphogen ...sharing at least 70% homology with ..." or to a "morphogen, the amino acid sequence of which comprises SEQ ID NO. 1, SEQ ID No. 2, SEQ ID NO.3 or SEQ ID NO. 4" did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a skilled person, contrary to the requirements of Article 83 EPC.

In point (9) the Board noted that it would have to be examined at the oral proceedings whether or not this also applies to claims referring to compositions and their use in various therapeutic and/or diagnostic applications, which compositions comprise a morphogen different from OP1 or a morphogen characterised by sharing at least 60% identity with parts of OP1. It was stated that special attention would have to be paid to the evidence provided by the Respondent in order to show that the usefulness of a specific morphogen for one very specific therapeutic purpose cannot be generalized.

VI. In a letter dated 4 January 2010 the representative of the Appellant requested the Board to postpone the oral proceedings appointed for 14 April 2010 because the representative was due to speak at a conference which was to take place from 12 to 14 April 2010 (the actual date of his presentation was not given). As regards a

possible substitute, the representative submitted that his firm's "Life Science team [were] all committed to attend" the conference in question. In a communication dated 19 January 2010 the Board refused the postponement request because the reason for the request appeared to be of a work pressure nature, which was in itself not an acceptable reason for postponement.

VII. The Appellant's representative then made a renewed request to postpone the oral proceedings in a letter dated 22 January 2010. He submitted that he had been surprised that the reasons supporting his previous request were considered not sufficient as work pressure reasons. He had not intended to convey that his reasons were of a work pressure nature but simply that he could not "be in two places at one time". The renewed request gave a new reason for postponement, namely the representative's pre-booked holiday from 9 to 16 April 2010.

As regards a substitute, the representative submitted that a party has the right to select a representative and, if he is unable to attend oral proceedings, it is unreasonable to insist that he be replaced. In the present case, the patent application was filed in March 1992 and would expire in March 2012. Since the representative had been responsible for finalising grant of the patent and the opposition and appeal proceedings, it would be unreasonable to expect another attorney to take over representation after nearly 20 years from filing the application and immediately prior to the appeal oral proceedings, at only three months notice and less than a month until the date for filing final written submissions. Even if another

representative could take over at this late stage, his firm has only a small life sciences department consisting of him and one other attorney who was also unable to attend because he would be attending the same conference from 12 to 14 April 2010, speaking together with the current representative at the conference in the afternoon of 13 April 2010, and required to attend the conference as an exhibitor on 13 and 14 April 2010.

- VIII. In a further communication dated 29 January 2010 the Board refused the renewed postponement request for substantially the reasons in points 9 and 12 below. The oral proceedings were however re-scheduled for 29 June 2010 because it was possible to exchange dates with another appeal before the same Board which was to be expedited.
- IX. In a letter dated 30 March 2010, the Appellant's representative informed the Board that he had now been instructed not to attend the oral proceedings.
- X. Oral proceedings were held on 29 June 2010 in the absence of the Appellant.

The Appellant, in writing, requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, claims 1 to 17 as granted, or one of auxiliary requests 1 to 14 filed on 14 July 2006.

The Respondent requested that the appeal be dismissed.

XI. Claim 1 of Appellant's main request (claim 1 as granted, read as follows:

"A composition comprising

(1) (*sic*) a biocompatible acellular matrix that provides an anchoring substratum for mammalian progenitor cells and is essentially free of substances that inhibit morphogenesis; and

(b) (*sic*) a morphogen sorbed on said matrix at a concentration sufficient for inducing the developmental cascade of tissue-specific morphogenesis when said composition is disposed at a non-skeletal tissue locus *in vivo*, said matrix having components specific for said tissue locus."

XII. Claim 1 of auxiliary request 1 differed from claim 1 of the main request in that sub-paragraph (1) was re-named (a). Moreover, the claim at its end defined the morphogen as follows:

"...; and wherein the morphogen comprises a dimeric protein that induces tissue-specific morphogenesis in said mammal and comprises a pair of folded polypeptides, the amino acid sequence of each of which comprises a sequence sharing at least 60% identity with residues 43-139 of hOP1 (SEQ ID NO. 5)."

The identical formulation was contained in claim 1 of each of auxiliary requests 1 to 5.

Claim 1 of each of auxiliary requests 7, 9, 11 and 13 referred to the use of a purified morphogen for the

manufacture of a medicament for promoting non-skeletal tissue regeneration, wherein the morphogen was defined as in claim 1 of auxiliary request 1.

- XIII. Claim 1 of auxiliary request 6 referred to a composition according to claim 1 of the main request "...; wherein the morphogen is selected from OP1, OP2, DPP, Vgl, Vgr-1, CBMP-2a, CBMP-2b and GDF-1."

Claim 1 of each of auxiliary requests 8, 10, 12 and 14 referred to the use of a purified morphogen for the manufacture of a medicament for promoting non-skeletal tissue regeneration, wherein the morphogen was defined as in claim 1 of auxiliary request 6.

- XIV. The following document is referred to in this decision:

(65) Annex A, submitted by the Appellant with letter dated 7 December 2005

- XV. The Appellant's arguments in writing, in so far as they relate to the substantive issues of this decision, can be summarised as follows:

It was not a requirement for sufficiency of disclosure for each and every possible embodiment of a claimed invention to be exemplified in a patent specification. In contrast, according to established case law of the Boards of Appeal the requirement was that a skilled person had to be able to perform the invention working from the teaching provided by the patent. The specification provided sufficient teaching to enable a skilled person to perform the invention over the entire claimed scope. Experimental data were provided

demonstrating a number of effects of morphogens, including for example OP1. Although the specification did not exemplify each and every embodiment of the claimed invention it provided sufficient teaching and experimental data to demonstrate that there was a technical contribution to the art and to enable a skilled person to perform the invention over the entire claimed scope without undue burden.

As evidence in support of this argument, Exhibit A had been filed in the proceedings before the Opposition Division, which summarized references published after the filing date of the patent and demonstrated that the morphogens recited in the claims demonstrated the technical effects asserted when used according to the claims.

XVI. The Respondent's arguments, in so far as they relate to the substantive issues of this decision, can be summarised as follows.

The results obtained in the experimental part of the patent with regard to OP1 could not be generalized to any other morphogen. Neither "morphogens" in general nor morphogens different from OP1 nor morphogens sharing a certain sequence homology with part of OP1, were shown in the patent to give rise to any biological effect. Knowing that different morphogens could cause opposite effects when applied to the same tissue, and that even one and the same morphogen when applied in different doses could give rise to different or even opposite effects, applying any conclusion drawn from OP1 to other morphogens was impossible. As the patent did not demonstrate that morphogens different from OP1

caused the technical effects indicated in claim 1 of each of Appellant's request, the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Reasons for the Decision

Change of date of oral proceedings

1. Article 15(2) RPBA provides as follows:

"A change of date for oral proceedings may exceptionally be allowed in the Board's discretion following receipt of a written and reasoned request made as far as in advance of the appointed date as possible."

Some guidance is to be found in the Notice dated 16 July 2007 concerning oral proceedings before the boards of appeal ("the Notice" - last published in OJ EPO, 1/2010, Supplement, pages 67-68, paragraphs 2.1 and 2.2) as to reasons for non-attendance at oral proceedings by a party (not, it must be noted, non-attendance by a representative *per se*) which may or may not be accepted as sufficient to fix a new date.

2. It is to be noted that the official texts use the expressions "change of date" and "fix a new date" rather than "postponement". In the Board's view this is significant. Postponement of oral proceedings to a later date necessarily has the consequence that the later date becomes unavailable for oral proceedings in

another appeal and thus all the appeals pending before the Board in which oral proceedings may be necessary are, however minimally, postponed. This is unfair on those parties in other appeals who do not want postponements but who must thereby wait at least a little longer for oral proceedings and for a decision. This effect on other parties to other appeals is a consideration the Board must take into account in exercising its discretion (see point 16 below). It is also why the Board, if satisfied that a change of date is necessary, will usually consider first the possibility of bringing forward rather than postponing the oral proceedings.

3. It is inherent in the discretionary nature of the decision whether or not to change a date for oral proceedings that a request will not simply succeed just because the reasons for it fall within the examples of acceptable reasons in the Notice. It must be noted that those examples are given as "serious substantive reasons to **request** the change of date of oral proceedings" (see the Notice, paragraph 2.1, emphasis added). It is significant that they are called "reasons to request the change of date" and not "reasons to allow the change of date". That can only mean that those reasons, or other comparably serious substantive reasons, are required before a request will even be considered but that such reasons are not in themselves bound to or, according to the circumstances, even likely to result in a change of date. This is supported by case law which shows that one of the exemplified reasons (in that case, pre-booked holidays) may not in itself be sufficient:

"...while holiday is a possible valid basis for a request, it is not necessarily a sufficient reason for postponement. All circumstances of the case and all the criteria referred to in the Notice have to be taken into account by the Board when exercising its discretion" (see decision T 1102/03 of 28 May 2008, Reasons, point 2).

4. The Notice also provides (see paragraph 2.3) that,

"Every request for fixing another date for oral proceedings should contain a statement why another representative within the meaning of Articles 133(3) or 134 EPC cannot substitute the representative prevented from attending the oral proceedings."

Therefore, when the reason for a request to fix another date is based on the non-attendance of a representative, there are two stages in the Board's discretionary decision. First, it must decide whether the representative in question is prevented from attending. Second, if and when the Board is satisfied that the representative is prevented from attending, it must then consider whether another representative can substitute for the prevented representative.

The Appellant's requests to postpone the oral proceedings

5. Applying these provisions to the present case, the Board had no difficulty in deciding that the Appellant's requests, both as originally presented and in their renewed form, did not justify a change of date of oral proceedings.

6. The reason given for making the original request was that the representative was due to speak at a conference which ran from 12 to 14 April 2010. He did not then give the exact date on which he was due to speak, although it appeared from his later request that this was in fact 13 April 2010 (in fact, the day before the oral proceedings). Such a commitment - to speak at a conference - is additional to the normal professional responsibilities of a representative. A representative who undertakes such a commitment does so in the knowledge that this will make him unavailable to his clients, and unavailable to appear at any oral proceedings, on the date or dates in question. Therefore, as a reason for changing the date of oral proceedings, it is a reason which by definition results from excessive work pressure - excessive if only because it is a commitment which the representative was not obliged to undertake but which, having undertaken it, makes him unavailable. Excessive work pressure is specifically mentioned in the Notice as a non-acceptable reason (see paragraph 2.2 of the Notice). In view of the clear meaning of "reasons to request" in paragraph 2.1 of the Notice (see point 3 above), the examples of non-acceptable reasons in paragraph 2.2 are equally clearly examples of reasons which are unacceptable as reasons even to request a change of date. Accordingly, such reasons cannot attract a favourable exercise of the Board's discretion.
7. In his renewed request for postponement of the oral proceedings, the representative wrote, with reference to the Board's communication of 19 January 2010 refusing his original request, that he was surprised that the reasons supporting his previous request were

considered insufficient as work pressure reasons, and that he had not intended to convey that his reasons were of a work pressure nature but simply that he could not "be in two places at one time". The Board entirely accepts that he did not **intend** to convey that his original reason (there was only one reason - the conference speaking engagement) was a work pressure reason. However, he should not have been surprised that the Board should view that reason as a work pressure reason. As his later letter put it, he could not "be in two places at one time": when that situation arises for work-related reasons, then it is quite clearly "excessive work pressure".

8. The Board considers it likely that what the representative really meant was that he was surprised that a conference speaking commitment was not regarded as an adequate reason. As indicated above (see point 6), the Board cannot see how such a commitment can ever in itself be an acceptable reason for a change of date. Several requests for change of date are based on such engagements - speaking at conferences, lecture tours, attending trade shows, even staffing stands at exhibitions. Such marketing activities are now commonplace activities for professionals such as lawyers, patent attorneys and others who act as representatives and are no doubt considered an important part of their business activities. However, the sheer frequency or importance to representatives of such activities does not make them any more acceptable as reasons to request a change of date. On the contrary, the more they are frequent and/or important, the more must those who undertake them ensure that they do not prevent attendance at oral proceedings (if necessary,

by a substitute - see point 4 above). No responsible representative would deliberately delay his or her client's case for a marketing opportunity. If a representative asked a client "Do you mind if I postpone your case while I market my firm's services to others?" the answer would be obvious. The Board's refusal to entertain such marketing commitments as reasons to request changes of oral proceedings dates is merely the equivalent answer, not just for itself but also on behalf of other parties and the public (see point 16 below).

9. The renewed request of the Appellant's representative identified a new reason for requesting postponement of the oral proceedings, namely that he had a pre-booked holiday from 9 to 16 April 2010. (Curiously, since his previous reason was that he would be attending a conference from 12 to 14 April 2010, this meant that for three days he would in fact, to use his own expression, be in two places at one time.) The Notice (see paragraph 2.1) gives pre-booked holidays as an example of an acceptable reason to request a change of date. As already indicated (see point 3 above), that does not mean a change of date is to be allowed without more, but it does mean the request must then be considered in the light of all the circumstances. In the present case the Board assumed at this stage that the new reason could be acceptable and proceeded to the question of substitution.

Substitution of another representative

10. In a case such as the present, where the putative non-attendance is that of a representative, one of those circumstances is the possibility of substitution by another representative - indeed it is a necessary second step in the Board's consideration (see point 4 above). When, regardless of other circumstances, it may be conclusive for the request, it becomes appropriate to consider it once the requesting party has demonstrated an acceptable reason for making the request. A key factor in the assessment of the substitution question is the time available between, on the one hand, the date of making the request and, on the other hand, the date appointed for the oral proceedings. If the time between those two dates is on any objective view sufficient to allow a replacement representative to prepare adequately then, as regards this consideration, the Board cannot exercise its discretion in favour of a change of date. (Article 15(2) RPBA requires the request to be made "as far as in advance of the appointed date as possible"; thus, if the request has not been made promptly on receipt of the summons to oral proceedings, the date to be taken for measuring the start of the time period available should clearly be the date when the request could and should have been made. Otherwise, those seeking to delay could circumvent the substitution question by simply waiting until the near the date of the oral proceedings.

11. In the present case, the need to consider the question of substitution did not arise on the request as first made although the Board did, in its communication of

19 January 2010 refusing that first request, state that, even if it had been satisfied that the Appellant's representative was not prevented from attending, it was not satisfied that another representative could not substitute for him. In this respect the representative had submitted that his firm's "Life Science team [were] all committed to attend" the conference at which he was to speak. Thus essentially the same work pressure reason was put forward for the inability of any other representative (at least within the same firm - see point 15 below) to substitute for the current representative. The summons for oral proceedings had been sent to the parties with the Board's letter dated 15 December 2009, thus almost four months before the scheduled date of 14 April 2010 - which was also the last day of the conference. At the date of the communication, there still remained almost three months until the oral proceedings which clearly allowed ample time either to change the date of the representative's talk at the conference, or to find an alternative speaker, or for another representative to familiarise him- or herself with the case. Moreover, as mentioned above (see point 8), it must be incumbent on representatives who undertake marketing activities to ensure that their other duties can be dealt with. Thus to accept a conference speaking engagement without arranging for such duties as may arise to be covered by others must entail a risk. To send all those who might provide such cover to the same marketing event entails the yet higher risk of no-one being able to perform those duties at all.

12. As indicated above (see point 9), when the renewed request to change the date of oral proceedings was made, the Board treated the representative's pre-booked holiday as an acceptable reason for making the request and thus proceeded directly to the question of a substitute. In this respect, the representative argued that a party has the right to select a representative and, if he is unable to attend oral proceedings, it is unreasonable to insist that he be replaced. The Board agrees entirely with the first statement and disagrees entirely with the second. A party does indeed have the right to be represented by the representative of its choice. However, that does not then give the selected representative the right to a postponement of oral proceedings by reason of any other commitment he or she may have undertaken. If that was the case, paragraph 2.3 of the Notice would serve no purpose. There is no question of the Board, or anyone else, insisting on a replacement - if a representative has by his own choice made himself unavailable, the Board must exercise its discretion under Article 15(2) RPBA and take account of other factors as well as the selected representative's convenience. To allow a change of date purely for such convenience would allow one party (indeed, one party's representative) to make its own arrangements and then to dictate changes to others which would be inherently unfair. No one party can arrogate to itself, let alone one representative arrogate to him- or herself, the management of the Board's proceedings.
13. It follows that the Board cannot envisage a combination of the following circumstances as being "exceptional" as required by Article 15(2) RPBA, namely:

(a) the non-availability of a party's representative (which, if for a non-acceptable reason such as a marketing event, is the end of the matter (see 6 above) or, if for a satisfactory reason, is only a reason for making the request and still requires consideration of all the circumstances including a possible substitute - see points 3 and 9 above); and

(b) that party's natural preference for that representative (which is the party's right but which may not dictate a change of date - see point 12 above); and

(c) adequate time to instruct an alternative (adequate time being an objective question to be decided on the facts of each case - see point 10 above).

A request for postponement in such circumstances amounts (without more) to a request to meet the convenience of one person (the unavailable representative) to the possible prejudice of others. To allow such a request would thus be inherently unfair.

14. As regards the Appellant's representative's additional submissions for non-substitution, the Board could not accept either the age of the patent and/or the advanced stage of the proceedings as reasons for non-substitution - on the contrary, both were self-evidently equally good (if not better) reasons for ensuring the appeal was disposed of without further delay. As for the submission that there was only one possible substitute in the representative's firm (not, the Board notes, a "team" who were "all" unavailable as previously submitted) who was also unavailable because

he would not only be speaking at the conference as well but also be manning an exhibition stand, the Board's views expressed above (see points 8 and 11) apply with the same if not more force. If European representatives wish to speak at conferences (even with the approval of clients whose cases are thereby delayed), the work of the Boards of Appeal and the interests of their clients' adversaries and the public should not be affected as a result.

15. The Board also notes that paragraph 2.3 of the Notice refers to "another representative within the meaning of Articles 133(3) or 134 EPC". That is quite clearly not limited to another representative from the same firm as the representative putatively prevented from attending oral proceedings. The question which that paragraph of the Notice addresses is why another representative cannot substitute and not why one of the representative's colleagues cannot substitute. The question asked is objective and calls for an objective answer; the particular circumstances of the representative's firm, the availability of others within that firm, the possible inconvenience or cost to that firm or to the party in question are all irrelevant - these are either internal matters for the representative and his or her firm or at most matters which concern only them and their clients. The inquiry called for by paragraph 2.3 is posited entirely on the non-availability of one European representative or authorised employee and it requires only explanation as to why another European representative or authorised employee cannot take his or her place. The Board sees no scope for reading more into paragraph 2.3.

Consideration of all the circumstances

16. The Board is obliged to consider requests to change the date of oral proceedings in all the circumstances and not just in the light of the submissions supporting the request. Primarily, this means the board must consider the interests of others. In the immediate context of the present appeal, that means the Respondent. Of course, if both or all parties to an appeal are agreed that oral proceedings should be postponed, then the Board can in principle agree (see T 1102/03, cited in point 3 above, Reasons, point 2.2) subject to having notice adequate enough to allow the appointment of oral proceedings in another appeal on the date thereby vacated, so as to avoid any delay to pending appeals. But, absent any such agreement, the Board has to assume that delay may prejudice other parties and respondents in particular since (unless also appellants) they did not choose to have appeal proceedings. There must be highly persuasive reasons to allow Appellants to delay proceedings they themselves began. The Board must also consider the interest of parties in other appeals whose cases will be delayed by a postponement (see point 2 above). It must also consider the wider general public interest in the administration of justice, which can only be served by disposing of appeals as expeditiously as possible, and in having as soon as possible a final decision about the existence or extent of a monopoly right.

17. Since there was adequate time either for the Appellant's representative to change his conference speaking arrangements or for the Appellant to instruct another representative, the Board was not satisfied

that the arguments for a change of date of the oral proceedings, either as originally or subsequently presented, should exceptionally outweigh the other interests it must consider. Accordingly, both requests for such a change had to be refused. However, since another pending appeal which could be expedited permitted an exchange of dates, the Board took that course. It must be observed such opportunities very seldom arise and are not to be relied on to solve representatives' availability problems.

Sufficiency of disclosure - Article 83 EPC

18. The present decision, besides the procedural issue dealt with in points (1) to (17) above, is solely concerned with the requirements of Article 83 EPC, requiring that a European patent shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Claim 1 of each of Appellant's main request and auxiliary requests 1 to 6 refers to a composition comprising a matrix and a (purified) morphogen sorbed on said matrix. The morphogen, when present in sufficient concentration and when disposed at a suitable locus, is able to induce the developmental cascade of non-skeletal tissue-specific morphogenesis.

Claim 1 of each of Appellant's auxiliary requests 7 to 14 refers to the use of a purified morphogen for the manufacture of a medicament for promoting non-skeletal tissue regeneration in case of various indicated diseases and medical applications.

19. Where a therapeutic application is claimed either in the form of a composition for a specific therapeutic use or in the form allowed by the Enlarged Board of Appeal in its decision G 5/83 (OJ EPO 1985, 64), i.e. in the form of the use of a substance or composition for the manufacture of a medicament for a defined therapeutic application, attaining the claimed therapeutic effect is a functional technical feature of the claim (see G decisions 2/88 and G 6/88, OJ EPO 1993, 93 and 114; point 9 of the reasons, for non-medical applications, see also decision T 158/96 of 28 October 1998; point 3.1 of the reasons). As a consequence, under Article 83 EPC, unless this is already known to the skilled person at the priority date, the application must disclose the suitability of the substance or composition for the claimed therapeutic application. Once evidence for this suitability is available from the patent application, then post-published expert evidence may be taken into account, but only to back-up the findings in the patent application in relation to the use of substance or composition, and not to establish sufficiency of disclosure on its own (cf decision T 609/02 of 27 October 2004; point 9 of the reasons).
20. The original application, published as WO 92/15 323, discloses on pages 55 to 60 and 62 to 65 (paragraphs [0071] to [0081] and [0088] to [0096] of the patent) several biological effects of one specific morphogen, namely OP1. These effects are considered to render OP1 useful for various pharmaceutical purposes. The demonstrated effects of OP1 include induction of differentiation of neuronal cells and re-differentiation of transformed cells, reduction of bone

mass loss, stimulation of proliferation of progenitor cells, induction of cartilage and endochondral bone formation, morphogenesis of injured liver tissue and dentinogenesis of CNS repair/nerve generation.

While the morphogen in these paragraphs is mostly designated "OP1", on page 63, lines 6 to 7 of the application as published (paragraph [0089] of the patent) it is designated as "purified recombinant human OP1, mature form".

The meaning of the term "OP1" is defined in table 1 on pages 14 and 15, the application as published (page 5 of the patent). There it is stated that this term defines human mature OP1 (SEQ ID NO.5) or mouse mature OP1 (SEQ ID NO.6) which are said to be "the mature, morphogenically active proteins".

21. The application as published, neither on pages 55 to 60 and 62 to 65, nor at any other point, discloses any biological effect of a morphogen different from "purified recombinant human OP1, mature form".

In more detail, no such effect is disclosed for

- "a morphogen" (claim 1 of the main request)
- a morphogen comprising a dimeric protein "the amino acid sequence of each of which comprises a sequence sharing at least 60% identity with residues 43 to 139 of hOP1 SEQ ID NO.5" (claim 1 of each of auxiliary requests 1 to 5, 7, 9, 11 and 13), or

- a "morphogen selected from OP1, OP-2, DPP, Vgl, Vgr-1, CBMP-2a, CBMP-2b and GDF-1 (claim 1 of each of auxiliary requests 6, 8, 10, 12 and 14).

22. With regard to the definition of the morphogen requiring that it shares at least 60% sequence identity with residues 43 to 139 of hOP1 (SEQ ID NO.5), the Board notes the following:

Mature hOP1 consists of 139 amino acids (AA). "At least 60%" of the 97 AA defined by AA 43 to 139 thereof means 59 AA, which make up 42% of the 139 AA of mature hOP1. Thus a protein falling within this definition has to share only 42% sequence identity with hOP1, the only morphogen for which some biological effects have been shown in the application as published.

23. The Appellant argued that it was not a requirement for sufficiency of disclosure for each and every possible embodiment of a claimed invention to be exemplified in a patent specification. Rather, it was submitted that a skilled person must be able to perform the invention on the basis of the teaching provided by the patent. This was supported by the case law of the Boards of Appeal, in decisions T 890/02 (OJ EPO 2005, 497) and T 624/04 of 8 November 2006.

A document, designated as Exhibit A (hereinafter referred to as document (65)) had been submitted in the proceedings before the Opposition Division, which summarized the disclosure in forty-eight scientific articles "published after the filing date of the present patent and demonstrates that the morphogens

recited in the claims do demonstrate the technical effects asserted when used according to the claims."

24. In the case underlying decision T 890/02 (supra) the Board had raised doubts as to the suitability of enzymes derived from an organism different from the one exemplified in the application for obtaining the desired effect. During the oral proceedings before the Board a document had been submitted which dispelled the Board's doubts and the Board decided that the requirements of Article 83 EPC were met.

As this situation is different from the present one, where no such clarifying document had been submitted (rather the opposite, see points 25 and 27 below), decision T 890/02 (supra) does not apply.

Decision T 624/04 (supra) referred to by the Appellant on page 4, fourth paragraph, line 4, of its letter dated 14 July 2006, is not concerned with the requirements of Article 83 EPC and is therefore of no relevance for this issue.

25. Document (65) has been filed by the Appellant in order to show that after the filing date of the patent "the morphogens recited in the claims do demonstrate the technical effects asserted". In other words, it should be demonstrated that the biological effects disclosed in the application as published for purified recombinant human OP1, mature form, were also obtained by all morphogens falling under the broad definitions used in the claims (see point (21) above).

As already mentioned in point (19) above, post-published expert evidence, such as that provided by document (65), may be taken into account only to back-up the findings in the patent application and not to establish sufficiency of disclosure per se. As no relevant findings in this respect are contained in the patent application, the disclosures in document (65) could be disregarded for this reason alone.

26. However, when taking a closer look at the actual disclosure in the various references discussed in document (65), the Board is convinced that not only does this document not contain a disclosure that "the morphogens recited in the claims do demonstrate the technical effects asserted", but, on the contrary, that it is not possible to draw any conclusion from one specific morphogen and the biological effects obtained by it to any other morphogen. According to document (65) the generalization of the specific results obtained by the patent with regard to recombinant, mature human OP1 to other morphogens, as intended by the claims, is not scientifically tenable.

27. The following passages from references referred to in document (65) are given for example only:

The third reference of document (65) bridging pages 1 and 2 thereof (Development, Sep. 2004; 131(17):4155-65) reads in lines 7 to 8:

"We find that, as expected, Bmp4 can suppress bud extension in isolated epithelium stimulated by Fgf10, but interestingly, Bmp7 has no discernable effect. Bmp7

does, however, stimulate a distinct response in mesenchymal cells."

The eleventh reference of document (65) on page 5 thereof (Neuron., May 2003; 38(3):389-401) reads in line 3:

"Of three Bmps expressed in the roof plate, BMP7, but not BMP6 or GDF7, mimics the roof plate activity in vitro."

Document (65) also contains evidence that the achievement of a specific biological effect can depend on different dosages of one and the same morphogen, so that a generalization even at this level seems to be questionable. The thirty-ninth reference of document (65) on page 17 thereof (Am. J. Physiol., Dec 1997; 273(6):961-75) reads in lines 3 to 5:

"Osteogenic protein-1 (OP1) at a dose of 0.25 nM, increased explant growth by 30% (P=0.001). In contrast, 100-fold greater concentrations of OP1 (28 nM) decreased explant growth by 10% (P>0.001). BMP-2 was entirely inhibitory (maximum inhibition of 7% at 5 nM, P>0.0004)."

26. In summary, the Board arrives at the decision that the patent does not disclose that morphogens as defined in claim 1 of all requests (see point (21) above) demonstrate the biological effects asserted, namely to induce the developmental cascade of non-skeletal tissue specific morphogenesis (main request and auxiliary requests 1 to 6) or to be useful for the manufacture of a medicament for promoting non-skeletal tissue

regeneration in a number of disease states (auxiliary request 7 to 14).

The patent does not describe the invention according to claim 1 of all requests in a manner sufficiently clear and complete for it to be carried out by a skilled person and does not meet the requirements of Article 83 EPC.

Order

For these reasons it is decided:

The appeal is dismissed.

Registrar:

Chairman:

C. Vodz

C. Rennie-Smith