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**Datasheet for the decision
of 6 May 2014**

Case Number: T 0687/10 - 3.3.07

Application Number: 00987277.1

Publication Number: 1231903

IPC: A61K9/34, A61K9/36

Language of the proceedings: EN

Title of invention:

COATING OF TABLET CORES

Patent Proprietor:

Sandoz AG

Opponent:

Tschampel, Sarah M.

Headword:

Coating of tablet cores/Sandoz AG

Relevant legal provisions:

EPC Art. 100(b)
RPBA Art. 13, 12

Keyword:

"Auxiliary requests 3a, 5a, 6, 8, admission into the proceedings (yes)"
"All requests, sufficiency of disclosure (no)"

Decisions cited:

Catchword:



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Case Number: T 0687/10 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 6 May 2014

Appellant:
(Patent Proprietor)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 25 January 2010
revoking European patent No. 1231903 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman: J. Riolo
Members: D. Boulois
D. T. Keeling

Summary of Facts and Submissions

I. European Patent 1 231 903 was granted on the basis of a set of seven claims. Independent claim 1 read as follows:

"1. A process for the coating of tablet cores, said tablet core comprising an effective amount of at least one pharmaceutically active compound selected from the group consisting of cefuroxime axetil, cefpodoxime proxetil, amoxicillin, sumatriptan and olanzapine, comprising spraying a coating solution or suspension of a coating mixture consisting of a sugar including sugar alcohols, or a starch including modified starches soluble starches and starch hydrolysates, or a mixture of a sugar and a starch, and optionally of parting agents, and/or pigments, and/or colouring agents, and/or sweeteners, and/or flavouring agents, and/or wetting agents, and/or preservatives and/or lubricants (glidants) and/or antifoaming agents, onto the tablets or tablet cores with the proviso that film-forming agents in the coating solution or suspension are excluded, to obtain coated tablets."

II. An opposition has been filed against the granted patent. The patent was opposed under Article 100 (a) and (b) EPC on the grounds that its subject-matter lacked novelty and inventive step and that the patent was not sufficiently disclosed.

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

(3): EP 0169319 B1

(5): Journal of Controlled Release, 38 (1996), 75-84

(7): Pharmaceutical Unit Operations: Coating, Drug Manufacturing Technology Series, Vol. 3, 1999, pages 55-63

IV. The present appeal lies from the decision of the Opposition Division to revoke the patent. The decision was based on three sets of claims, namely a main request filed with letter dated 15 May 2007 and auxiliary requests 1 and 2 filed with letter dated 6 August 2009.

The subject-matter of claim 1 of the main request was identical to claim 1 of the granted patent. Claim 1 of auxiliary request 1 was amended by the addition of the feature "*wherein the weight of the coat is 20% and less of the weight of the coated tablet*" and claim 1 of auxiliary request 2 by the further restriction to a process for the coating of a "*dispersible tablet core*".

According to the decision under appeal, the opposition division considered that the presence of the term "*with the proviso that film-forming agents in the coating solution or suspension are excluded*" in claim 1 of the main request led to an inconsistency with the claimed excipients used for forming the said coating.

The patent failed to provide a fully self-sufficient technical concept, and the skilled person was not able to determine the scope of claim 1 without the burden of an undue amount of experimentation or the application of inventive ingenuity.

Hence, the opposed patent in its amended form lacked sufficient disclosure.

The objection raised against the main request was literally valid for auxiliary requests 1 and 2, since the amendments did not overcome the objection.

V. The proprietor (appellant) filed an appeal against that decision.

VI. By a letter dated 2 June 2010, the appellant confirmed the set of claims filed with letter dated 15 May 2007 as the main request, and filed new auxiliary requests 1, 2, 3a, 3b, 4, 5a, 5b, 6-8.

It also submitted arguments regarding sufficiency of disclosure and a new document:

(9a): Lehrbuch der Pharmazeutischen Praxis, pages 338-341

The subject-matter of claim 1 of auxiliary requests 3a, 6, 8 read as follows (difference compared with the main request shown in bold):

(a) Auxiliary request 3a:

"1. A process for the coating of tablet cores, said tablet core comprising an effective amount of at least one pharmaceutically active compound selected from the group consisting of cefuroxime axetil, cefpodoxime proxetil, amoxicillin, sumatriptan and olanzapine., comprising spraying a coating solution or suspension of a coating mixture consisting of a sugar including sugar alcohols, or a starch including **modified starches** soluble starches and starch hydrolysates, or a mixture of a sugar and a starch, and optionally of parting agents, and/or pigments, and/or colouring agents, and/or sweeteners, and/or flavouring agents, and/or wetting agents, and/or preservatives and/or lubricants (glidants) and/or antifoaming agents, onto the tablets or tablet cores with the proviso that film-forming agents in the coating solution or suspension are excluded, to obtain coated tablets."

(b) Auxiliary request 6:

"1. A process for the coating of tablet cores, said tablet core comprising an effective amount of at least one pharmaceutically active compound selected from the group consisting of cefuroxime axetil, cefpodoxime proxetil, amoxicillin, sumatriptan and olanzapine., comprising spraying a coating solution or suspension of a coating mixture consisting of a sugar including sugar alcohols, or a starch ~~including modified starches soluble starches and starch hydrolysates~~, or a mixture of a sugar and a starch, and optionally of parting agents, and/or pigments, and/or colouring agents, and/or sweeteners, and/or flavouring agents, and/or wetting agents, and/or preservatives and/or lubricants (glidants) and/or antifoaming agents, onto the tablets or tablet cores with the proviso that film-forming agents in the coating solution or suspension are excluded, to obtain coated tablets, **wherein the starch is selected from potato starch, maize starch and soluble starches.**"

(c) Auxiliary request 8:

"1. A process for the coating of tablet cores, said tablet core comprising an effective amount of at least one pharmaceutically active compound selected from the group consisting of cefuroxime axetil, cefpodoxime proxetil, amoxicillin, sumatriptan and olanzapine., comprising spraying a coating solution or suspension of a coating mixture consisting of a ~~sugar including sugar alcohols, or a starch including modified starches soluble starches and starch hydrolysates, or a~~ mixture of a sugar and a **soluble** starch, and optionally of parting agents, and/or pigments, and/or colouring agents, and/or sweeteners, and/or flavouring agents, and/or wetting agents, and/or preservatives and/or lubricants (glidants) and/or antifoaming agents, onto

the tablets or tablet cores with the proviso that film-forming agents in the coating solution or suspension are excluded, to obtain coated tablets."

- VII. By a letter dated 14 December 2010, the opponent (respondent) submitted arguments regarding sufficiency of disclosure.
- VIII. On 21 March 2014 the Board sent a communication pursuant to Article 15(1) RPBA.
The Board gave *inter alia* a preliminary opinion regarding the requirements of sufficiency of disclosure and concluded that documents (3), (5) and (7), showed undeniably that the starch derivatives of these documents were film-forming agents. The fact that document (9a) showed that usual film-polymers used in forming pharmaceutical films do not include these compounds, does not deprive the compounds cited in documents (3), (5) and (7) from having said film-forming properties. It appeared therefore that the teaching of the description presents an inconsistency as regards one of its key element, namely the feature "*with the proviso that film-forming agents in the coating solution or suspension are excluded*" present in all requests.
- IX. By a letter dated 17 April 2014, the appellant filed new auxiliary requests 1 and 5a, as well as two documents:
(18): Pharmaceutical Excipients (online), London, Pharmaceutical Press, "Starch Modified"
(19): Pharmaceutical Online, "Pure-Cote® Corn Starches"
- The subject-matter of claim 1 of auxiliary request 5a read as follows (difference compared with the main request shown in bold):

"1. A process for the coating of tablet cores, said tablet core comprising an effective amount of at least one pharmaceutically active compound selected from the group consisting of cefuroxime axetil, cefpodoxime proxetil, amoxicillin, sumatriptan and olanzapine., comprising spraying a coating solution or suspension of a coating mixture consisting of a sugar including sugar alcohols, or a soluble starch ~~including modified starches soluble starches and starch hydrolysates~~, or a mixture of a sugar and a **soluble** starch, and optionally of parting agents, and/or pigments, and/or colouring agents, and/or sweeteners, and/or flavouring agents, and/or wetting agents, and/or preservatives and/or lubricants (glidants) and/or antifoaming agents, onto the tablets or tablet cores with the proviso that film-forming agents in the coating solution or suspension are excluded, to obtain coated tablets."

X. Oral proceedings took place on 6 May 2014. During the oral proceedings the appellant withdrew auxiliary requests 1 ,2, 3b, 4, 5b and 7.

XI. The arguments of the appellant, as far as relevant for the present decision, may be summarised as follows:

It was clear from the description that the purpose and problem of the invention was to avoid the use of film-forming agents in the composition coating, in order to to not establish a barrier to water penetration in the tablet core (see par. [000] or [0010]). A definition of film-forming agent was given in the description (page 2, par. [0002]).

A solution to this problem was the process of claim 1, namely spraying a tablet with a coating composition comprising sugar, starch or starch derivative, as well as a mixture of sugar and starch.

The result was a dispersible coated tablet having a disintegration time identical to the same dispersible tablet without a coating, as measured by the disintegration test of paragraph [0015] of the description, and as demonstrated by the examples, in particular example 5 of the description.

This was achieved by a coating structure which was not a film, namely "*a continuous skin-like structure*" or "*a continuous, "elastic and uniform covering"*" as defined in paragraphs [0015] and [0002].

As regards document (3), this document was about maltodextrin, and showed that maltodextrin could not be seen as a film-forming agent, since "*tablet film coating experts have not recognized maltodextrin as a film coating, because of its brittleness and tendency to crack*" (see document (3) page 3, lines 46-47).

Maltodextrin required thus the use of additional excipients to form films. The absence of film-forming properties for maltodextrin was confirmed by example 5 of the present invention, which showed that it was possible to prepare a coating with maltodextrin, without any film structure. The teaching of the examples showed that it was rather a problem of clarity than a problem of disclosure.

Moreover, document (3) did not prove that dextrans in general, or starch hydrolysates in general are film-forming agents.

Document (5) was about amylose, one of the two main components of starch with amylopectin, and showed a film formed by said amylose. It could not be concluded from this document that starch in general was a film-forming agent, since this property result could not be extrapolated from amylose to starch in general, as starch might have different properties than amylose. Document (5) did not provide any evidence that starch was a film-forming agent.

Document (7) mentioned that some modified starches might form films (see table page 60), such as Pure-Coat® modified starch, as further confirmed by document (19) which was about said Pure-Coat starch, an effective film-forming agent. Document (18) made clear that modified starches constituted a vast family for which some types of modified starches could be used for their film-forming properties or as wall forming material in capsules (see document (18), page 3). The skilled person only needed to select the products without film-forming properties, which was not an undue burden, as shown for instance by the technical document (19) on PURE-COAT® starch. The invention was thus sufficiently disclosed.

Modified starches had been deleted from the subject-matter of claim 1 of auxiliary request 3a, facilitating the task of the skilled person.

The subject-matter of claim 1 of auxiliary request 5a and 8 had respectively been restricted to soluble starches or mixtures of soluble starch and sugar alcohol, thus presenting a sufficient disclosure. The claims did not comprise any modified starches anymore. The The subject-matter of claim 1 of auxiliary request 6 had been restricted to starch in general.

XII. The respondent's arguments, as far as relevant for the present decision, may be summarised as follows.

The definition of "*film-forming agent*" was problematic. It was indeed not possible to determine *a priori* if an agent was a film-forming agent or not, since the excipients might be used for several of their properties. This was shown by document (9a) which gave lists of film-forming agents also known for other uses,

such as povidone or cellulose derivatives, which could also be used as binding or disintegrating agents. The invention as claimed was not sufficiently disclosed. There was no teaching in the description of the patent as to which film-forming agents were to be excluded, and no teaching to identify such products. The claims related to a process performed without any film-forming agent, regardless of the final product that might be prepared through said process. It was in particular possible to prepare a tablet coating with a film-forming agent, without forming a film structure. The passage of page 2, lines 7-8 of the description could not be seen as a definition of film-forming agents, since it stated that "*film-forming agents are usually polymers...*", thus relating only to a vague and general statement.

Documents (3), (5) and (7) showed that starch products were effective film-forming agents.

Document (3) showed the use of maltodextrin as film-forming agent, even if this product was mentioned as a non usual film-forming agent, due to a lower film quality (see document (3)m, page 3, lines 46). The contested patent did however not exclude film-forming agents forming an unperfect film, such as maltodextrin. As regards the use of sugar alcohols as plasticizers in document (3), the same products were used in the examples of the contested patent. Anyway, the use of excipients to form films was not excluded by the contested patent.

Document (5) proved that amylose was a film-forming agent. Amylose was a part of starch, and there was no starch without amylose, and thus without any film-forming agent.

Document (7) showed that modified starches might be film-forming agents, such as PURE-COTE®. There was no

teaching in the patent as to which modified starches might be film-forming agents or not.

The definition of the contested patent gave further a definition of what was meant by starch in paragraph [0009], including *inter alia* also modified starches. The deletion of some listed terms regarding starch or the restriction to specific starches in claim 1 of the auxiliary requests could thus not modify what was meant by starch, and all auxiliary requests lacked sufficient disclosure for this reason. The subject-matter of claim 1 of auxiliary request 3a was also considered to be the same as the main request.

The subject-matter of claim 1 of auxiliary requests 5a, 6 and 8 further constituted a new case and should not be admitted into the proceedings for this reason.

XIII. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the case be remitted to the Opposition Division on the basis of the main request discussed before the Opposition Division and filed with letter dated 15 May 2007 or, in the alternative on the basis of auxiliary request 3a filed with letter dated 2 June 2010, auxiliary request 5a filed with letter dated 17 April 2014 and auxiliary requests 6 and 8 filed with letter dated 2 June 2010. Furthermore, the appellant (patent proprietor) requested the reimbursement of the appeal fee.

The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Admission of auxiliary requests 5a, 6 and 8 into the proceedings*

The admission of auxiliary requests 5a, 6 and 8 has been contested by the respondent on the ground that they constitute a new case.

2.1 *Auxiliary request 5a*

Auxiliary request 5a was submitted with letter dated 17 April 2014, less than one month before the oral proceedings, and is thus a late-filed request.

The subject-matter of claims 1 and 2 of this request differs from the main request or from the claims as granted by the restriction of the claimed starch to "*a soluble starch*". This specific feature was comprised in the subject-matter of claim 1 of the main request and of the granted patent, namely through the term "*a starch including modified starches, soluble starches...*" and was also present in dependent claim 6 of the main request or of the granted patent.

The subject-matter of claims 1 and 2 of auxiliary request 5a therefore constitutes a simplification with regard to the subject-matter of the main request, and does not raise new issues which the Board or the respondent could not reasonably be expected to deal with. The Board thus cannot follow the respondent's opinion that the subject-matter of auxiliary request 5 constituted a new case.

The Board sees no reason not to admit auxiliary request 5a into the proceedings (Article 13 RPBA).

2.2 *Auxiliary request 6*

Auxiliary request 6 was introduced with the statement of grounds of appeal.

The subject-matter of claims 1 and 2 of this request differs from the main request and from the claims of the patent as granted by the specification of specific starches, namely, "*wherein the starch is selected from potato starch, maize starch, and soluble starches*". The feature added to claims 1 and 2 of this request was already partially present in dependent claim 6 as granted as regards "*potato starch, soluble starch*", and the remaining feature, namely "*maize starch*", was presented in the description as a preferred embodiment (see description, page 3, line 16).

Furthermore, auxiliary request 6 was submitted at the earliest possible stage of the appeal proceedings. Hence, the respondent could not have been taken by surprise by this request and had sufficient time to react to it.

Under these circumstances auxiliary request 6 is admitted into the proceedings (Article 12 RPBA).

2.3 *Auxiliary request 8*

Auxiliary request 8 was filed with the statement of grounds of appeal.

The subject-matter of claims 1 and 2 of this request differs from the main request in the restriction "*to a mixture of sugar and a soluble starch*", which was already present in the the subject-matter of claims 1 and 2 of the main request and of the patent as granted. The Board thus sees no reason not to admit this request into the proceedings (Article 12 RPBA).

3. *Main request - Article 100(b) EPC*

- 3.1 Claim 1 of the main request refers to a process for the coating of tablet cores, which in particular comprises a step of "spraying a coating solution or suspension of a coating mixture consisting of a sugar including sugar alcohols, or a starch including modified starches, soluble starches and starch hydrolysates, or a mixture of a sugar and starch" further restricted "with the proviso that **film-forming agents** in the coating solution or suspension are excluded".

The meaning of the term "*film-forming agent*" is not further specified in the description of the patent. In particular, the description neither mentions under which conditions the film-forming agent must be capable of forming a film, nor identifies any film-forming agent. The term "*film-forming agent*" thus encompasses any agent with film-forming abilities and is not limited to agents capable of forming spontaneously a film upon application to a solid surface, namely in present case a tablet core.

The description of the opposed patent further defines what is meant by starch in the claimed invention, namely "*a starch includes all kind of starches, and compounds having a chemical structure derived from a starch, e. g. including modified starches, such as potato starch, maize starch, soluble starches, starch hydrolysates, e. g. dextrans, maltodextrin, cyclodextrans*" (see page 3, lines 15-17). Starch, soluble starch and maltodextrin are disclosed in the examples of the patent.

Several cited documents show and prove however that at least some starches or starch derivatives falling under

the definition of the invention are effective film-forming agents:

- (a) Document (3) discloses the use of maltodextrin as film-forming agent for coating tablets by application of a suspension containing said maltodextrin thereof (see page 2, lines 40-42, 45-46, 50-54). This document recognizes lower film-forming properties to maltodextrin, since *"tablet film coating experts have not recognized maltodextrin as a film coating, because of its brittleness and tendency to crack"* (see page 3, lines 46, 47). A plasticizer is further added to improve the quality of the film (see page 2, line 57 - page 3, line 2).

The nature of the film formed by maltodextrin, as well as the possible use of further excipients to improve its quality, is however not a point which deprives said maltodextrin from having inherent film-forming properties. The film-forming competency indeed encompasses also compounds unable to form spontaneously a high quality film, as well as compounds forming films only through a specific process or thanks to the contribution of excipients such as plasticizers.

- (b) Document (5) relates to the use of amylose, a natural occurring polysaccharide extracted from starch, thus a starch derivative as defined in the contested patent, as a film-forming agent (see Abstract; page 76, last par.). The coating of pellets by fluid bed coating allows drug delivery to the colon. Amylose is thus undeniably a film-forming agent, and starch as such undeniably comprises a film-forming agent. Moreover, the fact that amylose, one of the main components of any starch, possesses film-forming properties renders unlikely the complete absence

of any film-forming property in all starches and starch derivatives. It is thus not credible that all starches, such as amylose-rich starches, are deprived of any film-forming property.

- (c) Document (7) mentions that food starch modified, such as Pure-Cote®, may form films (see page 60). Document (19) further specifies that said Pure-Cote® corn starch is used to produce clear and flexible films.
- (d) Document (18) is a monography of modified starches disclosing that "*some types of modified starch are used for their film-forming properties in non-functional and functional film coatings*" (see page 3, par. 7.). Document (18) does not further identify which modified starches may be used for their film-forming properties.

These documents thus show undeniably that the claimed starch, as further defined in the description of the contested patent, might in fact be an effective film-forming agent, but neither the description of the contested patent, nor any of the cited documents makes it possible to make a clear identification or distinction among starches or starch derivatives which are capable or not of forming a film.

The skilled person is thus not taught by the patent specification or by any other cited document how to reliably and effectively select a starch or starch derivative not excluded by the proviso excluding film-forming agents. The skilled person is in a position where he has to evaluate the film-forming properties of any starch or starch derivatives, the film being obtainable by any kind of process or any further addition of excipients to improve the quality of the film, in order to identify which starch or modified starch may be used for the invention.

Hence, the invention as defined in the independent claims 1 or 2 cannot be performed by a person skilled in the art without undue burden.

3.2 Further arguments from appellant

3.2.1 The appellant referred to paragraph [0002] of the contested patent which states that "*film-forming agents are usually polymers which form a continuous, elastic and uniform covering, e. g. like a skin, around the tablet core which is at least partially detachable as a continuous layer*" and to paragraph [0015] which states that a "*dispersible tablet according to the present invention may be used for the production of a drink solution or suspension avoiding the unfavourable behaviour of film-coated tablets which is that a standard film coating, due to its characteristic of forming a continuous skin like structure, remains in the liquid of the drink solution in the form of continuous pieces or segments of film*", in order to further define the film-forming agents and which kind of coating they would form.

The cited passages refer however only to the film as such and provide nothing more than a definition of a film structure that a skilled person would expect and neither define nor specify the film-forming agents of the proviso of claim 1. Moreover, said passages neither give further information or teaching on how the film structure might be formed, in particular with regard to the process used or the contribution of additional excipients, nor information on the film quality or durability.

The paramount point remains thus the lack of information for the choice among starches and starch derivatives of agents without any film-forming

properties and whatever the film quality they may produce.

- 3.2.2 The appellant also relied on the absence of any film coating in the coated tablets of the invention, despite the use of starch or starch derivatives, as evidenced by the examples and on the tablet disintegration test disclosed in the description (see par. [0015]) and in example 5) to demonstrate a sufficient disclosure of the invention.

The Board is not persuaded by these arguments.

The claimed invention neither refers to a film-coated tablet, nor to the disintegration test of the description, which requires that the coated tablets of the invention have the same disintegration time as the uncoated tablet cores, and which represents a specific embodiment of the invention.

As to the examples, the claimed invention is also not restricted to their teaching.

The point as regards sufficient disclosure is the avoidance of any excipient in the coating composition, especially among starches or starch derivatives, having possible film-forming properties and the difficulty of the selection of said excipient.

Moreover, although the teaching of said examples is not contested, they also raise undeniably questions as to a sufficient disclosure of the invention. The compounds used in the coating composition of the examples include starch, soluble starch or maltodextrin. The apparent absence of any film-like structure through the use of these compounds poses the question of the choice of the appropriate starch, starch derivative, or maltodextrin, as well as the influence of the coating process or the contribution of further excipients of the coating composition, on the absence of the formation of any

film around the tablet cores. These questions are unanswered in the description of the contested patent: hence there is a lack of sufficient disclosure.

- 3.2.3 According to the appellant, the possible inconsistency in the claims between the subject-matter of the proviso and the use of starch and its derivatives appears to be a problem of clarity under Article 84 EPC, rather than a lack of disclosure.

The Board agrees that the inconsistency between the nature of the agents used in the coating solution or suspension and the exclusion of the film-forming agents in the proviso leads to a lack of clarity under Article 84 EPC. It remains however that the lack of information in respect of the core of the claimed invention amounts also to an undue burden for the skilled person trying to select among the claimed compounds adequate starches or starch derivatives having no film-forming properties and thus to reproduce the invention

- 3.3 Consequently, the main request does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and does not satisfy the requirements of Article 100(b) EPC

4. *Auxiliary request 3a - Article 100(b) EPC*

- 4.1 Claim 1 of auxiliary request 3a has been amended by the deletion of the term "*modified starches*" and relates now to a process for the coating of tablet cores, which a step of "*spraying a coating solution or suspension of a coating mixture consisting of a sugar including sugar alcohols, or a starch including soluble starches and starch hydrolysates, or a mixture of a sugar and*

starch" still restricted *"with the proviso that film-forming agents in the coating solution or suspension are excluded"*.

This amendment has no limitative effect or incidence on the scope of the claimed invention in comparison to the main request.

As for the main request, the skilled person trying to select among the claimed compounds adequate starches, soluble starches or starch hydrolysates having no film-forming properties still faces a lack of information from the description, hence an undue burden.

The reasoning and the conclusions drawn above for the main request thus apply *mutatis-mutandis* for auxiliary request 3a.

4.2 As regards the suggestion of the appellant to delete the definition of starch in the description (see page 3, lines 15-17 or point 3.1 above), the Board observes that the deletion or amendment of said definition would not have had any positive incidence with regard to sufficiency of disclosure, since such modification would only amplify the lack of information available to reliably and effectively select *"a starch"* not falling under the proviso, thus not having any film-forming property.

4.3 Consequently, auxiliary request 3a does not satisfy the requirements of Article 100(b) EPC.

5. *Auxiliary request 5a - Article 100(b) EPC*

Claim 1 of auxiliary request 5a has been modified by the restriction to *"soluble starch"* and refers now to a process for the coating of tablet cores, which a step

of "spraying a coating solution or suspension of a coating mixture consisting of a sugar including sugar alcohols, or **a soluble starch**, or a mixture of a sugar and **soluble starch**" still restricted with the same proviso.

A soluble starch is a natural or modified starch derivative of dissolving in water. The skilled person has not been taught by the patent specification or by any other cited document how to reliably and effectively select a "soluble starch" not possessing any film-forming ability and thus excluded by the proviso. The reasoning and the conclusions drawn above for the main request thus apply *mutatis mutandis* for auxiliary request 5a.

Hence, the invention as defined in claim 1 of auxiliary request 5a cannot be performed by a person skilled in the art without undue burden.

Consequently, auxiliary request 5a does not satisfy the requirements of Article 100(b) EPC.

6. *Auxiliary request 6 - Article 100(b) EPC*

Claim 1 of auxiliary request 6 has been amended by the deletion of the terms "*including modified starches, soluble starches and starch hydrolysates*" and relates now to a process for the coating of tablet cores, which a step of "spraying a coating solution or suspension of a coating mixture consisting of a sugar including sugar alcohols, or **a starch**, or a mixture of a sugar and starch" with the specification "**wherein the starch is selected from potato starch, maize starch and soluble starches.**", still restricted "**with the proviso that film-forming agents in the coating solution or suspension are excluded**".

The feature "**potato starch, maize starch and soluble starches**" still encompasses a lot of different starches and starch derivatives having various compositions, structure and thus properties. The skilled person is not taught by the patent specification or by any other cited document how to reliably and effectively select a "**starch selected from potato starch, maize starch and soluble starches**" not possessing any film-forming ability and thus excluded by the proviso.

The reasoning and the conclusions drawn above for the main request thus apply *mutatis mutandis* for auxiliary request 6.

Consequently, auxiliary request 6 does not satisfy the requirements of Article 100(b) EPC.

7. Auxiliary request 8 - Article 100(b) EPC

The subject-matter of claim 1 of auxiliary request 8 has been amended by the deletion of the term "*a sugar including sugar alcohols, or a starch including modified starches, soluble starches and starch hydrolysates*" and has thus been restricted to a process for the coating of tablet cores, which a step of "*spraying a coating solution or suspension of a coating mixture consisting of a **mixture of a sugar and a soluble starch***" still restricted "**with the proviso that film-forming agents in the coating solution or suspension are excluded**".

The restriction to "**a mixture of a sugar and a soluble starch**" does not have any incidence as regards the lack of sufficient disclosure. As for the main request and auxiliary request 5a, the skilled person is not taught by the patent specification or by any other cited

document how to reliably and effectively select a "soluble starch" not possessing any film-forming ability and thus excluded by the proviso. Hence, the invention as defined in claim 1 of auxiliary request 8 cannot be performed by a person skilled in the art without undue burden.

Consequently, auxiliary request 8 does not satisfy the requirements of Article 100(b) EPC.

8. Reimbursement of the appeal fee

As the appeal is not allowable, there is no need to consider a reimbursement of the appeal fee under Rule 103 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Cañueto Carbajo

J. Riolo

Decision electronically authenticated