**Internal distribution code:**

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

# Datasheet for the decision of 3 June 2015

**Case Number:** T 2538/11 - 3.3.07

**Application Number:** 01978285.3

**Publication Number:** 1315479

**IPC:** A61K9/48, C08J5/18, C08L5/06, C08L3/08, C08L89/06

**Language of the proceedings:** EN

**Title of invention:**
PECTIN FILM COMPOSITIONS

**Patent Proprietor:**
Capsugel Belgium NV

**Opponent:**
Cargill, Inc.

**Relevant legal provisions:**
EPC Art. 56

**Keyword:**
Inventive step - (no)

**Decisions cited:**
G 0009/92

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**
**Boards of Appeal**
**Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

**Case Number: T 2538/11 - 3.3.07**

# D E C I S I O N
# of Technical Board of Appeal 3.3.07
# of 3 June 2015

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | Capsugel Belgium NV<br>Rijksweg 11<br>2880 Bornem (BE) |
| **Representative:** | Finnegan Europe LLP<br>16 Old Bailey<br>London EC4M 7EG (GB) |
| **Respondent:** (Opponent) | Cargill, Inc.<br>15407 McGinty Road West<br>Wayzata<br>Minnesota, MN 55391-5624 (US) |
| **Representative:** | Wibbelmann, Jobst<br>Wuesthoff & Wuesthoff<br>Patentanwälte PartG mbB<br>Schweigerstrasse 2<br>81541 München (DE) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 September 2011 concerning maintenance of the European Patent No. 1315479 in amended form.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | A. Usuelli |
| **Members:** | R. Hauss |
| | P. Schmitz |

## Summary of Facts and Submissions

I. European patent No. 1 315 479 was granted on the basis of fifteen claims.

II. A notice of opposition was filed in which revocation of the patent in its entirety was requested under Article 100(a) EPC for lack of novelty and lack of inventive step.

III. The documents cited during the opposition and appeal proceedings included the following:

(1) WO 00/18835 A1

(3) JP 4-27352

& English translation of document (3), filed by the patent proprietor with letter dated 22 March 2008

(10) Lachman & al: The Theory and Practice of Industrial Pharmacy, 3rd ed. 1986, 374 to 412

In the present decision, any references to document (3) will be to the English translation of that document.

IV. The appeal by the patent proprietor (appellant) lies from the decision of the opposition division, pronounced in oral proceedings on 15 September 2011 and posted on 28 September 2011, refusing the patent proprietor's amended main request and first auxiliary request, both filed during oral proceedings of 15 September 2011.

The opposition division also found that the patent as amended in the form of the second auxiliary request filed during oral proceedings on 15 September 2011 met the requirements of the EPC.

Independent claims 1 and 8 of the main request read as follows:

*"1. Film composition for enteric hard capsules comprising*

*a) pectin,*
*b) a second film-forming polymer and*
*c) a setting system,*

*the setting system consists of:*

*(i) pectin and divalent cation salts, or*

*(ii) pectin and an additional setting agent selected from the group consisting of carrageenan, gellan gum and mixtures thereof, and*

*wherein the content of pectin is from 10 to 40% by weight in the film composition, and that of the second polymer from 50 to 85% by weight in the film composition.*

*8. Film-forming aqueous solution of the composition according to claim 1 for the manufacture of hard enteric capsule* [sic] *wherein the content of the composition is between 15 to 40% by weight of the aqueous solution."*

Further independent claims are directed to the use of the aqueous solution of claim 8 for the manufacture of hard enteric capsules by a dip-moulding process, a corresponding manufacturing process and the use of the aqueous solution of claim 8 for the banding of enteric capsules.

The claims of the first auxiliary request are identical to claims 1 to 7 of the main request, but claim 1 specifies additionally that when the setting system consists of pectin and divalent cation salts, *"the content of the divalent cation salts are* [sic] *from 0.04 to 2% by weight in the film composition"*.

Claim 1 of the second auxiliary request corresponds to claim 1 of the main request in which option (i) for the setting system has been deleted; thus the setting system consists of pectin and an additional setting agent selected from the group consisting of carrageenan, gellan gum and mixtures thereof.

V. In the decision under appeal the opposition division considered that the subject-matter of claim 1 of the main request lacked novelty over the disclosure of document (3), which described (see page 3, paragraph 4) a composition comprising 10 to 15 parts low methoxyl pectin, 100 parts gelatin and a certain amount of calcium ions.

While the parties had in their written submissions regarded document (1) relating to hard capsules as the closest prior art, the opposition division considered that document (3), albeit relating to soft capsules, was a more suitable starting point for the assessment of inventive step of the first auxiliary request, since it addressed a capsule shell material for enteric drug delivery, whereas document (1) merely mentioned adding an enteric coating as an optional embodiment.

The film composition of claim 1 according to the first auxiliary request differed from the pectin-containing embodiment described on page 3 of document (3) in the specified concentration of divalent cation salts of 0.04% to 2% by weight. The technical problem could be defined as the provision of coating formulations which could be used in the fabrication of hard capsules for enteric drug delivery. The solution to that problem was provided by the film composition of claim 1 as defined in the first auxiliary request, which was mainly characterised by a higher content of divalent cations.

It was known, i.a. from document (3), that pectin crosslinked in the presence of calcium ions. The person skilled in the art would have been aware that the degree of crosslinking would increase with the concentration of $Ca^{2+}$ ions, and would find indications in document (1) to increase the content of $Ca^{2+}$ ions disclosed in document (3) in order to prepare aqueous film-forming polymer solutions having a sufficient setting ability to be useful in a dip moulding process for the preparation of hard capsules. Hence the subject-matter of claim 1 of the first auxiliary request did not involve an inventive step.

Inventive step was acknowledged in the case of the second auxiliary request, since a setting system consisting of pectin and a further setting agent selected from carrageenan or gellan gum or mixtures thereof could not be derived from the cited prior art.

VI. The appellant (patent proprietor) lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant submitted a main request, auxiliary requests I and II and document (10). Auxiliary request II was identical to the former second auxiliary request which was found by the opposition division to meet the requirements of the EPC.

VII. The respondent (opponent) did not reply to the appellant's statement of grounds and did not submit any requests.

VIII. With letter dated 7 November 2014, the respondent indicated in reply to a summons issued by the board that "neither the opponent nor the representative of the opponent" intended to participate in the oral proceedings scheduled for 3 June 2015.

IX. With letter dated 26 February 2015, the appellant filed a new set of claims as auxiliary request I and declared that former auxiliary requests I and II were to be renumbered as auxiliary requests II and III, respectively. With the same letter, the appellant also submitted new copies of the main request and auxiliary requests II and III.

The appellant furthermore announced that it ("the patentee") would not be attending the oral proceedings and requested that the board issue its decision based on the written submissions.

The **main request** is identical to the main request which was considered in the decision under appeal, except that in claim 1, the wording *"selected from the group consisting of carrageenan, gellan gum and mixtures thereof"* has been replaced by *"selected from carrageenan or gellan gum or mixtures thereof"*.

Claim 1 of **auxiliary request I** reads as follows:

*"1. Film-forming aqueous solution of a composition for the manufacture of hard enteric capsule* [sic],
*the composition comprising*
*a) pectin,*
*b) a second film-forming polymer and*
*c) a setting system,*
*the setting system consists of:*
*(i) pectin and divalent cation salts, or*
*(ii) pectin and an additional setting agent selected from carrageenan or gellan gum or mixtures thereof,*
*and wherein the content of pectin is from 10 to 40% by weight in the film composition, and that of the second polymer from 50 to 85% by weight in the film composition,*

*wherein the content of the composition is between 15 to 40% by weight of the aqueous solution."*

**Auxiliary request II** corresponds to the first auxiliary request which was considered in the decision under appeal, except that in claim 1, the wording "selected from the group consisting of carrageenan, gellan gum and mixtures thereof" has been replaced by "selected from carrageenan or gellan gum or mixtures thereof".

The claims of **auxiliary request III** are identical to those of the second auxiliary request of the opposition proceedings.

X. The appellant's arguments with regard to inventive step can be summarised as follows:

*Main request*

Document (1) was a more suitable starting point for the assessment of inventive step than document (3), which had been the opposition division's choice.

Document (1) disclosed a hard capsule composition based on hydroxypropyl starch or hydroxyethyl starch with a setting system consisting of one or more hydrocolloids (e.g. pectin) and cations (e.g. $Ca^{2+}$ or $Mg^{2+}$). It was also mentioned that pectin could be combined with the starch material to modify the film mechanical properties. Document (1) proposed coating as a way to impart enteric properties to the capsules but did not name pectin among suitable coating materials.
The problem addressed in the patent in suit was how to make enteric hard capsules in which the enteric properties were due to the material used to make the capsule shell and so avoid the need for coating (page 1, lines 22 to 23 and page 3, lines 1 to 3 of the application as filed). Document (1) disclosed a

maximum ratio of pectin to second film-forming polymer of 10:88, whereas claim 1 of the main request defined a minimum ratio of 10:85. The technical effect of that difference was that the hard capsule shell material had enteric properties even when no further enteric coating was present. The technical problem was how to modify the teaching of document (1) to avoid the need for separate enteric coating yet still provide enteric properties. Document (1) itself did not teach that pectin provided enteric properties and disclosed only low concentrations of the hydrocolloid of the setting system in its example formulations, with kappa-carrageenan and not pectin being the preferred hydrocolloid. None of the examples in document (1) used pectin as the hydrocolloid, so merely following those examples would not provide a shell material with enteric properties. The skilled person attempting to solve problems in the hard capsule art would furthermore not consult document (3), which related to soft capsules. As evidenced by document (10), which represented common general knowledge, hard capsule art and soft capsule art were considered to be significantly different. Even if the skilled person consulted document (3), the teaching in that document was to use a source of calcium which only released calcium ions when exposed to acid, to avoid cross-linking by calcium ions before exposure of the capsules to gastric juices. It was not obvious to select only the pectin disclosed in document (3) as a possible option of a polysaccharide with enteric properties and to apply this to the hard capsule art in order to solve the technical problem.

*Auxiliary request I*

The aqueous solution of claim 1 of auxiliary request I differed from the disclosure of document (1) in that

the minimum ratio of pectin to second polymer was higher than the maximum defined in document (1) (again, 10:85 vs. 10:88). The line of argumentation was thus in principle the same as in the case of claim 1 of the main request.

In addition, the conventional dip moulding process for producing hard capsules required low viscosity solutions with quick-setting properties suitable for providing a uniform coating on the surface of steel moulds ("pins") dipped into the solution of the capsule shell material. The rotary die process typically used (and also envisaged in document (3)) for making soft capsules, on the other hand, required viscous ribbons of material having a rather lower water content, suitable for being fed into a hollow mould and sealed together. No teaching could be found in document (1) or document (3) to suggest taking only part of a high-viscosity soft-capsule composition and applying it to a hard-capsule dipping solution having completely different viscosity and film-forming behaviour.

*Auxiliary request II*

Document (1) disclosed a maximum ratio of pectin to second film-forming polymer of 10:88, whereas claim 1 of auxiliary request II defined a minimum ratio of 10:85. Further differences consisted in the specified concentration of divalent cations of 0.04 to 2% by weight and in the combination of pectin and divalent cations to provide the setting system.

With respect to the different ratios of pectin to second film-forming polymer the argumentation was the same as in the context of the main request. Additionally, document (1) taught a setting system of divalent cations only in conjunction with hydrocolloids such as carrageenan, and the calcium concentration used

in document (3) was less than half the minimum recited in claim 1.

XI. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request filed with letter of 26 February 2015, or alternatively on the basis of the claims of auxiliary requests I, II or III filed with letter of the same date.

## Reasons for the Decision

1. Decision based on written submissions

1.1 Having initially requested oral proceedings, the appellant subsequently announced that it would not be attending the oral proceedings and requested that the board issue its decision based on the written submissions (see point IX. above).

1.2 Since such a statement amounts to a withdrawal of the appellant's previous request for oral proceedings, the board was in a position in which the case could be decided without holding oral proceedings (Article 116(1) EPC).

2. Main request - inventive step

*Patent in suit*

2.1 The patent in suit aims to provide hard enteric capsules which are not brittle and which can be produced by a conventional dip moulding process also used for hard gelatin capsules.

2.2 Pectin is to be used in the capsule shell material to confer the desired enteric properties on the capsules.

As pectin, like other enteric materials, is brittle, it is combined with a second polymer, and optionally a plasticiser, for improving the mechanical properties of the capsule shell material. A setting system is employed to obtain setting ability sufficient for use of the composition in a dip moulding process using conventional equipment for gelatin capsule production. The setting system consists of the combination of pectin with either (i) divalent cation salts or (ii) an additional setting agent selected from carrageenan or gellan gum (see the patent specification in paragraphs [0018], [0021], [0030], [0026], [0016]).

*Disclosure of prior-art documents (1) and (3)*

2.3 Document (1) discloses film compositions based on modified starches such as starch ethers or oxidised starch combined with a setting system consisting of hydrocolloids and cations. The compositions may in particular be used for manufacturing hard capsules by a conventional dip moulding process as typically employed in the production of hard gelatin capsules (see document (1): claims 1 and 2 and page 1: lines 1 to 15).

Such capsules are manufactured by dipping mould pins into a hot solution of gelatin, removing the pins from the gelatin solution, allowing the gelatin solution to set by cooling, drying and stripping the solidified shells from the pins. The setting of the solution on the mould pins after dipping is the critical step to obtain a uniform thickness of the capsule shell. When attempting to manufacture capsules in the same manner from materials other than gelatin, it is thus important to achieve the required quick-setting properties in the liquid mixture employed.

Document (1) teaches that a hydrocolloid, which may be combined with cations, acts as a setting system which provides adequate setting when the capsules are produced from a starch material such as hydroxyethyl starch or hydroxypropyl starch. The preferred material for the hydrocolloid is a polysaccharide; i.a. pectin is mentioned as a suitable material (see document (1): page 2, lines 22 to 27; page 4, lines 7 to 23; page 5, lines 1 to 15; claims 5 and 6). Monovalent or divalent cations are disclosed (page 6, lines 4 to 8).

According to another consideration, mechanical film properties may be improved by combining the starch material with other hydrosoluble polymers or polysaccharides; preferably pectin, alginates, polyvinyl alcohol or high molecular weight polyethylene glycol (see document (1): page 3, line 25 to page 4, line 2). Thus document (1) teaches that pectin may be employed both as a complementary capsule shell polysaccharide material and as a component of the setting system.

The capsules of document (1) may optionally be coated with a suitable coating agent to provide enteric properties (see page 7, lines 4 to 8 and claim 21). This corresponds to the conventional state of the art which is described in paragraph [0005] of the patent in suit as follows: "Usually enteric properties of pharmaceutical compositions are achieved by a coating process with enteric materials on e.g. granules, pellets, tablets or hard or soft capsules."

In claim 4, document (1) discloses film-forming compositions wherein the content of hydroxypropylated starch is 88 to 98% by weight, of water 2 to 12% by weight, of polysaccharides 0.01 to 10% by weight, and of cation 0.001 to 5% by weight.

In claim 26, document (1) discloses aqueous solutions of compositions according to claims 1 to 17 for the manufacturing of capsules; claim 29 concerns the use of such solutions for the manufacturing of hard capsules in a dip moulding process.

2.4 Document (3) relates to soft enteric capsules based on gelatin and plasticiser (claim 1). Enteric properties are provided to the capsules by including in the capsule shell material a water-soluble polysaccharide crosslinkable with calcium ions, and a source of calcium ions. The crosslinkable polysaccharide may be selected from sodium alginate (claim 2), low methoxyl pectin (claim 3) or gellan gum (claim 4). Low methoxyl pectin may be used in a proportion of 10 to 15% of the gelatin mass (see document(3): page 3, paragraph 4).

Document (3) teaches that a certain amount of calcium ions (indicated on page 4, line 8 as 50 to 200 ppm) is contained in the mandatory gelatin component, which is sufficient for some crosslinking of the water-soluble polysaccharide to occur during the manufacture of the soft capsules by the rotary die method. Due to the limited degree of crosslinking, the resulting rise in viscosity is not excessive and does not cause problems in the manufacturing process as might otherwise be expected with crosslinkable polysaccharides (page 3, paragraph 2 and page 4, paragraph 2). The capsules thus prepared are not as yet very resistant to gastric juices. The source of calcium, which is a mandatory component of the soft capsules of document (3), contains calcium carbonate, which is insoluble in water but slowly releases calcium ions when the capsules are contacted with the acidic gastric juices after ingestion. The polysaccharides are momentarily crosslinked by the calcium ions and the capsules thereby attain stability against gastric juices.

*Starting point in the prior art*

2.5 The board agrees with the appellant's view that document (1), which relates to hard capsules produced by dip moulding, may be considered a suitable starting point for the assessment of inventive step, irrespective of whether document (3) may also be suitable.

*Claim 1 - Technical problem and solution*

2.6 The film composition of claim 1 of the main request, when the setting system (c) is defined in accordance with option (i), differs from the compositions according to claim 4 of document (1) in the selection of pectin as a capsule shell material and setting agent, in the selection of a divalent cation salt as part of the setting system and in the required weight ratio of pectin to second film-forming polymer of at least 10:85 (as calculated from the lower concentration limit of pectin of 10% by weight and the upper concentration limit of second film-forming polymer of 85% by weight in the film composition).

2.7 The presence of pectin in a sufficient proportion has, according to the patent in suit, the effect of imparting enteric properties to the capsule shell material (see paragraph [0018] of the patent specification: "Pectin has excellent enteric properties. A relatively low content of pectin from 5 to 25%, preferably 10 to 20% by weight in the composition, is sufficient to obtain capsule films with enteric properties.")

According to the patent specification in paragraph [0023], the content of pectin in the film composition could be in the range of 5 to 50% by weight and that of the second film-forming material in the range of 40 to 95% by weight, which corresponds to a

minimum ratio of pectin to second film-forming polymer of 10:190. The more restricted concentration ranges specified in claim 1 and the corresponding lower limit of the ratio of 10:85 have not been linked to any technical effect in particular.

The use of a setting system is intended to provide setting properties, as taught in document (1). The selection of pectin and divalent cation salts as components of the setting system has not been linked to any technical effect in particular, beyond providing said setting properties.

2.8 Thus the film composition as defined in claim 1 may be regarded as a pre-mix which is suitable, after dilution, for use in a dip moulding process (due to its setting properties provided by a setting system) for manufacturing hard capsule shells with enteric properties (due to the content of pectin).

2.9 The technical problem when starting from the teaching of document (1) may thus be defined as the provision of a film composition suitable for use in a dip moulding process for manufacturing enteric hard capsules which do not require separate enteric coating.

2.10 The board accepts that the technical problem is solved by the film composition as defined in claim 1 of the main request, which contains an adequate proportion of pectin, as part of a setting system.

In that context, the term "setting system" employed in claim 1 may be understood to imply that the proportions of pectin and additional component(s) of the setting system are suitable to achieve gelling sufficient for obtaining hard capsules, and concomitantly for obtaining a certain degree of enteric properties.

*Claim 1 - Obviousness of the solution*

2.11 Pectin is envisaged in document (1) both as a complementary capsule shell material and as a component of the setting system.

2.12 Document (3), relating to enteric capsules, teaches that pectin may also confer enteric properties to a capsule shell material by being crosslinked (or gelled), in particular with the help of divalent ions in the form of calcium ions. It is, moreover, part of the common general knowledge that divalent cations contribute to gelling by interacting with the hydroxyl and carboxyl groups of pectin.

2.13 Thus the person skilled in the art, starting from the compositions of document (1), would find an incentive in document(3) to select pectin (combined with divalent ions) from the polysaccharides and hydrocolloids suggested in D1, in order to solve the above-mentioned technical problem.

2.14 The board does not share the appellant's view that the skilled person seeking for a way to provide enteric properties to hard capsules would have been deterred from consulting document(3) by the fact that it relates to soft capsules.

As evidenced by document (1) and by document (10), the difference between hard capsule technology and soft capsule technology lies not so much in the qualitative composition of the capsule shell material (which in some cases might differ only by the concentration of plasticiser; see page 3, lines 19 to 24 of document (1) and table 13-2 on page 400 of document (10)), but in the typical manufacturing processes. In particular, as pointed out by the appellant, the dip moulding process conventionally used for hard capsules and the rotary die process conventionally used for soft capsules require different viscosities of the aqueous dilutions

employed in those processes (see the appellant's letter of 6 February 2012, pages 3 to 6). This is part of the common general knowledge in the art.

The board concludes from this information that the skilled person would not in principle see it as problematic to use an ingredient proposed for soft capsules in a composition for hard capsules and would therefore also consult the relevant prior art relating to soft capsules.

2.15 As clearly explained in document (3), the reason for employing an insoluble calcium source is process-related and serves to prevent an immediate excessive rise in viscosity during processing, in particular when using the rotary die process for soft capsules which already works with a rather viscous mixture. The person skilled in the art would understand that different requirements and constraints apply to the dip moulding process using a more diluted system, and would be able to routinely adapt the film composition and aqueous dipping solution accordingly. While it is necessary to prevent concentration peaks causing lump formation, adding most of the divalent cations in insoluble form would not be seen as an absolute requirement for the purpose intended in the patent in suit.

2.16 The general teaching of document D1 (see claim 1 or the paragraph bridging pages 3 and 4 of D1) is not restricted to a maximum ratio of other polysaccharides (such as pectin) to modified starch, the ratio of 10:88 only appearing in dependent claim 4. Also, D1 contains no teaching that higher ratios should be avoided. As mentioned above (see point 2.7), the restriction to a minimum ratio of 10:85 in claim 1 of the main request appears to be arbitrary.

2.17 As a consequence of the above considerations, the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC.

*Claim 8 - Technical problem and solution*

2.18 The aqueous solution of claim 8 of the main request differs from the solution according to claim 26 when referring to the composition of claim 4 of document (1) in the selection of pectin as a capsule shell material and setting agent and in the selection of a divalent cation salt as part of the setting system.

According to the appellant's interpretation, another difference lies in the weight ratio of pectin to second film-forming polymer of at least 10:85, based on the assumption that the film-forming aqueous solution is composed only of water and the composition of claim 1 (which is actually not required by the wording of claim 8).

Claim 26 of document (1) does not indicate any concentrations, but in the context of the general teaching of document (1) it would reasonably be assumed that the dilution should be suitable for use as a dipping solution for manufacturing hard capsules. The envisaged concentrations are, for instance, 10 to 60% starch derivative (document (1): claim 27 and page 4, lines 25 to 27), up to 5% hydrocolloid and up to 3% cations (claim 27). Thus the lower concentration limits according to document (1) are not below the concentrations required according to claim 8 of the main request.

2.19 In analogy to the analysis provided for the film composition of claim 1, the claimed aqueous solution is suitable for use in a dip moulding process (due to its

setting properties provided by a setting system) for manufacturing hard capsule shells with enteric properties (due to the content of pectin).

2.20 The technical problem may thus be defined as the provision of an aqueous solution suitable as a dipping solution for use in a dip moulding process for manufacturing enteric hard capsules which do not require separate enteric coating.

2.21 The board accepts that the problem is solved by the solution as defined in claim 8.

*Claim 8 - Obviousness of the solution*

2.22 With regard to obviousness in the light of the prior art, the same line of argument as developed in the context of claim 1 (see points 2.11 to 1.15 above) is also applicable to claim 8 of the main request.

2.23 As a consequence, the subject-matter of claim 8 of the main request does not involve an inventive step within the meaning of Article 56 EPC.

3. Auxiliary request I - inventive step

3.1 Claim 1 of auxiliary request I corresponds to claim 8 of the main request.

3.2 Thus the same reasoning applies as explained in the context of the main request (see points 2.18 to 2.22 above).

3.3 As a consequence, the subject-matter of claim 1 of auxiliary request I does not involve an inventive step within the meaning of Article 56 EPC.

4. Auxiliary request II - inventive step

4.1 Claim 1 of auxiliary request II corresponds to claim 1 of the main request, but specifies additionally that when the setting system consists of pectin and divalent cation salts, the content of the divalent cation salts is from 0.04 to 2% by weight in the film composition.

4.2 While document D1 does not specify concentrations of the cations of the setting system in the film forming composition, the cation concentrations proposed for the dipping solution (less than 3%, preferably 0.01 to 1 % by weight, see D1: page 6, lines 6-8) are in the same general range as those employed in the patent in suit (see for instance paragraph [0026] and examples 1 to 3 of the patent specification; 0.01 to 0.5% $CaCl_2$).

4.3 The specified concentration range of 0.04 to 2% by weight in the film composition has not been linked to any specific technical effect going beyond the effects which have already been acknowledged in the context of claim 1 of the main request (see points 2.7 to 2.10 above). Thus the additional feature does not change the assessment of inventive step which has been given above for claim 1 of the main request.

4.4 As a consequence, the subject-matter of claim 1 of auxiliary request II does not involve an inventive step within the meaning of Article 56 EPC.

5. Auxiliary request III - prohibition of *reformatio in peius*

5.1 The claims of auxiliary request III are identical to those of the second auxiliary request of the opposition proceedings (see point IX above).

5.2 If the patent proprietor is the sole appellant against an interlocutory decision concerning the maintenance of a patent in amended form, neither the board of appeal

nor the non-appealing opponent as a party to the proceedings as of right under Article 107, second sentence, EPC, may challenge the version of the patent as amended in accordance with the interlocutory decision.

5.3 Since in the present case the condition under point 5.2 above is met, no decision on auxiliary request III is taken.

## Order

## For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani A. Usuelli

Decision electronically authenticated