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D E C I S I O N
of 7 February 1997

Case Number: T 0019/94 - 3.3.3

Application Number: 87904599.5

Publication Number: 0321464

IPC: C08L 1/00

Language of the proceedings: EN

Title of invention:
Coatings based on polydextrose for aqueous film coating of pharmaceutical, food and confectionery products

Applicant:
COLORCON, INC.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes) - no incentive"

Decisions cited:
-

Catchword:
-

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Case Number: T 0019/94 - 3.3.3

D E C I S I O N
of the Technical Board of Appeal 3.3.3
of 7 February 1997

Appellant: COLORCON, INC.
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Decision under appeal: Decision of the Examining Division of the European Patent Office posted 28 July 1993 refusing European patent application No. 87 904 599.5 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: C. R. J. Gérardin
Members: H. H. R. Fessel
J. A. Stephens-Ofner

Summary of Facts and Submissions

I. European patent application No. 87 904 599.5, filed on 19 June 1987 and published under the Patent Cooperation Treaty on 30 December 1987 under the international publication number WO 87/07902 was refused by a decision of the Examining Division 2.1.15.014 of the European Patent Office dated 28 July 1993.

That decision was based on a set of 8 claims filed on 22 September 1992. Claim 1 of that set of claims reads as follows:

"A method of coating pharmaceutical tablets, food and/or confectionery forms with a protective film by spraying an effective amount of a coating suspension onto said tablets to form a film coating on said tablets and drying the film coating on said tablets, food and/or confectionery forms, characterized in that said coating suspension is provided by mixing polydextrose, plasticizer, detackifier and secondary film former into water to form an aqueous coating suspension, wherein

- said polydextrose being 30 to 90% by weight of the non-water ingredients of the aqueous coating suspension and having a peak molecular weight of approximately 1230

- said plasticizer being polyethylene glycol, triacetin, propylene glycol or acetyltriethyl citrate in a range of 2,5 to 10% by weight of the non-water ingredients of the aqueous coating suspension

- said detackifier being lecithin or mineral oil in a range of 1 to 3% by weight of the non-water ingredients of the aqueous coating suspension, and

- said secondary film former being sodium alginate or propylene glycol alginate in a range of 2 to 10% by weight of the non-water ingredients of the aqueous coating suspension.

That wording incorporates three minor amendments (deletion of the letter "h" in the words "weight" and "acetyltriethyl") to correct obvious editorial errors.

The subject-matter of dependent Claims 2 to 8 concerns preferred embodiments of the method according to Claim 1.

II. The reason for the decision was that the subject-matter as claimed met the provisions of Article 123(2) EPC, but lacked inventive step within the terms of Articles 52(1) and 56 EPC.

The following documents were cited in support of these objections:

(1) EP-A-169 319;
(2) US-A-3 766 165;
(3) Kirk-Othmer, third edition, volume 22 (1983), page 504; and
(4) Acta pharm. Techn. 28(2) (1982), pages 127 to 129.

More specifically, it was stated that due to the replacement of maltodextrine (glucose units bound by α-1,4 linkage) by polydextrose (predominant 1,6-glycosidic linkage) novelty could be acknowledged. As to inventive step, the technical problem underlying the present application was said to be the provision of a coating composition other than sugar and free of the

slimy taste of hydroxypropylcellulose (hereinafter HPMC) which could be applied by spraying, a problem said to be already solved by document (1). The object of the present application vis-à-vis (1) was thus to provide an alternative solution to the above problem. The Examining Division considered that the solution of that problem by substitution of maltodextrin by polydextrose would have been obvious to a skilled person in view of the teachings given by documents (1) and (4), the content of the latter being confirmed by the late published, i.e. 1992, 9th edition of Römpp.

III. On 27 September 1993 a Notice of Appeal was lodged against that decision together with payment of the prescribed fee. The Statement of Grounds of Appeal was submitted on 29 November 1993. The Appellant (Applicant) disputed the findings of the Examining Division and argued that the molecular weight ranges of maltodextrin and polydextrose were **very different**. A person skilled in the art expecting polydextrose of low molecular weight to produce an extremely weak film would, however, find polydextrose based coatings to have, surprisingly and unexpectedly, excellent properties.

The issuance of the decision to refuse the application without granting an interview, which the Appellant had asked for, was alleged to be a procedural violation of Articles 113 and 116 EPC justifying rectification according Article 109(1)EPC and reimbursement of appeal fees according to Rule 67 EPC.

IV. By fax dated 9 January 1997 the Appellant withdrew his previous requests and requested specifically that

- the decision under appeal be set aside
- patentability of the subject-matter of Claim 1 filed on 22 September 1992 be acknowledged and
- the case to be remitted to the Examining Division for adaptation and amendment of the dependent claims and description,
- alternatively, oral proceedings be arranged.

Reasons for the Decision

1. The appeal is admissible.

2. No objection pursuant Article 123(2) EPC arises having regard to the wording of Claim 1.

With respect to original Claim 1 the wording of present Claim 1 differs mainly in (a) the use of the two-part form, and (b) the qualitative and quantitative definitions of the various ingredients of the aqueous coating suspension. Amendment (a) has obviously no impact on the scope of the claim. As to amendments (b) they are not objectionable, since (i) the definition of the polydextrose is supported by the first feature of Claim 12 as originally filed and page 2, lines 16 to 19 of the original application, (ii) the definition of the plasticizer by Claims 3 and 4 as originally filed, (iii) the definition of the detackifier by Claims 5 and 6 as originally filed, and (iv) the definition of the secondary film former by Claims 7 and 8 as originally filed.

Dependent Claims 2 to 8 are not specifically dealt with in the present decision. Nevertheless the Board would like to note the following comments:

Claims 2 and 7 make reference to "stationary forms" which appear not to be disclosed in the original application (Article 123(2)EPC).

Claim 3 was already objected to by the Examining Division as being directed to a method involving the use of compounds which are trademarks (Article 84 EPC).

Claim 6 comprises two embodiments, namely the substitution of a cellulosic polymer either (i) for the secondary film former and the detackifier or (ii) for the secondary film former. Embodiment (i) would correspond to a ternary composition which is not consistent with Claim 1, which requires a quaternary composition; moreover it does not appear from the original application, page 4, lines 11 to 13, that the detackifier and the secondary film former can both be a cellulosic polymer. The Claim appears thus to be objectionable under Article 84 EPC.

3. The coating suspension used in Claim 1 of the present patent application is provided by mixing a polydextrose having a peak molecular weight of 1230 with specific components. The Examining Division objected "peak molecular weight" as being unclear within the meaning of Article 84 EPC due to the lack of any information concerning its method of measurement.

The Board, however, is satisfied that Table 1 in document (4) provides enough information as to the nature and measurement of M_p. In that document the peak molecular weight M_p is determined by gel permeation chromatography and is said to be indicative of the molecular weight of the main component (see page 128, left column, 3rd. paragraph).

4. Novelty was accepted in the decision under appeal and the Board sees no reason to deviate from this finding.

5. The subject-matter claimed in the present patent application relates to a method of coating pharmaceutical tablets, food and/or confectionery forms with a protective film by spraying a coating suspension of a mixture of polydextrose, plasticizer, detackifier and secondary film former. The film coatings thus produced do not have an undesirable taste and are not slimy in texture as other cellulosic polymer compositions used previously for the aqueous film coating of pharmaceutical tablets (cf page 1, lines 10 to 13; page 2, lines 1 to 5).

The objective of document (1) is also a method for preparing pharmaceutical, confectionery or food tablets which do not have the characteristic taste of the tablet ingredients and do not have a slimy taste (loc.cit. page 3, lines 15 to 21). These tablets are produced by spray-coating a mixture of maltodextrose, plasticizer, detackifier and secondary film former (loc.cit. Claims 21 to 31).

Owing to the same objective and the high similarity of the two methods, differing mainly by the use of polydextrose instead of maltodextrin, the Board considers, as the Examining Division already did, (1) to represent the closest prior art.

Since there is no evidence in the proceedings that a special effect has been produced by the above mentioned substitution together with the peak molecular weight of the polydextrose, the Board considers the problem to consist in the finding of an alternative method to that known from (1).

In view of the examples in the application in suit the Board accepts that this problem is effectively solved by the method as defined in Claim 1.

6. It has next to be decided whether it would have been obvious for a skilled person to use polydextrose having a peak molecular weight of approximately 1230 instead of maltodextrin as disclosed in (1) and not specifying any M_p.

6.1 As already mentioned above, document (1) has the same objective, and its method is also closely similar. Nowhere in that document, however, is any hint given as to coatings other than maltodextrin coatings. A definition of maltodextrin is given on page 7, 2nd full paragraph; a restriction to a specific molecular weight which ought to be used, especially Mp, is not given. The only indication which may imply a Mw is the DE (dextrose equivalent) given on page 7, line 20.

It follows that no hint is provided by document (1) as to the substitution of a specific polydextrose for the unspecified maltodextrin.

6.2 Document (2) relates to processes for the production of polyglucoses, called polydextrose, and polymaltoses from glucose and maltose, respectively, and the use of these materials in food products as non-nutritive substitutes for carbohydrate sweeteners or starches (column 1, lines 33 to 44). These polyglucoses have been found to have a number average molecular weight Mn

of about 1,000 to about 24,000 (column 7, lines 4 to 7). These polysaccharides, which are said to affect rheology and texture in a manner analogous to sugar, can replace sugar as a bulking agent in baked goods (column 7, lines 62 to 65). Moreover in chocolate coatings the polyglycoses allow the elimination of 20-50% of the fat, oil or triglyceride normally included while still retaining the required food characteristics such as texture, gloss, viscosity and taste of the food product (column 8, lines 7 to 11 in conjunction with Ex. XXVII).

This teaching would thus be regarded by a person skilled in the art faced with the above defined problem as an incentive to use a polydextrose having a number average molecular weight of 1,000 to 24,000, which does not correspond to the solution as defined in Claim 1.

6.3 From document (4) a person skilled in the art would learn that two batches of hydroxypropyl methylcellulose phthalate with similar weight average and number average molecular weights, but different viscosities, differ in their prevention of drug release when used as coatings. This effect is said to be due to the high molecular weight Mp and hence improved mechanical properties of the higher viscous compound (page 1, summary). By contrast, flaws and cracks in film coatings are attributed to low molecular fractions: "low molecular weight polymers with short chains are relatively weak but as the chain length and hence the molecular weight is increased the mechanical properties also improve until at some critical molecular weight there is no further improvement." In particular, the Mp from gel permeation chromatography for the critical molecular weight for HPMC and ethyl cellulose is found to be in the region of 8.0×10^4 (page 129, right hand column, lines 22 to 38).

In the Board's view this would be a clear teaching that the higher the peak molecular weight Mp the better the coating properties up to a critical molecular weight.

6.4 In document (3) a hint is given to the molecular weight of maltodextrin by indication of the amounts of DP. This does not, however, allow any conclusion to be drawn as to the molecular weight of polydextrose nor does it add anything to the information of document (1) as far as the peak molecular weight is concerned.

6.5 It follows that no document provides an incentive to choose a polydextrose having a low peak molecular weight, which must thus be regarded as an inventive feature.

6.6 For these reasons, the Board considers the subject-matter of Claim 1 to involve an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside

2. The case is remitted to the Examining Division for further prosecution.

The Registrar

E. Görgmaier

The Chairman

C. Gérardin