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Datasheet for the decision of 26 May 2010

Case Number: T 0316/08 - 3.3.04

Application Number: 96916513.3

Publication Number: 0831884

IPC: A61K 38/18

Language of the proceedings: EN

Title of invention:
Use of bone morphogenic proteins for healing and repair of connective tissue attachment

Patentee:
Genetics Institute, LLC, et al

Opponent:
Biopharm GmbH

Headword:
Morphogenetic proteins/GENETICS INSTITUTE

Relevant legal provisions:
EPC Art. 54, 123(2)
RPBA Art. 12, 13

Keyword:
"Main request, auxiliary requests I-IV - novelty (no)"
"Auxiliary requests V-VIII - admissibility (no)"

Decisions cited:
G 0005/83, T 0231/85, T 0836/01

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0316/08 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 26 May 2010

Appellants: (Patent Proprietors)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 27 November 2007 revoking European patent No. 0831884 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 Proprietors (Appellants) against the decision of the Opposition Division, whereby the European patent No. 831 884 was revoked pursuant to Article 102(1) EPC 1973.

II. The patent, which had been granted with a set of nine claims, had been opposed by one party (the Respondent) under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC).

The Opposition Division decided that the subject-matter of claim 1 of the only request before them was not novel in the light of the disclosure in documents (1), (3), (9) and (22) and did not meet the requirements of Article 54 EPC.

III. In the letter setting out the grounds for appeal, dated 3 April 2008, the Appellants requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or one of auxiliary requests I to IV appended thereto.

IV. The Board expressed its preliminary opinion in a communication dated 26 January 2010 which was annexed to the summons to oral proceedings. In this communication the board raised an objection under Article 123(2) EPC with regard to claim 1 of auxiliary request I and informed the parties of its preliminary opinion that at least the subject-matter of claim 1 of Appellants' main request and auxiliary requests I

and II seemed to be not novel over the disclosure in document (1).

V. In a letter dated and faxed on 19 March 2010 the Appellants requested that the final date for filing written submissions in response to the Board's communication be postponed to 26 April 2010, to which the Board agreed by a communication from its Registrar dated 25 March 2010.

VI. In a further letter dated 21 April 2010 and filed by fax on 26 April 2010, the Appellants made written submissions in response to the Board's communication and in anticipation of the oral proceedings. Apart from amending their auxiliary request I to meet the objection under Article 123(2) EPC, they maintained their requests filed with the statement of grounds of appeal. They also filed four additional auxiliary requests numbered V to VIII. The Appellants submitted that all amendments in these requests were supported by the application as filed and made the claims novel over any of the prior art documents. The remainder of the letter reiterated arguments relating to novelty and inventive step of the main request.

VII. The Respondent filed a letter dated 19 May 2010 requesting that the Appellants' auxiliary requests V to VIII be not admitted into the proceedings or, if admitted, that the case then be remitted to the opposition division.

VIII. Oral proceedings were held on 26 May 2010.

The Appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed on 3 April 2008 or one of auxiliary requests I (filed on 26 April 2010) or II to IV (filed on 3 April 2008) or V to VIII (filed on 26 April 2010) or, if the Board found one of those requests novel but had concerns about inventive step, to remit the case to the Opposition Division for further prosecution.

The Opponent (Respondent) requested that the appeal be dismissed, that the Appellants' auxiliary requests V to VIII be held inadmissible or, if held admissible, that the case be remitted to the Opposition Division for further prosecution.

IX. Claim 1 of Appellants' main request I read as follows:

"Use of one or more of the bone morphogenetic proteins BMP-2, BMP-4, BMP-5, BMP-6, BMP-7, BMP-8, BMP-9, BMP-10, BMP-11 or a BMP heterodimer consisting of BMP-2 and BMP-6, for the preparation of a pharmaceutical composition for regeneration of a functional attachment between tendon or ligament tissue and bone."

Claim 1 of Appellants' auxiliary request I read as follows:

"Use of one or more of the bone morphogenetic proteins BMP-2, BMP-4, BMP-5, BMP-6, BMP-7, BMP-8, BMP-9, BMP-10, BMP-11 or a BMP heterodimer consisting of BMP-2 and BMP-6, for the preparation of a pharmaceutical

composition for regeneration of a functional attachment between tendon and ligament tissue and bone in reconstructive surgery on the knee, shoulder, hand, ankle or elbow."

Claim 1 of auxiliary request II differed from claim 1 of the main request in that it was restricted to the regeneration of a functional attachment between tendon tissue and bone.

Claim 1 of auxiliary request III differed from claim 1 of the main request in that it was restricted to the use of BMP-9, BMP-10, BMP-11 or a BMP heterodimer consisting of BMP-2 and BMP-6.

Claim 1 of auxiliary request IV differed from claim 1 of the main request in that it was restricted to the use of BMP-10, BMP-11 or a BMP heterodimer consisting of BMP-2 and BMP-6.

Claim 1 of auxiliary request V differed from claim 1 of the main request in that it contained at its end the additional feature "wherein said tendon or ligament tissue is to be attached into a bone tunnel."

Claim 1 of auxiliary request VI differed from claim 1 of auxiliary request I in that it contained at its end the additional feature "wherein said tendon or ligament tissue is to be attached into a bone tunnel."

Claim 1 of auxiliary request VII differed from claim 1 of auxiliary request II in that it contained at its end the additional feature "wherein said tendon or ligament tissue is to be attached into a bone tunnel."

Claim 1 of auxiliary request VIII read:

"Use of bone morphogenetic protein BMP-2 for the preparation of a pharmaceutical composition for regeneration of a functional attachment between tendon tissue and bone, wherein said tendon tissue is to be attached into a bone tunnel, and wherein the tendon is fixed to the bone with sutures."

Dependent claims 2 to 6 of all requests referred to preferred embodiments of the use according to the respective claim 1.

X. The following documents are referred to in this decision:

(1) WO 95/16 035

(3) WO 95/33 502

(17) The Journal of Bone and Joint Surgery, vol. 75-A, no. 12, Dec. 1993; pages 1795 to 1803

XI. The Appellants' arguments in writing and at the oral proceedings, in so far as they relate to this decision, can be summarised as follows:

Amendments

Claim 1 of auxiliary request I was based on page 2, lines 8 to 9 of the application as published and met the requirements of Article 123(2) EPC.

Novelty of the main request and auxiliary requests I to IV over Documents (1) and (3)

Document (1) disclosed that two newly identified members of the family of bone morphogenetic proteins, BMP-12 and BMP-13, had prophylactic use in preventing damage to tendon and ligament tissue as well as use in the improved fixation of tendon or ligament to bone. Furthermore it was stated that pharmaceutical compositions containing BMP-12 and BMP-13 might also contain additional therapeutically useful agents such as BMP-1 to BMP-11. However, these proteins were included for their well known ability to induce bone and cartilage growth. The medical indication specified in claim 1 of the main request and of auxiliary requests I to IV was not disclosed in document (1) in connection with any of BMP-1 to BMP-11.

According to the established case law, a claim formulated in the Swiss-type format and referring to the use of a known compound for a specific medical indication, which indication was not mentioned in the prior art, had to considered to be novel. Therefore, document (1) did not anticipate the subject-matter of claim 1 of any of Appellants' main request and auxiliary requests I to IV.

Document (3) related to methods and compositions for in vivo replacement of body parts based on a donor derived matrix. As this matrix was not capable of inducing the regeneration of the replacement body parts on its own it had to be impregnated or infused with osteogenic proteins such as BMPs. The theoretical description of the desired methods and compositions stood in clear

contradiction to the actual results obtained which in fact showed growth of cartilage tissue only.

The present patent was based on an entirely different clinical situation when compared with document (3) with the consequence that a new clinical sub-group of patients could be treated. According to the case law, this provided for novelty of a given teaching over the prior art.

Consequently, document (3) also did not anticipate the subject-matter of claim 1 of the main request or any of auxiliary requests I to IV.

Admissibility of auxiliary requests V to VIII

These requests only introduced one new feature - a bone tunnel - which was already present in the patent, which was clear and not technically complex. They had not been filed in order to protract the proceedings. The Appellants had been relatively surprised to observe from the Board's communication that in its provisional opinion auxiliary requests I and II were anticipated by document (1). The additional requests represented a legitimate attempt to establish novelty.

XII. The Respondent's arguments in writing and at the oral proceedings, in so far as they relate to this decision, can be summarised as follows.

Novelty of the main request and auxiliary requests I to IV over Documents (1) and (3)

The Appellants' argument that document (1) would only disclose that BMP-12 and BMP-13 were responsible for the fixation of tendon or ligament to bone, due to their ability to induce tendon- or ligament-like tissue, while other BMPs had only a bone growth inducing effect, was not correct. The mention of BMP-1 to BMP-11 in document (1) was directly correlated with the possibility of the fixation of tendon or ligament to bone. As the medical indication of claim 1 of the main request and of auxiliary requests II to IV was identical to the medical indication disclosed for the same substances in document (1), the subject-matter of claim 1 of each of these requests was not novel over the disclosure in document (1).

The clinical situation underlying the subject-matter of claim 1 of the main request and of auxiliary requests I and II was identical to the clinical situation on which the disclosure in document (3) was based. Considering the subject-matter of the claims it was irrelevant whether the tendon or ligament tissue to be functionally attached to the bone was endogenous to the treated patient or was received from a donor. Accordingly claim 1 of each of these requests was not novel over the disclosure in document (3).

Admissibility of auxiliary requests V to VIII

These auxiliary requests introduced a feature which had never appeared before in any proposed claims, which was drawn from the description and not just from a dependent claim, and which had not been relied on before by the Appellants at any stage of the proceedings which had been pending for several years.

It was clear from the Opposition Division's decision that novelty was a problem and the Appellants had had ample time to address that but these requests had only been filed at the very end of the term allowed for filing submissions prior to the oral proceedings (which was extended at the Appellants' request) and without any explanation for such lateness. Article 12(2) RPBA had not been complied with.

The requests would seem to be unallowable. The feature of use of a bone tunnel was known in the prior art, as shown by document (17) and paragraphs [0006] and [0008] of the patent itself, so using it to delimit the claims was unconvincing. The Appellants appeared to be using these new requests to protract the proceedings.

If the additional auxiliary requests were admitted into the proceedings, there would be insufficient time to make appropriate searches and to analyse the results. Therefore, the case should then be remitted to the Opposition Division so that the patentability of the new subject-mater can be considered at two instances.

Reasons for the Decision

Main request and auxiliary requests I to IV

Amendments

1. Although claim 1 of each of these requests differs from claim 1 as granted, the only objection raised by the Respondent and dealt with by the Board during the

entire appeal procedure concerned the additional feature introduced at the end of claim 1 of auxiliary request I.

The feature "... in reconstructive surgery of the knee, shoulder, hand, ankle or elbow" is based on page 2, lines 8 to 9 of the application as published. The introduction of this feature has the effect that the scope of protection is reduced when compared with claim 1 as granted.

Therefore this amendment meets the requirements of Articles 123(2) and (3) EPC.

Novelty

2. Claim 1 of each of the main request and auxiliary requests I to IV is formulated in the so-called Swiss-type format and refers to the use of one or more substances for the preparation of a pharmaceutical composition for a specific medical indication.

The substances, bone morphogenetic proteins BMP-2, BMP-4, BMP-4, BMP-5, BMP-6, BMP-7, BMP-8, BMP-9, BMP-10, BMP-11 or a BMP heterodimer consisting of BMP-2 and BMP-6, are known per se and their pharmaceutical use is already described in prior art documents, for instance document (1) and document (3).

3. The Enlarged Board of Appeal in decision G 5/83 (OJ EPO 1985, 64; see point 21 of the reasons; see also G 1/83, OJ EPO 1985, 60 and G 6/83, OJ EPO 1985, 67) decided, that the novelty of such claims can be derived from

their sole new feature, that is the new pharmaceutical use (indication) of that known substance.

4. The question to be answered is therefore whether the medical indication disclosed in the present patent is new in the light of the disclosure in the prior art, namely in documents (1) and (3).

The medical indication is defined in claim 1 of the main request and of auxiliary requests III and IV as being the "regeneration of a functional attachment between tendon or ligament tissue to bone." Claim 1 of auxiliary request II refers to "tendon tissue" only and, according to claim 1 of auxiliary request I, the regeneration takes place "in reconstructive surgery on the knee, shoulder hand, ankle or elbow."

5. Document (1) refers to particular new members of the family of bone morphogenetic proteins, BMP-12 and BMP-13 and to compositions containing them. The compositions are useful for the induction of tendon/ligament formation (page 1, lines 10 to 13) as well as in the improved fixation of tendon or ligament to bone or other tissues (page 14, lines 9 to 12). They may further contain additional proteins such as the BMP proteins BMP-1 to BMP-11 (page 16, lines 25 to 30).

Page 17, lines 10 to 16 of document (1) read:

"For example, a composition comprising both BMP-2 and BMP-12 implanted together gives rise to both bone and tendon/ligament-like tissue. Such a composition may be useful for treating defects of the embryonic joint where tendon, ligaments, and bone form simultaneously

at contiguous anatomical locations, and may be useful for regenerating tissue at the site of tendon attachment to bone".

6. Contrary to the argument presented by the Appellants, who seem to take the view that the fixation of ligament/tendon tissue to the bone is caused exclusively by the induction of ligament/tendon growth, the teaching in document (1) rather suggests that the fixation of tendon or ligament to bone takes place with the participation of at least two tissues, i.e. the tendon or ligament and the bone. Thus, both the induction of bone and of tendon or ligament tissue has a positive effect on "the regeneration of a functional attachment between tendon or ligament tissue and bone."

7. This teaching in document (1) seems to mirror the general understanding of the skilled person in the field of bone and joint surgery. Document (17), a scientific publication co-authored by two of the present inventors, dealing with tendon-to-bone healing in a dog model not using any BMPs, states in this respect on page 1802, left paragraph: "The present study demonstrated progressive ingrowth of bone into the tendon, which created a biological attachment between the bone and the tendon."

8. It is worth mentioning that also the patent itself discloses that the bone forming effect of, especially, BMP-2 causes the reattachment of tendon/ligament to bone. The section disclosing the results of the only example referring to "BMP-2 and Collagen Sponge Polymer Carrier in Surgically Created Tendon to Bone Detachment Defects", on page 5, column 8, lines 3 to 13 reads:

"Serial histologic analysis revealed extensive proliferation of fibroblasts, plump osteoblast-like cells, and new bone trabeculae in the tendon-bone interface in the rhBMP-2 treated limbs, compared with limbs that received the collagen carrier only. As healing progressed, the new bone trabeculae in the interface in the rhBMP-2 treated limbs matured and were in closer proximity to the tendon, while in the limb without rhBMP-2, there was a zone of fibrous or granulation tissue separating the tendon and the bone tunnel."

Further down in the same column it is stated in lines 34 to 41, that "... rhBMP-2 induced extensive new bone deposition in this interface tissue, resulting in closer apposition of bone to the tendon at earlier time points and more regular establishment of Sharpey's fibers between the tendon and the bone in the rhBMP- 2-treated limbs. The increased strength of fixation correlates with the histologic degree of bone ingrowth seen in the rhBM4P-2 treated limbs."

Thus, the patent itself also discloses that the induction of bone tissue, caused by the administration of BMP-2, positively effected the fixation of tendon to bone and thus the "regeneration of a functional attachment between tendon or ligament tissue and bone."

9. The generally accepted idea that bone tissue induction **and** tendon/ligament tissue induction both have a positive effect on tendon/ligament fixation to bone, is moreover also confirmed by a statement on page 3, column 4, lines 47 to 52 of the patent:

"In a preferred embodiment, the osteogenic protein (which preferably is BMP-2, see page 3, column 4, line 28; insertion added by the Board) is administered together with an effective amount of a protein which is able to induce the formation of tendon- or ligament-like tissue. Such proteins include BMP-12, BMP-13, and other members of the BMP-12 subfamily, as well as MP52."

10. In summary, the Board is convinced that the medical use of BMP-2 and BMP-4 to BMP-11 (main request), BMP-9 to BMP-11 (auxiliary request III) and BMP-10 and BMP-11 (auxiliary request IV) "for regeneration of a functional attachment between tendon or ligament tissue and bone" as well as the use of BMP-2 and BMP-4 to BMP-11 "for regeneration of a functional attachment between tendon tissue and bone" (auxiliary request II), is disclosed in document (1). As a consequence the subject-matter of claim 1 of the main request and of auxiliary requests II, III and IV is anticipated by the disclosure in document (1) contrary to the requirements of Article 54 EPC.

11. In decision T 231/85 (OJ EPO 1989, 74), relied on by the Appellant, the Board had to judge the novelty of a second non-medical use of a known substance. The known use was use as a growth regulator and the new one, claimed by the Applicant, use as a fungicide.

This situation is significantly different from the situation in the present case, where the medical use of a substance disclosed in a prior art document and the medical use claimed by the patent have been found by

the Board to be identical (see points 1 to 10 above). This decision does not therefore apply to the present case.

12. Document (3) relates to materials and methods for the repair and regeneration of plural distinct tissues at a single defect site in a mammal (page 1, lines 6 and 7) using osteogenic proteins to induce formation of said plural distinct tissues (page 1, lines 6 and 7; claim 1). The used osteogenic proteins are BMP-2, BMP-3, BMP-4, BMP-5, BMOP-6, OP1 (BMP-7) and OP2 (BMP-8) (page 23, lines 4 to 16; claim 17). It is a particular object of document (3) "to provide materials and methods for the repair of tissue defects in an articulating mammalian joint, so as to form a mechanically and functionally viable joint comprising **bone** and articular cartilage, **ligament, tendon,** synovial membrane and synovial capsule tissue" (page 6, lines 29 to 31; emphasis added by the Board).

The disclosed methods and material are used for the replacement of torn or compromised ligaments and/or tendons and are found to be sufficient to restore the mechanical and functional viability of ligament/tendon tissue with a skeletal joint (page 7, lines 7 to 10 and page 9, lines 1 to 2).

On page 15, lines 7 to 24, various mammalian joints which can be repaired by the claimed materials and methods are mentioned, including knee, shoulder, fingers and toes and elbow. On the same page in lines 25 to 28 it is stated that invention will be "illustrated in connection with the articulating surfaces of the femur in a knee joint".

13. The Appellant argues that the "clinical concept" underlying the disclosure in document (3) is entirely different from the one of the patent in suit. Document (3) was concerned with the replacement of body parts by providing a biocompatible and bioresorbable matrix. The matrix was derived from an allogenic or xenogenic donor and was devitalized to be substantially free of pathogens and antigenic stimuli to avoid graft rejection (page 7, lines 12 to 17 of document (3)). Before implantation the interstices of the matrix, which on its own was not capable of inducing the regeneration of the replacement body part or tissue, were impregnated or infused with osteogenic proteins such as bone morphogenetic proteins (passage bridging pages 7 to 8).

In contrast, the methods of the present invention were based on the effects of osteogenic proteins on tendon/ligament-to-bone healing and could thus be used in a broader context without the need of using donor tissue. This new clinical concept identified a new clinical situation which was associated with the treatment of a new clinical sub-group of patients. A physician would treat a patient undergoing reconstructive fixation of an endogenous tendon or ligament by administering the BMPs referred to in the claims of the present patent, however, he/she would not consider the teaching of document (3) for treating this patient in view of the clear information therein that BMPs are responsible for the reconstitution of devitalized grafted donor tissue.

By referring to decision T 836/01 of 7 October 2003, the Appellant argued that it was this new sub-group of patients which established novelty of the subject-matter of claim 1 of the main request and of auxiliary requests I to IV over the disclosure in document (3).

14. The medical use of a pharmaceutical composition containing the indicated BMPs according to claim 1 of the main request is the "regeneration of a functional attachment between tendon or ligament tissue and bone." Claim 1 is thus not restricted to the fixation of endogenous tendon or ligament tissue to bone but comprises also the fixation of grafts derived from all sorts of donors.

Moreover, it is clear from the description that the patent in suit and particularly independent claim 1 also relate to the clinical situation wherein tendon or ligament grafts are fixed to bone in reconstructive surgery. Paragraph [0008] of the patent on page 3, column 3 reads:

"Other common clinical examples for which the invention has direct application include the following: rotator cuff tendon repair to the greater tuberosity of the humerus, reattachment of the glenoid labrum to the scapular neck, reconstruction of the lateral ankle ligaments using a **tendon graft** placed through bone tunnels, reconstruction of the medial collateral ligament of the elbow or knee using a **tendon graft** fixed to the surface of the bone or through bone tunnels, reconstruction of the ulnar collateral ligament of the thumb using a **tendon graft** placed in a bone tunnel, and repair of the flexor or extensor

tendons of the digits into bone tunnels or to the surface of the bone of the phalanges" (emphases added by the Board).

15. Appellant's argument, pointing to a new clinical situation created by the patent which allowed the treatment of a new sub-group of patients, is therefore without merit.

The case law of the Boards of Appeal, for instance decision T 836/01 (supra), referring to a situation where indeed (unlike in this case) a new sub-group of patients was identified to be treated with an known substance, does not apply to the present case.

16. In a further line of argument the Appellant held that the description of document (3) was speculative and visionary and stood in clear contradiction to what was actually realized according to its examples. While the description referred to the repair and regeneration of plural distinct tissues and to the manufacture in vivo of autogenous replacement body parts, all what was proven by the experiments was the formation of cartilage tissue.

17. Example 1 of document (3) describes the reconstruction of a mammalian hemi-joint in an animal model using New Zealand white rabbits which received allografts from donor animals. Histological and mechanical confirmatory evaluations were conducted upon sacrifice of the animals at five weeks and six month months after surgery. Joints regenerated with OP-1 (BMP-7) treated allografts regained near normal range of motion at five weeks post-reconstruction (example 2, page 30, lines 20

to 21). Histological evaluations, allowing the assessment of new bone and bone marrow formation (page 29, lines 19 to 20), showed that the devices of the invention were competent to induce and maintain both bone and articular cartilage formation (example 3, page 31, lines 21 to 22).

This equals in fact the results of the only example of the present patent, carried out in a different animal model using mongrel dogs (page 5, column 8 of the patent).

Thus, Appellants' argument, that document (3) does not contain any evidence showing that the goal it aimed at has indeed been realized, must fail.

18. In summary, the Board is convinced that the medical use of BMP-2 and BMP-4 to BMP-11 "for regeneration of a functional attachment between tendon or ligament tissue and bone" (main request), "for regeneration of a functional attachment between tendon and ligament tissue and bone in reconstructive surgery on the knee, shoulder, hand, ankle or elbow" (auxiliary request I) and "for regeneration of a functional attachment between tendon tissue and bone" (auxiliary request II), is disclosed document (3). As a consequence the subject-matter of claim 1 of the main request and of auxiliary requests I and II is anticipated by the disclosure in document (3) contrary to the requirements of Article 54 EPC.

Auxiliary request V to VIII

Admissibility

19. These auxiliary requests were filed one month before the oral proceedings (see section (VI) above).

Article 12(2) RPBA requires that the statement of grounds of appeal contains an Appellant's complete case, setting out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and specifying expressly all the facts, arguments and evidence relied on. While Article 12(1)(c) RPBA provides that appeal proceedings shall be based on, in addition to the grounds of appeal and reply, any communication sent by the Board and any answer thereto, this cannot mean that any new requests filed with such an answer are *per se* admissible since otherwise parties could withhold less preferred requests until after obtaining the Board's provisional opinion on more preferred requests, a tactic which would largely negate the function and value of provisional opinions.

20. Article 12(4) RPBA requires the Board to take into account everything presented by the parties under Article 12(1) RPBA if and to the extent it relates to the case under appeal and meets the requirements in Article 12(2) RPBA, which includes the complete case requirement. Thus the Board is quite clearly not required to take into account anything which does not satisfy that requirement, such as requests which could have been filed with the statement of grounds of appeal but were not.

21. This is complemented by Article 13(1) RPBA which requires that any amendment to a party's case after it has filed its grounds of appeal or reply - and a new set of claims with a new feature is clearly such an amendment - is admissible not as of right but at the Board's discretion, and that discretion is to be exercised in view of *inter alia* three criteria, namely the complexity of the new subject matter, the current state of the proceedings, and the need for procedural economy. Further, Article 13(3) RPBA provides that amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings.

22. As for the criteria in Article 13(1) RPBA, the complexity of the new subject-matter is unsurprisingly the subject of substantial difference between the parties. The Appellants argued that the addition of the feature of a bone tunnel was not technically complex - in the sense of **technical** complexity, that argument appears quite correct - and the feature was readily understandable.

23. However, the Board cannot accept that the concept of "complexity" in Article 13(1) RPBA is confined merely to the technical content of a proposed amendment to a party's case. It must also extend to any procedural complexity the amendment would entail and, in this connection, the Board accepts that the Respondent's arguments carry considerable weight - the new feature in the present case is taken from the description, has

never been relied on or even discussed previously at any stage of the opposition or appeal proceedings, and was not taken into account in any searches. At the very least the Respondent would want to conduct its own prior art searches and assess the results. Thus, as regards the complexity criteria, the Board finds the Respondent's arguments the more persuasive.

24. The same arguments must also be persuasive for the other criteria in Article 13(1) RPBA. The state of the proceedings when the new auxiliary requests were filed was one month before the oral proceedings which is clearly too late for them to be adequately considered without either adjournment of the oral proceedings (which in turn brings Article 13(3) RPBA into play) or remittal to the first instance. Indeed, if adjournment of the oral proceedings would not be correct, remittal would be more incorrect since it would reward the Appellants with even more delay than an adjournment. Finally, the criterion of procedural economy clearly dictates that the new requests be held inadmissible: the Appellants may not have intended to protract the proceedings as the Respondent alleges, but such protraction would be the inevitable effect of admitting the new requests.

25. The Board is also unimpressed by the Appellants' only other argument, namely that they were surprised by the Board's provisional opinion that auxiliary requests I and II were anticipated by document (1), the implication being that, since that opinion was unexpected, the additional auxiliary requests were filed by way of reaction to it. While the Appellants argued that these requests represented a legitimate

attempt to establish novelty, such an attempt should have been made as part of the Appellants' case in their statement of grounds of appeal.

26. It was manifestly apparent from, at the very latest, the issue of the Opposition Division's decision that lack of novelty was the Appellants' major difficulty in this case. If they wished the Board to consider two (or more) possible attempts to establish novelty and thereby overcome that decision, they should have set out all such attempts in their statement of grounds of appeal and, by not doing so, they failed to meet the complete case requirement of Article 12(2) RPBA.

27. If the provisional opinion in the Board's communication had raised a new objection or a wholly new approach to the prior art, there might well have been a reason for exercising the Board's discretion in favour of new requests - not least because that new issue would be equally new to both parties. However, the straightforward opinion that the Appellants' only approach in their grounds of appeal might be unsuccessful (an opinion based on one of the four documents found by the Opposition Division to be novelty destroying) cannot on any objective basis be seen as adding any new dimension to the case. Rather it merely informed the Appellants that the Board could reach much the same conclusion as the opposition division, a possibility that the Appellants could, and indeed should, have considered when filing their statement of grounds of appeal.

28. It must be stressed that this is not a case where, on seeing a Board's provisional opinion, a patentee files one or more auxiliary requests which reduce both the scope of the claims and the breadth of the dispute between the parties. Thus the introduction of a dependent claim into an independent claim as a reaction to a provisional opinion may, subject to other circumstances, be allowed in a Board's discretion because all the parties and the Board itself are already familiar with it and because it narrows rather than extends the dispute. While (as here) introducing a feature from the description never considered before will, as with any additional feature, narrow the scope of the claims, it may also add to the length of the proceedings. When (also as here) this means that opponents are faced with a partly new case which they could not have foreseen, particularly (again, as here) a case which could have been made but was not made earlier, then it would be plainly unjust to admit the new requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

P. Cremona C. Rennie-Smith