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Datasheet for the decision of 12 September 2019

Case Number: T 0873/17 - 3.3.05

Application Number: 07848591.9

Publication Number: 2125191

IPC: B01J13/02

Language of the proceedings: EN

Title of invention:
HARD SHELL CAPSULE FORMULATIONS

Applicant:
MW Encap Limited

Headword:
Hard shell capsule/Encap

Relevant legal provisions:
EPC Art. 84

Keyword:
Claims - clarity (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0873/17 - 3.3.05

D E C I S I O N
of Technical Board of Appeal 3.3.05
of 12 September 2019

Appellant: (Applicant)	MW Encap Limited Building 1 Oakbank Park Livingston West Lothian EH53 0TH (GB)
Representative:	De Clercq & Partners Edgard Gevaertdreef 10a 9830 Sint-Martens-Latem (BE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 16 September 2016 refusing European patent application No. 07848591.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	E. Bendl
Members:	G. Glod
	P. Guntz

Summary of Facts and Submissions

I. The present appeal of the applicant (appellant) lies from the decision of the examining division refusing European patent application EP 07 848 591.9 for not fulfilling the requirements of Article 56 EPC.

II. In the communication under Article 15(1) of the RPBA, the board was of the preliminary opinion that the appeal was to be dismissed.

III. By letter of 4 July 2019, the appellant filed new requests.

IV. Oral proceedings took place on 12 September 2019. The appellant filed a new main request and withdrew the previous requests.

Claim 1 of this request is as follows:

"*1. A method of encapsulating a formulation, the method comprising the steps of:*
- providing a hard shell capsule and a hygroscopic formulation to be filled into said capsule,
- hydrating said hygroscopic formulation by a selected amount to control the anticipated water equilibrium between said hygroscopic formulation and the hard shell capsule,
- filling said hydrated formulation into said hard shell capsule,
wherein said hygroscopic formulation consists of an active compound which is a protein or peptide and at least one hygroscopic excipient chosen from the list comprising: hygroscopic polyethylene glycols having an average molecular weight of less than 1000, hygroscopic sugars, or hygroscopic lactams, wherein

- when the hygroscopic excipient in said hygroscopic formulation is polyethylene glycol, the polyethylene glycol in said hygroscopic formulation is hydrated to between 20% w/w and 32% w/w water, or
- when the hygroscopic excipient in said hygroscopic formulation is a sugar, the sugar in said hygroscopic formulation is hydrated to between 11% w/w and 16% w/w water, or
- when the hygroscopic excipient in said hygroscopic formulation is a lactam, the lactam in said hygroscopic formulation is hydrated to between 6.5% w/w and 10% w/w water, and
wherein said hard shell capsule comprises a material selected from gelatin or hydroxypropyl methylcellulose."

V. The appellant stated that the claims limited the degree of hydration of the hygroscopic formulation as a whole and not only of the excipient. The amount of water defined thereby would result in the anticipated water equilibrium between the hygroscopic formulation and the hard shell capsule. The claims were therefore clear.

VI. The appellant (applicant) requests that the impugned decision be set aside and that a patent be granted based on the sole request (dated 11 September 2019) filed during oral proceedings of 12 September 2019.

Reasons for the Decision

1. Article 84 EPC

Claim 1 specifies that the hygroscopic formulation consisting of a protein or peptide and at least one hygroscopic excipient chosen from the list comprising

hygroscopic polyethylene glycols having an average molecular weight of less than 1000, hygroscopic sugars, or hygroscopic lactams, is hydrated such that the amount of water added makes it possible to control the anticipated water equilibrium between said formulation and the hard shell capsule.

It needs to be determined whether the wording of claim 1 is sufficiently clear for the skilled person to be in no doubt, when selecting an amount of water from the ranges indicated, whether this is within or outside the claimed scope.

The meaning of the wording "anticipated water equilibrium" is not well-defined; the same therefore also applies to control of the said equilibrium. Thus, for this reason alone the wording of claim 1 is considered unclear. However, even if it is assumed that the skilled person would interpret the term as meaning that the equilibrium is considered to be reached when no water loss occurs and the amount of water remains constant (as is also mentioned in the description on page 9, lines 9 to 21 and example 1, page 15, lines 5 to 8), there is no indication in the application of the conditions under which and the manner in which the equilibrium is to be assessed. It is undisputed that the equilibrium - and therefore the question of whether softening or cracking of the shell occurs - depends among other factors on the storage time and on the temperature and humidity of the surrounding environment. It is known, and apparent from the application, that the equilibrium also depends on the type of hard shell material and the type of excipient.

Furthermore, the amount of water in the hygroscopic formulation is not only defined in relation to the

"water equilibrium", but also in relation to one of the hygroscopic excipients present in the hygroscopic formulation. However, in spite of the ranges indicated in claim 1, the skilled person cannot deduce whether an amount of water selected from within the ranges given for hydration of the excipient is suitable for controlling the anticipated water equilibrium for a given composition, since neither the amount of hygroscopic excipient present in the formulation (i.e. the ratio of protein/-peptide to hygroscopic excipient) nor any compounds or their amounts in the hard shell capsule other than gelatin or hydroxypropyl methylcellulose are known. With any amount of water a kind of equilibrium will be established, but it is unclear whether this will be an equilibrium within the terms of the present application.

Consequently, the skilled person preparing a hygroscopic formulation with a specific protein or peptide, a specific hygroscopic excipient (e.g. polyethylene glycol 600) and a specific amount of water (e.g. 25% w/w) with respect to the polyethylene glycol, and filling said formulation into a hard shell capsule according to claim 1, does not know whether they are working within or outside the scope of the claim. They do not know which conditions should be used to determine whether an equilibrium between the formulation and the capsule has effectively been reached. Even assuming that the water equilibrium could be reached and determined without problems, it is undisputed that it makes a considerable difference whether a capsule is analysed immediately after filling, one month after filling with storage at 15°C and 35% humidity, or six months after filling with storage at 25°C and 60% humidity.

To summarise, the skilled person can carry out the steps defined in claim 1 but is still not sure whether the amount of water chosen from the ranges indicated makes it possible "to control the anticipated water equilibrium", as this term, at least in the present context, is not clear.

The requirements of Article 84 EPC are therefore not met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Vodz E. Bendl

Decision electronically authenticated