BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

Datasheet for the decision of 25 February 2010

Case Number: T 1673/08 - 3.3.10

Application Number: 01126359.7

Publication Number: 1181908

IPC: A61F 2/30

Language of the proceedings: EN

Title of invention:
Support for chondrocyte transplantation in cartilage and joint repair

Patentee:
Verigen AG

Opponent:
Geistlich Söhne AG für chemische Industrie
ORTHOGEN AG

Headword:
Collagen matrix for chondrocyte transplantation / VERIGEN

Relevant legal provisions:
EPC Art. 76(1)

Relevant legal provisions (EPC 1973):
-

Keyword:
"All requests: amendments (not allowable) - not directly and unambiguously derivable from patent application as filed, neither explicitly nor implicitly"

Decisions cited:
T 0823/96

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1673/08 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 25 February 2010

Appellant: (Patent Proprietor)
Verigen AG
Hemmelrather Weg 201
D-51377 Leverkusen (DE)

Representative:
Vossius & Partner
P.O. Box 86 07 67
D-81634 München (DE)

Respondent I: (Opponent I)
Geistlich Söhne AG für chemische Industrie
Bahnhofstrasse 40
P.O. Box 157
CH-6110 Wolhusen (CH)

Representative:
Klunker, Hans-Friedrich
Klunker Schmitt-Nilson Hirsch
Patentanwälte
Destouchesstraße 68
D-80796 München (DE)

Respondent II: (Opponent II)
ORTHOGEN AG
Graf-Adolf-Strasse 43
D-40210 Düsseldorf (DE)

Representative:
Schrell, Andreas
Gleiss Grosse Schrell & Partner
Patentanwälte Rechtsanwälte
Leitzstrasse 45
D-70469 Stuttgart (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 17 June 2008 revoking European patent No. 1181908 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: R. Freimuth
Members: J. Mercey
J.-P. Seitz

Summary of Facts and Submissions

I. The Appellant (Proprietor of the Patent) lodged an appeal on 27 August 2008 against the decision of the Opposition Division dated 17 June 2008 revoking European patent No. 1 181 908 and on 27 October 2008 filed a written statement setting out the grounds of appeal.

II. Notice of Opposition had been filed by the Respondents I and II (Opponents I and II respectively) requesting revocation of the patent in its entirety on the grounds of *inter alia* extending the subject-matter of the patent in suit beyond the content of the application as filed (Article 100(c) EPC), in particular beyond the content of the parent application as filed (Article 76(1) EPC).

III. The Opposition Division held that the amendments made to the patent according to the then pending main request extended the subject-matter of the patent in suit beyond the content of both the application as filed and the parent application as filed. Claim 1 of the main request read as follows:

"Use of a cell-free collagen matrix having a porous surface and a dense surface, for the manufacture of a cartilage repair structure for repair of a defect in articular cartilage, the matrix having chondrocyte cells adhered to its porous surface."

Most particularly it found that the features "a cell-free collagen matrix having a porous surface and a dense surface" and "the matrix having chondrocyte cells

adhered to its porous surface" of claim 1 were not disclosed *per se,* let alone the use of such a matrix with chondrocyte cells adhered thereto "for the manufacture of a cartilage repair structure for repair of a defect in articular cartilage".

IV. With letter dated 27 October 2008, the Appellant submitted three auxiliary requests.

Claim 1 of auxiliary request 1 differed from claim 1 of the main request in that the collagen matrix was additionally defined as a Type I and Type III collagen matrix.

Claim 1 of auxiliary request 2 differed from claim 1 of auxiliary request 1 in that the matrix was further "characterised in that the cell-free Type I and Type III collagen matrix having a porous and a dense surface was a pure and resorbable bilayer collagen membrane obtainable by extracting the collagen from pigs, purifying to avoid antigenic reactions, without performing further cross-linking or chemical treatment, and sterilizing by irradiation (e.g. Bio-Gide®)".

Claim 1 of auxiliary request 3 differed from claim 1 of auxiliary request 2 in that the repair of a defect in articular cartilage was supplemented by the feature "by transplantation of chondrocyte cells to a surface to be treated".

V. The Appellant argued that claim 1 of all requests found a basis in the parent application as filed. More particularly, the basis for the feature that the chondrocyte cells were adhered to the porous surface of

the collagen matrix was to be found in Example 5 of the parent application as filed, the disclosure therein that chondrocytes had adhered to the edge of the Bio-Gide® being an indication that they had also adhered to the porous surface, particularly since cells had been placed directly on top of *inter alia* the porous surface of the Bio-Gide®. Furthermore, since the cells had been shown to grow into the collagen structure, they must previously have been adhered thereto. The use of said collagen matrix with chondrocytes adhered thereto was derivable from the combination of Example 5 and Figure 2 of the parent application as filed, since said example provided experimental data from which the skilled person could have derived that a Bio-Gide® membrane with chondrocytes adhered to its porous surface would be suitable for use in transplanting chondrocytes to the surface of a defect in the articular cartilage for repair of that defect *in vivo* as shown in Figure 2. The Appellant referred to a declaration by M. Brittberg dated 27 March 2008 filed during the proceedings before the Opposition Division for corroboration of its submissions regarding the disclosure of these two features.

VI. Respondents I and II argued that all of the requests contained subject-matter extending beyond the content of the parent application as filed, contrary to the requirements of Article 76(1) EPC. The feature that the chondrocyte cells were adhered to the porous surface of the collagen matrix was not supported by Example 5 of the parent application as filed, as said example disclosed merely that chondrocytes were adhered to the edge of the Bio-Gide®, an edge being quite distinct from a surface, said example itself using quite distinct

terminology for the dense surface, porous surface and edge of the collagen matrix used therein. The fact that cells were noticed adhered to the edge of the Bio-Gide® did not necessarily mean that cells were also adhered to the porous surface thereof. They could have adhered exclusively to the edge and possibly also to the NUNCLON™ plate onto which the Bio-Gide® was placed for cell culture. Furthermore, no therapeutic use of a collagen matrix with chondrocytes adhered thereto was disclosed in the parent application as filed at all.

VII. The Appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request, namely the claims on which the decision under appeal was based, or, subsidiarily, on the basis of any of the auxiliary requests 1 to 3 submitted on 27 October 2008.

The Respondents requested that the appeal be dismissed.

VIII. Oral proceedings were held on 25 February 2010. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

All requests

2. *Article 76(1) EPC*

2.1 The ground for opposition under Article 100(c) has two aspects: (a) whether the subject matter of the patent

extends beyond the content of parent application as filed (in effect, contravening Article 76(1) EPC), or (b) whether the subject matter of the patent extends beyond the content of the divisional application as filed (Article 123(2) EPC).

The European patent application No. 01 126 359 corresponding to the patent in suit is a divisional application of the earlier European patent application No. 97 939 677 1. For the requirements of Article 76(1) EPC to be fulfilled, it is thus necessary that the content of the patent in suit does not go beyond the content of the parent application as filed.

2.2 In accordance with the established jurisprudence of the Boards of Appeal, the relevant question to be decided in assessing whether an amendment adds subject-matter extending beyond the content of the application as filed, is whether the proposed amendment was directly and unambiguously derivable from the application as filed.

2.3 Claim 1 of all requests is directed to the use of a collagen matrix having a porous surface and a dense surface having chondrocyte cells adhered to its porous surface.

2.4 In the decision under appeal, the Opposition Division found *inter alia* that the feature that the collagen matrix having a porous surface and a dense surface having chondrocyte cells adhered to its porous surface in claim 1 was not disclosed in the parent application as filed, let alone in combination with the claimed use

thereof. These features will hereinafter be examined for their basis in the parent application as filed.

2.4.1 A collagen matrix having chondrocyte cells adhered to its porous surface is not disclosed explicitly in the parent application as filed, and this fact was conceded by the Appellant. The Appellant submitted, however, that this feature was implicitly disclosed, citing Example 5, in particular page 12, line 16 of the parent application as filed in this respect, wherein it is stated that "chondrocytes had adhered to the edge of the Bio-Gide", Bio-Gide® being a collagen matrix having a porous and a dense surface.

However, taking this passage at face value, the skilled person would derive merely the bare disclosure that the chondrocytes were adhered to the edge of the Bio-Gide® and not to a surface thereof, let alone to the porous surface thereof. In the paragraphs preceding and succeeding that wherein chondrocytes adhered to the edge of the Bio-Gide® are disclosed, the separate terms "porous surface" (see page 12, lines 6, 9 and 22) and "dense surface" (see page 12, lines 7, 9 and 22) are used in connection with the Bio-Gide®, but not in combination with chondrocytes being adhered thereto.

2.4.2 The Appellant further submitted that if the chondrocytes could be observed on the edge of the Bio-Gide®, then this was an indication that they were also present on the porous surface thereof. It substantiated this allegation by pointing out that according to page 12, lines 8 to 9 of the parent application as filed, the cell-containing culture medium was placed directly on top of the Bio-Gide®, dispersed either over

the porous or the dense surface thereof, and the Bio-Gide® was then subsequently examined through an optical microscope, such a microscope not being capable of detecting chondrocytes on a surface, such that their presence on a surface of the Bio-Gide® was not excluded by the observation that they were adhered to the edge thereof. Indeed, since the cells had been placed *inter alia* directly on the porous surface of the Bio-Gide®, the cells observed on the edge were in fact those chondrocytes adhered to the porous surface which protruded thereover.

However, merely because the presence of chondrocytes adhered to the edge of the Bio-Gide® renders it conceivable that chondrocytes may also have adhered to the porous surface thereof, does not mean that chondrocytes adhered to the porous surface are specifically disclosed, thus not satisfying the requirement of a direct and unambiguous disclosure (see point 2.2. above). From a technical point of view, as plausibly argued by the Respondent I, the chondrocytes could indeed have adhered only to the edge of the Bio-Gide® membrane by virtue of a particular physical property of the edge thereof and/or by virtue of the conduciveness to cell growth of the NUNCLON™ plate onto which the Bio-Gide® was placed for chondrocyte cell culture, cells growing on said plate encroaching also onto the edge of the Bio-Gide®.

2.4.3 The Appellant also argued that since in Example 5 of the parent application as filed the cell-containing culture medium was placed directly on top of the Bio-Gide®, dispersed either over the porous or the dense surface thereof, chondrocytes were noticed on day 2

adhered to the edge of the Bio-Gide®, the cells were then incubated and cultured in a different medium on the porous or the dense surface for 3 to 7 days, and it was thereafter observed by electron microscopy that cells grew into the porous surface of the collagen structure (see page 12, lines 8 to 9, 16, 22 and 27 of the parent application as filed), the chondrocytes must inherently have been adhered to said porous surface in order for them to have been able to grow into said surface.

However, whether or not any chondrocyte cells were at any point in time adhered to the porous surface of the Bio-Gide® can be left aside, since chondrocytes adhered to the porous surface are not directly and unambiguously derivable from the parent application as filed, and hence not disclosed therein. In any case, the state of the Bio-Gide®/chondrocyte cells after incubation/culturing for 3 to 7 days is different to the state on day 2 before culturing, chondrocytes adhered to the edge of the Bio-Gide® being noticed only in that earlier state, no link being disclosed in the application as filed between chondrocytes adhered to the edge and chondrocytes growing into the porous surface of the Bio-Gide®.

2.5 With regard to the claimed use of the collagen matrix with chondrocytes adhered thereto, the question arises whether the use of such a specific product is disclosed in the parent application as filed.

2.5.1 In this respect, the Appellant submitted that such a use was derivable from the combination of Example 5 and Figure 2 of the parent application as filed, since

Example 5 provided experimental data from which the skilled person could have derived that a Bio-Gide® membrane with chondrocytes adhered to its porous surface would be suitable for use in transplanting chondrocytes to the surface of a defect in the articular cartilage for repair of that defect *in vivo* as shown in Figure 2.

However, the part of Example 5 on which the Appellant relies is concerned with "cell research work", the aim of which is to study the behaviour of the chondrocytes when in contact with a certain product (see also page 6, lines 25 to 30 of the parent application as filed). Said tests merely show that chondrocytes can be cultured *in vitro* on to the dense and porous surfaces thereof, whereby cells cultured on the porous surface grow into the collagen structure. The conclusion from this research work is that when the collagen patch covered a cartilage defect, the porous surface should be facing down towards the defect in which the cultured chondrocytes are to be injected, such that the chondrocytes could then penetrate the collagen. Thus, said example does not suggest the *in vivo* use of a Bio-Gide® membrane with chondrocytes adhered thereto, but on the contrary, suggests the use of a Bio-Gide® patch to cover the defect into which cultured chondrocyte cells are separately injected. As such, the teaching of Example 5 is in line with the teaching of the rest of the parent application as filed (including Figure 2; see below), namely that a cell-free patch and a hemostatic barrier, the Bio-Gide® membrane being able to act as both, should be used to cover and protect the chondrocytes which are placed separately, optionally **in** a suitable matrix, upon the surface to be treated (see

parent application as filed, page 3, lines 22 to 24, page 4, lines 29 to 30 and page 6, lines 10 to 12 and 21 to 23).

The claimed use also cannot be derived from a combination of Example 5 with Figure 2. Firstly, Example 5 is in itself self-contained: it suggests how the chondrocyte cells should be used in therapy, there being no link to Figure 2 at all. In any case, Figure 2 merely shows a cell-free semi-permeable material which forms a cap covering a cartilage defect, the brief description of said figure (see parent application as filed, page 4, line 31 to page 5, line 3) indicating that this cap covers the defective area of the joint into which the cultured chondrocytes/cartilage transplant has been placed. Thus the Appellant's argument that the chondrocytes had been placed on the cap is not supported by the facts, since said passage states that they were placed into the defective area of the joint.

2.5.2 Finally, the Appellant argued that the skilled person, in the light of the parent application as filed, particularly in view of Example 5 thereof, would have known that a collagen matrix with chondrocyte cells adhered to the porous surface thereof, would have been suitable for the use as indicated in the claims.

However, the content of an application as filed encompasses what is directly and unambiguously disclosed therein, either explicitly or implicitly. In this respect, the term "implicit disclosure" should not be construed to mean matter that does not belong to the content of the technical information provided by a

document but may be rendered obvious on the basis of that content. Whilst common general knowledge must be taken into account in deciding what is clearly and unambiguously implied by the explicit disclosure of a document, the question of what may be rendered obvious by that disclosure in the light of common general knowledge is not relevant to the assessment of what is implied by the disclosure of that document. The implicit disclosure means no more than the clear and unambiguous consequence of what is explicitly mentioned (see T 823/96, point 4.5 of the reasons, not published in OJ EPO).

Thus in the present case, since the question of whether the claimed use was obvious to the skilled person in the light of Example 5 is irrelevant to the question of what is directly and unambiguously disclosed therein, the use of a collagen matrix as defined in claim 1 is not implicitly disclosed in the parent application as filed.

2.6 For these reasons, the Board concludes that claim 1 of each request is amended in such a way that subject-matter extending beyond the content of the parent application as filed is added, contrary to the requirement of Article 76(1) EPC, there being neither an explicit nor an implicit disclosure in the parent application as filed for either the feature "a collagen matrix having a porous surface and a dense surface having chondrocyte cells adhered to its porous surface" or to the claimed use of such a matrix with chondrocyte cells adhered thereto. Thus the ground for opposition pursuant to Article 100(c) EPC in the case of all requests is justified, with the consequence that the

main request and auxiliary requests 1 to 3 are not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez R. Freimuth