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Datasheet for the decision of 17 December 2013

Case Number: T 1000/12 - 3.3.09

Application Number: 08168252.8

Publication Number: 2071964

IPC: A23K1/16, A23K1/18

Language of the proceedings: EN

Title of invention:
Method of supplementing animals with carotenoids by drinking water

Applicant:
Zhejiang Medicine Co., Ltd. Xinchang Pharmaceutical Factory

Headword:

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - enabling disclosure (no)

Decisions cited:
T 0051/87, T 0412/09, T 1641/11

Catchword:

Europäisches Patentamt
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Case Number: T 1000/12 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 17 December 2013

Appellant: (Applicant)	Zhejiang Medicine Co., Ltd. Xinchang Pharmaceutical Factory No.59 Huancheng Donglu Xinchang County Zhejiang 312500 (CN)
Representative:	De Anna, Pier Luigi DeAnna-Patent Lucile-Grahn-Strasse 48 81675 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 2 December 2011 refusing European patent application No. 08168252.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: M. O. Müller
Members: N. Perakis
K. Garnett

Summary of Facts and Submissions

I. European patent application No. 08168252.8, filed on 4 November 2008 in the name of Zhejiang Medicine Co., Ltd. Xinchang Pharmaceutical Factory, and claiming priority from CN 200710301265 (18 December 2007), was refused by decision of the examining division which was announced orally on 27 October 2011 and issued in writing on 2 December 2011.

II. In the examination proceedings, the following documents were cited:

D3: US 6,296,877 B1; and
D4: EP 1 460 060 A1.

III. The decision of the examining division was based on a main and first auxiliary request. Independent claims 1 and 5 of the main request read as follows:

"1. Microcapsules powders or beadlets for supplementing animals with carotenoids, comprising a yellow pigment and a red pigment, wherein: [...]
- said microcapsules powders or beadlets are dispersed in water [...]."

"5. A pigment dispersion containing the microcapsules powders or beadlets according to any one of claims 1 to 4 and water [...]."

Claim 1 of the first auxiliary request read as follows:

"1. Use of water soluble microencapsulated dry powders or beadlets for the coloration of poultry skin, meat or yolk eggs, said water soluble microencapsulated dry powders or beadlets comprising at least one yellow

pigment and at least one red pigment, wherein the weight ratio of the yellow pigment to the red pigment is 6:1 to 0.1:1, comprising

- dissolving in water the microencapsulated powders or beadlets, to obtain a yellow and red pigments solution and
- administering the solution of yellow and red pigments to animals by drinking [...]."

IV. In its decision, the examining division essentially held that the main request did not meet the requirements of Articles 56, 84 and 123(2) EPC and Rule 139 EPC.

It also held that the invention defined by the main and first auxiliary requests was insufficiently disclosed. The invention as defined by these requests related to a solution of microencapsulated carotenoids (according to the examining division, the dispersion in claims 1 and 5 of the main request had to be understood as a solution). This solution state could only be achieved with nanoparticles, ie with particles having a diameter lower than 1 micron. However, this was nowhere disclosed in the application as filed. Moreover, the nature of the microcapsules was not disclosed at all. Thus the skilled person was not presented with the information that was required to achieve the solution required by the invention. Since the present application failed to disclose that essential feature, it did not meet the requirements of Article 83 EPC.

The following additional reasoning in relation to Article 83 EPC was presented in an *obiter dictum:* According to the present application, the microcapsules provided a higher efficiency than those of the prior

art when administered to chickens in the form of a solution in drinking water. Thus, the fact that the microcapsules were solubilised when put into water was an essential feature of the invention. However, for being solubilised, the particles had to be nanoparticles. Therefore, the inventive effect, if any, was linked to a feature that was not disclosed. Also for this reason the present application did not meet the requirements of Article 83 EPC.

V. On 2 February 2012, the applicant (hereinafter "the appellant") filed a notice of appeal against the above decision. The prescribed fee had been paid on 1 February 2012.

VI. The statement setting out the grounds of appeal was filed on 2 April 2012 together with the following attachments:

Attachment 1: Product information on redivivo®(Lycopene) and OPTISHARP®(ZEAXANTHIN) of DSM;
Attachment 2: Experimental report on the solubility of microencapsulated powders and beadlets;
Attachment 3: Measurement data on the volume distribution of lutein;
Attachment 4: Measurement data on the volume distribution of canthaxanthin; and
Attachment 5: CN 101177540 B;

as well as a main request, claim 1 of which read as follows:

"1. Use of microencapsulated dry powders or beadlets for supplementing poultry with carotenoids by drinking water, comprising the following steps:

(1) making yellow and/or red pigments into microencapsulated dry powders or beadlets; wherein the content of the component of carotenoids in the microencapsulated dry powders or beadlets is 5~25% (w/w);

(2) mixing the aforementioned microencapsulated dry powders or beadlets in a certain proportion and dissolving them in water to prepare for a pigment solution; ...".

VII. By its communication of 6 May 2013, the board issued its preliminary opinion on all relevant issues. Regarding sufficiency of disclosure, it expressed the preliminary opinion that the invention underlying the main request was insufficiently disclosed for the following reasons:

Firstly, it appeared to be an essential feature of the invention as defined by the main request that the microencapsulated dry powders or beadlets contained carotenoids in an amorphous form. The application as filed did however not contain any teaching as to how such powders or beadlets could be obtained. Furthermore, such a teaching seemed not to be part of the skilled person's common general knowledge.

Secondly, claim 1 of the main request contained the step of dissolving microencapsulated dry carotenoid-containing powders or beadlets in water. In order to perform this step, the microencapsulated dry powders or beadlets had to be water-soluble. The present

application did not contain any teaching as to how normally non-water-soluble carotenoid powders or beadlets could be made water-soluble. There was furthermore no evidence that such a teaching belonged to the common general knowledge at the priority date of the present application.

Concerning attachment 5, this was a Chinese patent that was published after the priority date of the present application and thus attachment 5 could not constitute any evidence of what was common general knowledge at the priority date of the present patent application. An English language machine translation of attachment 5 was annexed to the board's communication and any reference to this attachment hereinafter will relate to this translation.

VIII. By its letter of 13 November 2013, the appellant filed a new main and an auxiliary request together with the following attachments:

Attachment RF1: X-ray diffraction pattern of a microencapsulated canthaxanthin;

Attachment RF2: Particle size distribution of a microencapsulated powder;

Attachment RF3: "Microencapsulation: its application in nutrition", P. M. M. Schrooyen et al, Proceedings of the Nutrition Society, volume 60, 2001 pages 475 to 479;

Attachment RF4: PhD thesis "Studies on the preparations and its characterizations of microcapsule powder / beadlets with high content carotenoids", published in August 2007 (in Chinese language);

Attachment RF4.1: German translation of chapters 2 and 6 of RF4; and
Attachment RF5: Experiments on chickens intake of carotenoids through drinking.

Claims 1, 5 and 6 of the main request read as follows:

"1. Microencapsulated dry powders or beadlets for supplementing animals with carotenoids by drinking water, wherein:

a) the microencapsulated dry powders or beadlets contain yellow and red pigments;
b) the yellow pigment comprises at least one selected from the group consisting of ß-apo-8'-carotene aldehyde, ß-apo-8’-carotene acetate, lutein and zeaxanthin;
c) the red pigment comprises at least one selected from the group consisting of canthaxanthin, citranaxanthin, and capsanthin
d) the content of the active component of amorphous carotenoids in the microencapsulated dry powders or beadlets is 5~25% (w/w); and
e) the weight ratio of the effective component of the yellow to red pigments mixed is 6:1 to 0.1:1."

"5. A water solution of the microencapsulated dry powders or beadlets according to claims 1-4, wherein the concentration of carotenoids in the pigment solution is 30 mg/kg ~ 400 mg/kg."

"6. A water solution of the microencapsulated dry powders or beadlets according to claims 1-4 for use in treating respiratory diseases of poultry, wherein the concentration of carotenoids in the pigment solution is 30 mg/kg ~ 400 mg/kg."

Claim 1 of the auxiliary request reads as follows:

"1. A water solution of microencapsulated dry powders or beadlets for use in treating respiratory diseases of poultry, wherein the microencapsulated dry powders or beadlets are directly obtained by:

making yellow and red pigments into the microencapsulated dry powders or beadlets; wherein

a) the yellow pigment comprises at least one selected from the group consisting of ß-apo-8'-carotene aldehyde, ß-apo-8'-carotene acetate, lutein and zeaxanthin;
b) the red pigment comprises at least one selected from the group consisting of canthaxanthin, citranaxanthin, and capsanthin
c) the content of the active component of amorphous carotenoids in the microencapsulated dry powders or beadlets is 5~25% (w/w); and
d) the weight ratio of the effective component of the yellow to red pigments mixed is 6:1 to 0.1:1;

and making a water solution of the microencapsulated dry powders or beadlets according to step a) to d), wherein the concentration of carotenoids in the pigment solution is 30 mg/kg ~ 400 mg/kg."

IX. On 17 December 2013, oral proceedings were held before the board. The appellant maintained its requests filed with the letter of 13 November 2013.

X. The appellant's position in the written and oral proceedings, in as far as relevant to the present decision, can be summarised as follows:

Water-solubility in terms of the present claims actually meant that the microencapsulated carotenoid particles formed a homogeneous dispersion in water that had the appearance of a solution. Water-solubility and amorphicity of the carotenoids were very important and, to obtain these properties, the diameter of the microencapsulated particles had to be in the range of 150 to 250 nanometers.

According to the application as filed, the carotenoid particles had to be prepared by the microcapsule technique. Even though rather silent about how microencapsulation had to be carried out, the application as filed still provided sufficient information about how to transform non-water soluble crystalline carotenoids into water-soluble and amorphous ones. More specifically, the skilled person simply had to rework example 1 of the application as filed in order to obtain the required water-solubility and amorphicity.

Furthermore, the skilled person would also have been able to obtain water-soluble amorphous carotenoids on the basis of his common general knowledge.

Firstly, as shown by RF3, spray drying was a commonly known method to obtain microencapsulated carotenoids and it was proven by the PhD thesis RF4 and its partial translation RF4.1 that by way of this method, water-soluble amorphous carotenoids were obtained. So all that the skilled person needed to do was to prepare microencapsulated carotenoids by the commonly known spray drying process.

Secondly, RF4.1 itself proved that it was commonly known at the priority date of the present application how the microencapsulation had to be carried out to obtain water-soluble amorphous carotenoids.

Thirdly, D3 disclosed a microencapsulation process that led to water-soluble amorphous carotenoids.

Fourthly, attachment 5 taught the skilled person how to obtain water-soluble amorphous carotenoids. The particles obtained in examples 1 to 5 of this document all had particle diameters in the range of 179 to 298 nm and thus were water-soluble.

Hence the method of preparing the microencapsulated dry powders or beadlets of the present application by the microcapsule technique belonged to the prior art. The skilled person was thus able to perform the invention on the basis of the application as filed and the common general knowledge available at the priority date of the present application.

XI. During the oral proceedings, the board made the following additional observations:

- Attachment 5 did not disclose microencapsulated amorphous carotenoids but it could be assumed that these were crystalline.
- Contrary to the appellant's assertions, not all spray drying methods led to water-soluble amorphous carotenoids. RF4.1 proved that it was necessary to control several parameters during spray drying and thus microencapsulation in order to obtain the required water-solubility and amorphicity.

XII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request, alternatively the auxiliary request, both filed with the letter of 13 November 2013.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. The claimed invention

2.1 Independent claim 1 refers to microencapsulated carotenoid powders or beadlets and requires these to contain amorphous carotenoids (item "d)" of claim 1; for the exact wording of claim 1, see point VIII above).

Independent claims 5 and 6 refer to "[a] water solution of the microencapsulated dry powders or beadlets according to claims 1-4" (for the exact wording of claims 5 and 6, see point VIII above). By way of being directed to a water solution, these claims require the microencapsulated carotenoid powders or beadlets to be water-soluble (which, as explained by the appellant, actually means that the microencapsulated carotenoid powders or beadlets must be able to form a homogeneous dispersion that has the appearance of a solution). By way of their back-reference to claim 1, claims 5 and 6 furthermore require the microencapsulated carotenoid powders or beadlets to contain amorphous carotenoids.

2.2 It is clear from the description of the present application that water-solubility and amorphicity of

the carotenoids are crucial to obtain the effects aimed at in the application as filed, in particular an increased efficiency of coloration (page 6, lines 13 to 23 and page 14, lines 14 to 16).

3. Sufficiency of disclosure (Article 83 EPC)

3.1 An invention is sufficiently disclosed if the skilled person, on the basis of the disclosure of the application in question and/or the common general knowledge at the priority date of the application, is able to carry out the invention as defined in the claims without undue burden.

3.2 As set out above, it is crucial to the invention underlying the main request, and it is part of the independent claims thereof, that the carotenoids referred to in these claims are water-soluble and amorphous.

3.3 Carotenoids as such are, however, not water-soluble and not amorphous but crystalline, as documented in the state of the art and admitted by the appellant:

> "One of the main difficulties in using the carotenoids in the field of colourants is their zero solubility in water, ..." (page 3, line 11 of D4);
>
> "...secondly carotenoids as the effective components in the pigments exist in the form of crystal, ..." (page 4, lines 2 to 3 of the application as filed);
>
> "To this extend [*sic*] the appellant submits that before the formulation of microencapsulation, the

raw material pigments [ie the carotenoids] are still in crystals, ..." (the appellant's statement in point 3a on page 3 of its letter of 13 November 2013, insertion in squared brackets by the board).

3.4 Therefore, the issue of sufficiency of disclosure boils down to whether the skilled person:

- on the basis of the application as filed; and/or
- his common general knowledge at the priority date of the application,

was able to transform non-water-soluble crystalline carotenoids into water-soluble amorphous ones. This is the object of the analysis that follows.

3.5 The information in the application as filed

3.5.1 All that the present application discloses, is that the carotenoids have to be subjected to microencapsulation. The application as filed refers in this respect to "the technique of microcapsule" (page 7, line 23) and "the microcapsule techniques" (page 8, lines 18 to 19 and page 9, lines 4 to 5). No information is however provided in the application as filed regarding how this microencapsulation technique has to be carried out, let alone how the initially water-insoluble crystalline carotenoids can be rendered water-soluble and amorphous thereby.

3.5.2 This lack of information would not be prejudicial to sufficiency of disclosure if all microencapsulation processes applied to carotenoids and available at the priority date of the present application could be assumed to lead to water-soluble amorphous carotenoids. In this case, the skilled person would simply have to

choose whatever microencapsulation process was available to him in order to obtain the required water-solubility and amorphicity.

3.5.3 In view of the PhD thesis RF4.1 (partial translation), however, it must be assumed that only very specific microencapsulation methods lead to water-soluble amorphous carotenoids:

Firstly, it is disclosed in RF4.1 that the properties of microencapsulated carotenoids, including their stability, solubility and other characteristics, depend on the choice of the shell material and the surfactant used for the microencapsulation. This is specifically disclosed in the paragraph bridging the first and second page of RF4.1:

"Die Entfaltung der Eigenschaften, einschließlich seiner **Stabilität**, **Löslichkeit** und **anderen Besonderheiten**, von Produkten der Mikroverkapselung wird durch die Wahl des Mikrokapselwandmaterials und de[s] Emulgator[s] im Ablauf der Herstellung der Mikroverkapselung und das Herstellungsverfahren der Mikroverkapselung entschieden. Qualitativ hochwertige Carotenoid mikroverkapselte Produkte erfordern die gute Stabilität des Kernmaterials, die Fließfähigkeit des Pulvers, gute Wasserlöslichkeit oder Druckfestigkeit und ausgezeichnete Bioverfügbarkeit, und all dies steh[t] mit dem Rezept der Mikroverkapselung und der Wahl des Bildungsverfahrens von de[n] Partikeln eng im Zusammenhang".

Secondly, it is stated in RF4.1 that the dissolution rate, and hence the water-solubility, of certain microencapsulated carotenoids depends on the diameter of the microcapsules (this was confirmed by the

appellant during the oral proceedings) and the composition of the shell material, including the molecular weight of gelatin and the ratio between gelatin and saccharide. This is disclosed in the first sentence of the second paragraph on the last page of RF4.1:

"Die Auflösungsrate von CWS-S [a microencapsulated carotenoid] wird stark von dem Durchmesser des mikroverkapselten Pulvers und dem Gehalt des Fließmittels beeinflusst, während die Zusammensetzung des Kapselwandmaterials von CWS-G [another microencapsulated carotenoid], einschließlich des Molekulargewichts von Gelatine und des Verhältnis[ses] zwischen Gelatine und Rohrzucker beachtenswerte Einflüsse auf die Löslichkeit von CWS-G hat" (insertion in squared brackets by the board).

Thirdly, it can be deduced from RF4.1 that the bioavailability of carotenoids, which is linked to the degree of amorphicity (see page 6, lines 21 to 23 of the application as filed) depends on the type of organic solvent used during microencapsulation. This is disclosed in the first full paragraph on page 3 of RF4.1:

"Um die endgültige Bioverfügbarkeit von Carotenoid mikroverkapselten Pulver[n]/Partikeln zu verbessern, ... ist die Wahl der organischen Lösungsmittel während der Lösung der Öl-Phase unerlässlich".

It is thus clear that at least:

- the nature of the shell material;
- the type of surfactant;

- the type of organic solvent; and
- the size of the microcapsules

must be controlled during microencapsulation in order to obtain the required water-solubility and amorphicity of the carotenoids. Since no information is available at all in the application as filed as regards any of these microencapsulation parameters, the application as filed does not enable the skilled person to obtain the claimed water-soluble amorphous carotenoids.

3.5.4 During the oral proceedings, the appellant argued that the skilled person simply has to rework example 1 of the application as filed in order to obtain the required water-solubility and amorphicity. However, apart from stating that "10% warm-water soluble lutein beadlets" (lutein is a yellow carotenoid pigment) are used, this example does not provide any information as to how these lutein beadlets could be prepared. Hence, example 1 suffers from the same deficiency as the remaining part of the application as filed, namely of not disclosing how microencapsulation has to be carried out such that non-water-soluble crystalline (yellow) carotenoids are transformed into water-soluble amorphous ones. The same objection applies to the remaining examples.

3.6 The skilled person's common general knowledge

3.6.1 It remains to be examined whether, on the basis of the common general knowledge available at the priority date of the present application, the skilled person would be able to obtain the required water-solubility and amorphicity.

3.6.2 The appellant argued in this respect that according to RF3, a commonly known method to microencapsulate carotenoids was spray drying and that it was proven by the PhD thesis RF4 and its partial translation RF4.1 that using this method, water-soluble amorphous carotenoids are obtained. So all that the skilled person needs to do is to prepare microencapsulated carotenoids by the commonly known spray drying process referred to in RF3.

The board acknowledges that microencapsulation in RF4.1 is carried out by spray drying (page 3, line 18 of RF4.1). However, as set out above (point 3.5.3), it is necessary to control several parameters during microencapsulation, and thus spray drying, in order to obtain the required water-solubility and amorphicity. Hence, contrary to the appellant's assertion, the general reference to "spray drying" in RF3 does not enable the skilled person to transform non-water-soluble crystalline carotenoids into water-soluble amorphous ones.

3.6.3 The appellant also argued that RF4.1 itself proved that it was commonly known at the priority date of the present application how the microencapsulation had to be carried out in order to obtain water-soluble amorphous carotenoids.

However, RF4.1 is a partial translation of the PhD thesis RF4 and generally the subject of a PhD thesis is not that which has already been commonly known in the art. Therefore, RF4.1 and in the same way RF4 do not represent common general knowledge.

3.6.4 The appellant also referred to D3 and stated that this document disclosed a microencapsulation process that led to water-soluble amorphous carotenoids.

What D3 describes is a specific microencapsulation process by which water-soluble carotenoid microcapsules are obtained in which the carotenoid is present in an amount of 70 to 100% in an amorphous state (column 4, lines 27 to 41).

However, D3 is a patent document and patent literature only under exceptional circumstances can be assumed to represent the skilled person's common general knowledge (see eg T 1641/11, point 3.6). Such exceptional circumstances apply according to the case law of the boards of appeal of the EPO where, for instance, a series of patent documents provide a consistent picture that a particular technical procedure was generally known (T 412/09, point 2.1.3). A further reason for exceptionally considering a patent document as proof of the skilled person's common general knowledge is when the field in question is a brand-new field of research so that any technical knowledge acquired in this field at the beginning through basic pioneering work has not yet been distilled into the form of textbooks (T 51/87, point 9). None of these exceptional circumstances applies in the present case. Firstly, D3 does not provide a consistent picture of procedures that transform non-water-soluble crystalline carotenoids into water-soluble amorphous ones and secondly carotenoids have been used in food chemistry for a long time and are certainly not a brand-new field of research.

In conclusion, the information contained in D3 is not part of the skilled person's common general knowledge.

3.6.5 The appellant finally argued that the skilled person would know how water-soluble amorphous carotenoids could be obtained on the basis of attachment 5.

Attachment 5 is a Chinese patent, the application for which was published on 14 May 2008, ie after the priority date of the present application (18 December 2007). Attachment 5 thus cannot constitute any proof of what was common general knowledge at the priority date of the present application.

Furthermore, attachment 5 does not contain any information as to how crystalline carotenoids can be transformed into amorphous ones. In fact, if anything, it must be assumed that the microencapsulated carotenoids in attachment 5 (phylloxanthin) are crystalline rather than amorphous. More specifically, page 3, lines 16 to 17 explicitly refers to "the crystal of the phylloxanthin" to be embedded in denatured starch (the shell material of the phylloxanthin microcapsules).

Lastly, like D3, attachment 5 is a patent document and as set out above also for this reason cannot be considered to represent the skilled person's common general knowledge.

3.7 Therefore, neither the present application nor the common general knowledge available at the priority date enable the skilled person to transform non-water-soluble crystalline carotenoids into water-soluble amorphous ones. The invention as defined in claims 1, 5 and 6 of the main request is thus insufficiently disclosed.

Auxiliary request

4. Sufficiency of disclosure (Article 83 EPC)

4.1 Claim 1 of the auxiliary request refers to "[a] water solution of microencapsulated dry powders or beadlets" and contains *inter alia* the feature that "the content of the active component of amorphous carotenoids in the microencapsulated dry powders or beadlets is 5~25% (w/w)" (for the exact wording of claim 1, see point VIII above).

In the same way as for claims 5 and 6 of the main request, claim 1 of the auxiliary request requires the microencapsulated carotenoids to be water-soluble and amorphous. For the same reasons as given above with regard to the main request, neither the application as filed, nor the skilled person's common general knowledge provide sufficient information to obtain the required water-solubility and amorphicity. Therefore, in the same way as with the main request, the invention defined by claim 1 of the auxiliary request is insufficiently disclosed.

Further objections

The board had raised further objections in its preliminary opinion (communication of 6 May 2013). However, since neither the main nor the auxiliary request is allowable in view of Article 83 EPC, these objections need not be dealt with in the present decision.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Cañueto Carbajo M. O. Müller

Decision electronically authenticated