

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

D E C I S I O N
of 23 May 2001

Case Number: T 0748/98 - 3.3.4

Application Number: 89111364.9

Publication Number: 0347899

IPC: A61K 35/54

Language of the proceedings: EN

Title of invention:

Pharmaceutical compositions on egg shell basis and their preparation and use

Patentee:

BIOMIN, akciová spoločnosť

Opponent:

aar Pharma, Adler-Apotheke Hans Ruepp

Headword:

Egg shell/BIOMIN

Relevant legal provisions:

EPC Art. 54, 56

Keyword:

"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:

T 0150/82, T 0248/85

Catchword:

-



Case Number: T 0748/98 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 23 May 2001

Appellant:
(Opponent)

aar Pharma, Adler-Apotheke Hans Ruepp
Alleestrasse, 11
D-42853 Remscheid (DE)

Representative:

Jönsson, Hans-Peter, Dr.Dipl.-Chem.
Patentanwälte
von Kreisler-Selting-Werner
Postfach 10 22 41
D-51462 Köln (DE)

Respondent:
(Proprietor of the patent)

BIOMIN, akciová spoločnosť
Potočná 1
919 43 Cifer (CS)

Representative:

Schmitt-Fumian, Werner, Prof. Dr.rer.nat.
Beetz & Partner
Patentanwälte
Steinsdorfstrasse 10
D-80538 München (DE)

Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 6 May 1998
rejecting the opposition filed against European
patent No. 0 347 899 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
S. U. Hoffmann

Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division issued on 6 May 1998 whereby the opposition was rejected pursuant to Article 102(2) EPC. It was decided that the subject-matter of the claims as granted was novel and inventive having regard to the cited prior art, in particular the following documents:

(E1) Derwent abstract of the Japanese Patent Laid-Open No 59-137415 of 7 August 1984;

(E3) "Die Grundlagen der Eierschalentherapie" of Prof. Dr. med. Stefan Krompecher, VEB GUSTAV FISCHER Verlag, Jena, 1958, pages 1 to 83.

Independent claims 1 and 6 as granted read as follows:

"1. Pharmaceutical compositions on the basis of egg shells, obtainable by

(A) emptying eggs, preferably chicken eggs,

(B) removing residues of egg yolk and white of egg, ballast constituents, contaminants and the membrane sticking to the interior egg shell surface, and purifying the egg shells,

(C) drying the egg shells with hot air,

(D) crushing and grinding the egg shells to a powder having a particle size of $\leq 150 \mu\text{m}$, and preferably of 10 to 80 μm ,

and

(E) sterilizing the egg shell powder at a temperature of 120 °C to devitalize pathogenic and conditionally pathogenic microorganisms."

"6. A method for preparing the pharmaceutical compositions according to one of claims 1 to 5, comprising the following steps:

(A) emptying eggs, preferably chicken eggs,

(B) removing residues of egg yolk and white of egg, ballast constituents, contaminants and the membrane sticking to the interior egg shell surface, and purifying the egg shells,

(C) drying the egg shells with hot air,

(D) crushing and grinding the egg shells to a powder having a particle size of $\leq 150 \mu\text{m}$, and preferably of 10 to 80 μm ,

and

(E) sterilizing the egg shell powder at a temperature of 120 °C to devitalize pathogenic and conditionally pathogenic microorganisms."

Dependent claims 1 to 5 concerned particular embodiments of the compositions according to claim 1, while dependent claims 7 to 9 were directed to particular embodiments of the method according to claim 6. Independent claim 10 concerned the use of the compositions of claims 1 to 5 for the manufacture of pharmaceutical compositions for the treatment of mineral deficiencies.

- II. With the statement of grounds of appeal, the appellant (opponent) submitted a report with comparative experiments.
- III. The respondent (patentee) made submissions in reply to the statement of grounds of appeal.
- IV. The appellant made further submissions on 3 August 2000.
- V. On 28 February 2001, the board issued an official communication to the parties with a provisional, non-binding view on the issues to be discussed.
- VI. In reply to the board's communication, the appellant made further submissions on 20 April 2001 and on 26 April 2001. Therewith the English translation of the full text of Japanese Patent abstracted in document (E1) and further comparative experiments were filed.
- VII. On 18 May 2001, the respondent drew the board's attention to the possible need to file amended patent documents or further evidence during the oral proceedings, in view of the fact that the appellant's submissions had been received at a late stage.
- VIII. Oral proceedings took place on 23 May 2001.

In addition to the documents cited above, the following documents were discussed:

(E2) US-A-3 558 771;

(E5) "Anmeldevordruck zur Eintragung einer Arzneispezialität in das Spezialitätregister" dated 11 November 1968 relative to the product "Calcium Vital";

(E6) Der Deutsche Badebetrieb - Sonderdruck, Vol. 6, 1967, Verlag Otto Haase, Lübeck, "Eierschalen als große Kraftreserve neben Meerwasser und Algen", pages 3 to 7.

IX. The appellant argued, with reference to the comparative experiments submitted, that there was no difference between the product obtainable according to the patent in suit and the product obtainable by following the teaching of document (E1). In this respect, it was noted that the process according to the patent in suit did not allow the removal of all the membrane components, in particular of the outer egg shell membrane (OEM), as shown by the comparative experiments submitted on 20 April 2001 and on 26 April 2001. Moreover, the said process did not bring about an improvement in sterility, as shown by the comparative experiments submitted with the statement of grounds of appeal. As a matter of fact, sterilisation for one hour at 120°C as described in the patent specification was inadequate to achieve a sufficient sterilisation. Thus, although document (E1) described a process wherein egg shells were heated only up to 80°C, there was no significant difference between the final product of (E1) and that of the patent in suit. For this reason, the compositions of claim 1 lacked novelty.

As for inventive step, the appellant submitted that there was a diffuse knowledge in the art about the use of powdered egg shells for pharmaceutical purposes (cf., for example, documents (E2), (E5) and (E6)). Moreover, there was no prejudice in the art against using for sterilisation a temperature higher than 80° C. In this respect, particular reference was made to document (E3) which reported inter alia experiments carried out in rats wherein the animals were fed with powdered egg shells which had been heated at 900°C. These experiments had shown that the therapeutic effect

due to the inorganic components, which was relevant for the treatment of mineral deficiencies, was not affected (cf results reported in Figure 49 on page 56). Thus, the skilled person would have expected that a temperature range between 75° and 900°C could be used for sterilisation. It was therefore obvious for the skilled person to modify the known process of document (E1) by heating the egg shells at a temperature of 120°C. In any case, as shown by the comparative experiments submitted on the sterilisation effect, this change made technically no difference. By the same token, it was also obvious, for example, to sterilise at a temperature of 120°C (this being the well known sterilisation temperature) powdered egg shell products such as those of document (E2) which were destined to application on wounds.

- X. The respondent argued that document (E1) failed to disclose the features of removal of the inner membrane and sterilisation at 120°C, and thus it could not affect novelty of claim 1.

As for inventive step, there were explicit indications in the prior art that heating of egg shells at higher temperatures was not desirable as it caused destruction of essential components (cf documents (E1) and (E3)). The patent in suit had gone against this prejudice in the prior art and had made available a product wherein important biogenic material present in the egg shell were preserved (cf page 3 lines 24 to 35 of the patent specification). For these reasons inventive step had to be acknowledged.

- XI. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained.

Reasons for the Decision

Novelty (Article 54 EPC)

1. The pharmaceutical compositions of claim 1 are defined in terms of their process of preparation ("product-by-process), namely by a succession of steps of treatment of egg shells, of which the last one (step E) is the sterilisation of the powder at a temperature of 120°C. The said succession of steps is the same that characterises the process of claim 6, the novelty of which is not disputed.

2. According to established jurisprudence of the EPO, a product-by-process claim can be allowed only if the claimed product **as such** fulfils the requirements for patentability, ie inter alia that of novelty (cf., for example, T 150/82, OJ EPO 1984, 309, and T 248/85 OJ EPO 1986, 261). If a product known from the prior art is produced by a new process, it does not necessarily acquire novelty only by the fact that it is defined in terms of this process, unless the latter confers to the product features which make it a different product.

3. Although compositions of the basis of finely divided egg shells are known from prior art documents (E1)-(E3) and (E5)-(E6), admittedly none of these documents refers explicitly to a composition which had been sterilised at 120°C. It is well known in the art that egg shells are complex products which contain several organic and inorganic components, and that the way in which they are treated can influence their final structure, as, for example, the temperature of treatment can alter or destroy some of the components (cf documents (E1) and (E3)). In view of this complexity, an exact structural definition of the

resulting products is difficult, if not impossible. Thus, a comparison of egg shell products must take due account of the process by which they have been obtained.

4. In disputing the novelty of the product of claim 1 vis-à-vis document (E1), the appellant essentially maintains that by operating according to the latter document a product is obtained which is substantially identical to that obtainable by operating according to claim 1. In support of this contention, the appellant provides comparative experiments allegedly showing that the level of sterility is the same, and that the process outlined in claim 1 does not result in the removal of all membrane components, in particular of the outer egg shell membrane components.
5. The board notes, firstly, that the comparison in the level of sterility was limited to testing the presence of bacilli, which is only one of the numerous types of microorganisms of the egg shell flora (cf document (E3), Figure 2 on page 16). No definite conclusions can be reached on the basis of such limited tests. In any case, even assuming an identical level of sterility, such tests are irrelevant to the question of the change in the overall composition of the powdered egg shells in consequence of the heating at 120°C, rather than at up to maximally 80°C. The appellant, who has the onus of proof, has not demonstrated that, contrary to the teaching of document (E3), heating at a higher temperature causes no changes in the structural composition of the egg shell powder.
6. As for the arguments in relation to the removal of the membrane components, the board, in agreement with the respondents, notes first of all that document (E1) does not give such any explicit instructions as to the removal of any membrane component nor information as to

the effects of any operation on the removal of any membrane component. Whether such a removal can be implied by the statement that the content of the raw eggs is removed and the egg shells are thoroughly washed with warm water or water before drying and crushing, is highly questionable and by no means proven. Secondly, it is not an explicit recommendation of the process according to the patent in suit to remove the outer egg shell membrane as the claim refers only to the removal of the membrane sticking to the interior egg shell surface. Under the present circumstances, the question whether or not the outer egg shell membrane is removed by the process outlined in claim 1, which is in any case irrelevant to a comparison with document (E1), is immaterial.

7. In the board's judgement, the marked differences between the process steps of claim 1 and the manner of operating of document (E1), when considered also in the light of the influence that in particular the heat treatment has on the composition of egg shells, necessarily lead to the conclusion that the products of claim 1 are not identical to the products obtainable by working according to document (E1). Thus, novelty is acknowledged.

Inventive step (Article 56 EPC)

8. In the board's judgement, the closest prior art is represented by document (E2) which suggests inter alia using a finely-divided egg shell preparation, which has been freed from the adhering membrane, as an accelerator of wound healing. Although the preparation is to be applied on open wounds, a sterilisation step is not explicitly referred to.

9. In the light of said prior art document, the problem underlying the patent specification can be defined as being the provision of alternative preparations suitable for medical use.

10. The solution proposed by the claims at issue are preparations obtainable by a method which includes sterilizing the egg shell powder at a temperature of 120 °C.

11. In the board's judgement, the idea of sterilising the egg shell powder before any medical use, including application on open wounds, would have readily occurred to the skilled person. From document (E3), a basic textbook in the area of therapy with egg shells, the skilled person knew that drying the egg shells up to 80°C would not have caused quantitative changes in the bacterial flora (see page 16, third paragraph). He or she would have been advised from the same textbook (see page 17, fifth paragraph) to carry out sterilisation at 75°C or 100°C, and warned at the same time that higher temperatures would have altered or destroyed essential components of the egg shells. Based on such indications, the skilled person **would not** have taken the route of sterilising at 120 °C, in spite of the common general knowledge that this was the temperature normally used to sterilise medical instruments and other material. This was because the skilled person knew that, differently from medical instruments and other material, care had to be taken when sterilising a complex mixture of organic and inorganic components. This need for care was confirmed by document (E3). The warning and the indication in document (E3) would have convinced the skilled person that operating between 80 and 100 °C would have ensured a sufficient degree of sterilisation.

12. The fact that the same document (E3) reported the results of experiments showing that the therapeutic effect due to the inorganic components was substantially not affected when egg shells were heated at 900°C (cf Figure 49 on page 56) would not have induced the skilled person to choose a sterilisation temperature higher than 75°C or 100°C, because, as confirmed also on pages 55 and 56 of document (E3), the beneficial effect of the presence of the organic components would have been lost.

13. Under these circumstances, the board considers that the choice of a temperature of 120 °C was not an obvious choice for the skilled person, and thus comes to the conclusion that the subject-matter of all the claims at issue involves an inventive step.

Order

For these reasons it is decided that:

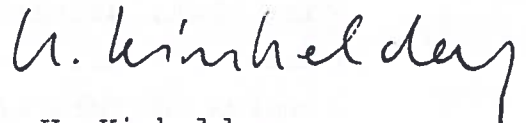
The appeal is dismissed.

The Registrar:



U. Bultmann

The Chairperson:



U. Kinkeldey