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**Datasheet for the decision
of 6 December 2012**

Case Number: T 0847/10 - 3.3.05
Application Number: 06727590.9
Publication Number: 1846153
IPC: B01J 13/10, B01J 13/08,
B01J 13/02, A61K 9/50,
A61J 3/07, A23L 1/00
Language of the proceedings: EN

Title of invention:

Microcapsules and emulsions containing low Bloom gelatin and
methods of making and using thereof

Applicant:

Ocean Nutrition Canada Limited

Headword:

Microcapsules/OCEAN NUTRITION

Relevant legal provisions:

EPC Art. 56, 123(2)

Relevant legal provisions (EPC 1973):

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Keyword:

"Extension beyond the content of the application as filed: no"
"Inventive step: yes - non obvious alternative"

Decisions cited:

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Catchword:

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Case Number: T 0847/10 - 3.3.05

D E C I S I O N
of the Technical Board of Appeal 3.3.05
of 6 December 2012

Appellant: Ocean Nutrition Canada Limited
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 1 December 2009
refusing European patent application
No. 06727590.9 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: G. Raths
Members: J.-M. Schwaller
C. Vallet

Summary of Facts and Submissions

I. This appeal lies from the decision of the examining division refusing European patent application No. 06 727 590.9 on the grounds that the main request then on file - dated 17 September 2009 - did not meet the requirements of Articles 123(2) and 56 EPC.

II. The main request consisted of 77 claims, with independent claims 1, 26, 50, 54 and 55 reading as follows:

"1. A microcapsule comprising an agglomeration of primary microcapsules and a loading substance, each individual primary microcapsule having a primary shell, wherein the loading substance is encapsulated by the primary shell, wherein the agglomeration is encapsulated by an outer shell, wherein the primary shell and the outer shell material is a two-component system of fish gelatin having a Bloom number of zero and another polymer component."

"26. A process for preparing a microcapsule according to claim 1, the process comprising:

(a) providing an aqueous mixture comprising a loading substance and a fish gelatin having a Bloom number of zero;

(b) adjusting the pH, temperature, concentration, mixing speed or a combination thereof to form a primary shell comprising the gelatin around the loading substance;

(c) cooling the aqueous mixture to a temperature above the gel point of the gelatin until the primary shells form an agglomeration; and,

(d) cooling the aqueous mixture to form an outer shell around the agglomeration wherein the aqueous mixture further comprises a second polymer component."

"50. A foodstuff comprising the microcapsule of claim 1."

"54. A pharmaceutical formulation comprising the microcapsule of claim 1 and a pharmaceutically acceptable carrier."

"55. A method for delivering a non-therapeutical loading substance to a subject, comprising administering to the subject the microcapsule of claim 1."

The dependent claims 2 to 25, 27 to 49, 51 to 53 and 56 to 77 represent specific embodiments of the subject-matter of the claims on which they depend.

III. The following documents were in particular relied upon during the examination proceedings:

D1: US 4 867 986

D3: WO 2004/041251 A1.

IV. In essence the reasoning held by the examining division is as follows:

There was no basis in the application as filed for the amendment "*fish gelatin having a Bloom number of zero*" in claim 1. In particular, the basis given by the applicant - namely page 9, paragraphs 1 and 2; Figure 3

and Example 1 - did not support such an amendment. As regards amended process claim 26, the sole basis could be seen in the process described on page 9, line 25 to page 10, line 1 of the application as filed, but the feature "*further adjusting pH*" was missing from step c) defined in claim 26.

When assessing inventive step the examining division did not consider the feature "fish" in the expression "*fish gelatin having a Bloom number of zero*", since said feature was considered added subject-matter. In the examining division's view, it followed that the claimed subject-matter differed from the disclosure in D3, which represented the closest state of the art, in that the gelatin had a Bloom number of zero. The thus claimed subject-matter did not give rise to any particular effect. It followed that the problem to be solved was to be seen in the provision of an alternative microcapsule or alternative process for preparing said microcapsule. Zero Bloom gelatin being commonly known in the art, the skilled person would replace the 50 to 350 Bloom gelatin used in D3 by a zero Bloom gelatin. D1 disclosed good results and advantages for microcapsules comprising a mixture of 50/50 (w/w) zero Bloom gelatin with gelatin of Bloom number 100 to 125. As D1 encouraged the skilled person to use a combination of zero Bloom gelatin with gelatin of higher Bloom number as capsule/shell material, the combination of D3 with D1 was "plausible".

V. With the grounds of appeal dated 9 April 2010, the appellant filed a set of 77 claims identical to those of the main request rejected by the examining division.

VI. The appellant requested that the contested decision be set aside and that a patent be granted on the basis of this set of claims.

Reasons for the Decision

1. Allowability of the amendments

1.1 In the board's view, the subject-matter of claim 1 at issue can be derived directly and unambiguously from the subject-matter of original claims 1 and 9 and from the disclosure in the description on page 6, lines 23 to 25; page 1, lines 19 to 22; Figure 3 and Example 1. The reasons are as follows:

The combination of features: "*A microcapsule comprising an agglomeration of primary microcapsules and a loading substance, each individual primary microcapsule having a primary shell, wherein the loading substance is encapsulated by the primary shell, wherein the agglomeration is encapsulated by an outer shell, wherein the primary shell and/or the outer shell material comprises gelatin having a Bloom number of zero*" results from the fusion of claims 1 and 9 as originally filed.

The sentence reading "*primary shell and the outer shell material is a two-component system of gelatin having a Bloom number of zero and another polymer component*" can be derived directly and unambiguously from the passage on page 6, lines 23 to 25 of the application as filed, said passage reading: "*In one aspect, **the material used to make the shells** of the single- or multicore*

microcapsules is a two-component system made from a mixture of low Bloom gelatin and one or more different types of polymers". This passage is worded in a generic way; it thus concerns any kind of low Bloom gelatin and, in particular, the specific one directly derivable from the combination of features resulting from the fusion of original claims 1 and 9 identified above, i.e. a gelatin having a Bloom number of zero.

That the gelatin originates from fish is neither in the above passage nor in claims 1 and 9 of the original specification, which however clearly outlines on its first page (second paragraph, in particular lines 22 to 25) under the heading "Background" that there was **a strong economic justification for the attempt to use low Bloom fish gelatin**, in particular cold water **fish gelatin which has no Bloom number**. The application as filed furthermore discloses in its specific embodiments (Figure 3; page 2, lines 10 to 12; Example 1) - the sole specific example of the specification - the use of **zero Bloom fish gelatin**.

In this case, where all the specific embodiments converge to a sole and unique specific material - here the zero Bloom fish gelatin - the board is of the view that the combination of this specific feature with the other generic features acknowledged above as being derived directly and unambiguously from the application as filed cannot be considered as extending beyond the content of the application as filed.

- 1.2 The subject-matter of dependent claims 2 to 25 is based on the disclosure in claims 3, 10, 12, 13, 14, 15, 16,

17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32 and 33 of the application as filed, respectively.

1.3 In the board's view, claim 26 - which was objected to under Article 123(2) EPC by the examining division - in fact results from the fusion of original claims 50 and 51, with the gelatin having been further defined as in claim 1 of this request. For essentially the same reasons as those indicated in point 1.1 above, the further definition of the gelatin as being "a fish gelatin having a Bloom number of zero" is not considered as extending the subject-matter of claim 26 beyond the content of the application as filed.

1.4 The subject-matter of dependent claims 37 to 77 is based on the following disclosure in the application as filed:

- Claims 37 to 49: original claims 52 to 74, respectively;
- Claims 50 to 52: original claims 80 to 82, respectively.
- Claim 53: original claim 84
- Claim 54: original claim 91
- Claim 55: original claim 95
- Claim 56: original claim 95 and page 4, line 16 and 17 of the application as filed
- Claims 57 to 60 : original claims 96 to 99, respectively
- Claim 61: page 4, lines 15 and 16 of the application as filed
- Claims 62 to 68: original claims 105 to 110
- Claims 69 to 77: original claims 112 to 120.

1.5 From the above, it follows that the amended claims meet the requirements of Article 123(2) EPC.

2. *Novelty*

No objection was raised in this regard and none of the known prior art documents discloses the combination of features defined in the subject-matter of the claims at issue. The board is satisfied that the requirements of Article 54(1)(2) EPC are met.

3. *Inventive step*

Applying the problem-solution approach developed by the boards of appeal, the board came to the conclusion that the claims of this request involve an inventive step for the following reasons:

3.1 The invention concerns microcapsules for delivering compounds, in particular microcapsules prepared from zero Bloom fish gelatin (claim 1) and methods of making and using thereof (page 1, lines 10, 11, 28 and 29 of the application as originally filed), more particularly a foodstuff and a pharmaceutical formulation.

3.2 Microcapsules, methods of preparing them and their use are disclosed in D3. More specifically, document D3 discloses in its claim 1 a multi-core microcapsule comprising: (a) an agglomeration of primary microcapsules, each primary microcapsule comprising a core and a first shell surrounding said core; (b) a second shell surrounding said agglomeration; and (c) a third shell surrounding said second shell; at least one

of said first, second and third shells comprising a complex coacervate.

The complex coacervate can be made of gelatine A and at least one further polymer component selected from the group consisting of gelatine type B, polyphosphate, gum arabic, alginate, chitosan, carrageenan, pectin and carboxymethylcellulose (D1; claim 7).

According to page 8, a particularly preferred form of gelatin A has a Bloom strength of 50 to 350, more preferably of about 275.

Hence the board agrees with the examining division to take document D3 as the closest state of the art.

- 3.3 With respect to the technical problem, no improvement has been put forward. It follows that starting from D3 the problem underlying the alleged invention is to be seen - as acknowledged by the examining division - in the provision of an alternative microcapsule.

- 3.4 As a solution to this technical problem, the application proposes the microcapsules according to claim 1, which is characterised in particular in that the gelatin of the two-component system constituting the primary and outer shell material is a fish gelatin having Bloom number of zero.

- 3.5 As to the success of the solution, example 1 of the application shows that free-flowing microcapsules filled with fish oil can be prepared from zero Bloom high molecular fish gelatin and another polymer component, namely a polyphosphate. The board is

therefore satisfied that the problem identified in point 3.3 has been effectively solved.

3.6 It remains to be decided whether the proposed solution is obvious in view of the state of the art starting from document D3, which does not disclose the use of fish gelatin having a Bloom number of zero.

In the board's view - contrary to the examining division's conclusions - the solution proposed in claim 1 at issue is not obvious, in particular from the content of document D1 for the following reasons.

D1 (claim 1) discloses a storage-stable, free-flowing, microemulsified, omega-3 acid-containing oil composition in the form of microspheres consisting essentially of (1) up to about 70% by weight of omega-3 acid-containing oil, and (2) gelatin, in which the oil is microemulsified by the gelatin. Specifically, the microspheres have a diameter ranging from about 50 µm to about 400 µm and are produced by spray-drying from a composition comprising gelatin having a Bloom value between about 25 and about 75 (D1, claim 3).

D1 (column 5, lines 12 to 17) further discloses that "good results can be achieved using a 50/50 (w/w) mixture of acid hydrolyzed gelatin (100-125 Bloom) and commercial enzymatically-hydrolyzed gelatin (5,000 average g/m, zero Bloom)".

D1 does not disclose an outer shell encapsulating an agglomeration of microcapsules, nor does D1 disclose the use of no Bloom fish gelatin. In respect of the no Bloom gelatins, the appellant stated that no Bloom fish

gelatin had a high molecular weight whereas the zero Bloom enzymatically-hydrolyzed gelatin of D1 had a low molecular weight.

In view of the above, for the board, the examining division's conclusion that the subject-matter of claim 1 was obvious from the teaching of D1 is based on ex-post considerations, because D1 is completely silent as to the preparation of multi-core microcapsules. As a consequence of this missing information, the skilled person seeking an alternative to the multi-core microcapsules of D3 would not take into consideration the content of D1 and thus not find a solution to its problem in this document.

Furthermore, none of the state of the art documents cited in the search report discloses the use of fish gelatin in multi-core microcapsules. This missing information in the prior art strengthens the above conclusion that the subject-matter of claim 1 is not obvious from the state of the art because - as explained by the appellant - the high molecular weight of the fish gelatin unexpectedly gives rise to the high rigidity and stability necessary for applications where processing conditions are harsh, in particular food processing (letter dated 9 April 2010, page 8, lines 8 to 10 and 24 to 26; page 10, lines 25 to 28).

- 3.7 It follows from the above considerations that the subject-matter of claim 1 at issue involves an inventive step within the meaning of Articles 52(1) and 56 EPC.

The same holds for the process claim 26 comprising the provision of an aqueous mixture comprising a loading substance and a fish gelatin having a Bloom number of zero as well as for the foodstuff (claim 50) and the pharmaceutical formulation (claim 54) comprising the claimed microcapsule, and the method (claim 55) for delivering a non-therapeutical loading substance to a subject comprising administering the claimed microcapsule.

Claims 2 to 25, 27 to 49, 51 to 53 and 56 to 77 derive their patentability from the independent claim on which they depend and do therefore also meet the requirements of Article 56 EPC.

4. No further objections were raised by the department of first instance. The board also does not see any further deficiencies, with the consequence that the claimed subject-matter thus satisfies the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of the set of claims filed with letter dated 9 April 2010, with the description and the Figures to be adapted, if appropriate.

The Registrar:

The Chairman

C. Vodz

G. Rath