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D E C I S I O N
of 7 July 2005

Case Number: T 0415/02 - 3.3.2

Application Number: 92903255.5

Publication Number: 0569408

IPC: A61K 9/30

Language of the proceedings: EN

Title of invention:
Wet powder film-forming compositions

Patentee:
WARNER-JENKINSON COMPANY, Inc.

Opponent:
Société d'exploitation de produits pour l'industrie chimique, S.E.P.P.I.C.

Headword:
Wet powder film-forming compositions/WARNER JENKINSON

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Admissibility of late filed requests and documents: (yes) with exception of auxiliary request 4"
"Novelty (yes): the method claimed is novel over the prior art"
"Inventive step (no): the method claimed results from an obvious combination of the prior art teachings in the light of the general knowledge"

Decisions cited:
T 0397/01

Catchword:
-

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Case Number: T 0415/02 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 7 July 2005

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 21 February 2002 revoking European patent No. 0569408 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega-Plaza
P. Mühlens

Summary of Facts and Submissions

I. European patent No. EP-0 569 408, based on application No. 92 903 255.5, was granted on the basis of 31 claims.

Independent claim 1 as granted read as follows:

"1. A wet powder, edible, film-toning *(forming)* composition for use in coating tablets and capsules consisting essentially of powdered pigment particles, a film-forming, water soluble, water soluble or water-dispersible, edible polymer selected from the group consisting of methyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, maltodextrin, polydextrose, modified starches and a natural gum selected from the group consisting of gum tragacanth, gum acacia and a xanthan gum and between 5% and 9% by weight of water, said composition being formed by blending said pigment particles and said polymer and applying said water onto the pigment-polymer blend in atomized form and said composition being capable of forming a stable suspension upon dilution with additional water."

Independent claim 9 as granted read as follows:

"9. A method of making a wet powder, edible, film-forming composition of powdered pigment particles for use in coating tablets and capsules comprising the steps of
(a) blending powdered pigment particles and a film-forming, water-soluble or water-dispersible, edible polymer;
and

(b) applying water onto the pigment-polymer blend in atomized form, said composition containing between 1% and 30% by weight of water."

Independent claim 16 as granted read as follows:

"16. A method of making a wet powder, edible film-forming composition of powdered pigment particles for use in coating tablets and capsules comprising the steps of
(a) blending powdered pigment particles and a film-forming, water-soluble or water-dispersible, edible polymer;
and
(b) applying an aqueous solution of a dispersing agent onto the pigment-polymer blend in atomized form, said dispersing agent being constituted by an acid salt which lowers the surface tension of the water in the composition and said composition containing between 1% and 30% by weight of water."

Independent claim 19 as granted read as follows:

"19. A wet powder, edible, clear, film-forming composition for use in coating tablets and capsules with a clear coating consisting essentially of a clear, film-forming water solution or water-dispersible, edible polymer selected from the group consisting of methyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, maltodextrin, polydextrose, modified starches and a natural gum selected from the group consisting of gum tragacanth, gum acacia and a xanthan gum and between 5% and 9% by weight of water, said composition being

formed applying water onto the polymer in atomized form and said composition being capable of forming a stable suspension upon dilution with additional water without the formation of fish eyes."

Independent claim 24 as granted read as follows:

"24. A method of making a wet powder, edible, clear, film-forming composition for use in coating tablets and capsules with a clear coating, which composition consists essentially of a clear, film-forming, water soluble or water-dispersible, edible polymer and between 1% and 30% by weight of water, the method comprising applying water onto said polymer in atomized form to form said composition without the formation of fish eyes."

Independent claim 29 as granted read as follows:

"29. A method of making a wet powder, edible, clear, film-forming composition for use in coating tablets and capsules with a clear coating, which composition consists essentially of a clear, film-forming, water soluble or water-dispersible, edible polymer, between 1% and 30% by weight of water, and a dispersing water constituted by an acid salt which lowers the surface tension of water in the composition, the method comprising applying an aqueous solution of said dispersing agent onto said polymer in atomized form to form said composition without the formation of fish eyes."

II. The following documents *inter alia* were cited during the proceedings:

(1) WO 91/14729
(7) US-A-4 543 370
(8) EP-A-0 318 314
(9) US-A-4 636 261
(18) Kirk-Othmer Encyclopedia of Chemical Technology, Third Edition, John Wiley and Sons, 1983, volume 21, pages 83-89.

III. Opposition was filed and revocation of the patent in its entirety was requested pursuant to Article 100(a) EPC on the grounds of lack of novelty and lack of inventive step and pursuant to Article 100(b) EPC for lack of sufficiency of disclosure.

IV. The appeal lies from the decision of the opposition division revoking the patent (Article 102(1) EPC).

The opposition division considered that the claimed invention was reproducible in respect of the whole of its claimed scope, since it was within the skilled person's general knowledge to mix together a polymer and a pigment and to add onto it a specific amount of atomized water. Moreover, this was also reflected by the contents of the examples.

The opposition division considered that the transfer of priority rights took place adequately and that the current patent proprietor was entitled to claim the priority date (20.12.1990) based on US 07/630815 (earliest priority).

In the opposition division's view, the earliest priority disclosed compositions containing a pigment as one of the essential features. Hence, the opposition division considered that the subject-matter of claims 19 to 31 of the patent as granted, where the presence of a pigment was not compulsory, was not entitled to the earliest priority.

The opposition division considered that the subject-matter claimed in claims 1 to 3, 5 and 19 of the set of claims as granted lacked novelty vis-à-vis document (1). In the opposition division's view, the compositions according to example 4 contained hydroxypropylmethylcellulose (HPMC), titan dioxide (pigment), triacetin (plasticizer) and 5% water since the dry extract was 95%. It also considered that the fact that the water was added in atomized form was a characterising feature for a process but not for the composition. Furthermore, it considered that the expression "consisting essentially" did not exclude the presence of other elements such as a pigment and/or a plasticizer.

The opposition division also investigated, with the parties' agreement, the issue of inventive step and stated in its decision that document (7) represented the closest prior art for the claimed subject-matter which was entitled to the earliest priority date (i.e. that of claims 1 to 18) and document (1) represented the closest prior art for the claimed subject-matter not entitled to the earliest priority date (i.e. that of claims 19 to 31).

Document (7) did not disclose the specific amounts of water. The problem to be solved was the provision of compositions in which a specific amount of water had been added. The subject-matter claimed lacked an inventive step since there was no unexpected effect linked to the specific amounts of water. Document (8) taught that water could be used as plasticizer for such compositions.

V. The appellant lodged an appeal against said decision, filed grounds of appeal and filed an amended set of claims.

VI. The respondent contested the appeal and brought arguments in support of its position.

VII. A communication from the board was sent on 8 October 2004 expressing the board's preliminary opinion.

VIII. The appellant filed with its letter of 20 December 2004 a main request and four auxiliary requests, an experimental report and a copy of a statutory declaration of Dr Charles A. Signorino, together with the results of comparative tests as Annex 2 thereto.

IX. A board's communication was sent as an annex to the invitation for oral proceedings expressing the board's preliminary opinion.

X. The respondent filed document (18) with its letter of 3 June 2005.

XI. The appellant filed with its letter of 7 June 2005 six auxiliary requests (auxiliary requests 1A and 1B, and 2 to 5) and requested the maintenance of the patent as granted (main request).

XII. The respondent contested the admissibility of the late-filed appellant's requests; it also requested an adjournment of the oral proceedings.

XIII. A communication from the board was sent on 14 June 2005 communicating the parties that the oral proceedings were to be held on the scheduled date. Furthermore, the board expressed its preliminary opinion on the admissibility of the late-filed requests.

XIV. With its letter of 28 June 2005, the appellant withdrew auxiliary requests 1A, 1B and 2 to 5 filed with its letter of 7 June 2005 and filed new auxiliary requests 1 to 5.

Claim 8 of auxiliary request 1 and claim 1 of auxiliary requests 2 and 3 are identical to claim 9 of the main request (set of claims as granted). Claim 1 of auxiliary request 5 merely differs from claim 9 of the main request in that the expression "comprising the steps of" has been replaced by the expression "consisting of the steps".

Claim 1 of auxiliary request 4 differs from claim 9 of the main request in that it contains a step "(c) incorporating a plasticizer into the wet, film-forming composition".

XV. Oral proceedings were held before the board on 7 July 2005.

XVI. With respect to the late-filed requests the appellant stated that the requests filed with its letter of 28 June 2005 corresponded to auxiliary requests 1B and 2 to 5 filed with its letter of 7 June 2005, with the minor amendment that the expression "modified starches" was deleted in some of the claims of auxiliary requests 1 and 3 to 5. This was a direct and simple response to the board's comment on the validity of the priority date made in the board's communication of 14 June 2005 for auxiliary request 1A. This amendment dealt with the opposition ground concerning the issue of inventive step, since document (1) was no longer prior art under Article 54(2) EPC for those claims.

The appellant further stated that the late filing of the main request and the auxiliary requests was made, in preparation for the oral proceedings, as a direct response to the objections raised in the board's communication sent as an annex to the invitation to oral proceedings. Moreover, the late-filed requests did not extend the framework of the discussion. Hence, the opponent could not be surprised. Moreover, the auxiliary requests could be easily dealt with. It cited decision T 397/01 of 14 December 2004.

Auxiliary request 4 took over features of dependent product claims as granted. The features were encompassed by the granted method claims.

With respect to the subject-matter of claim 9 of the main request, the appellant stated that the opposition division had not questioned its novelty vis-à-vis the contents of document (1). The granular particles of example 4 were prepared following two steps: first dispersion in water of the pigment titan dioxide and second dispersion in water of hydroxypropylmethyl cellulose (HPMC) and triacetine (plasticizer). Both dispersions were then mixed together and water was added. The mixing took place in a blender. In order to get a homogeneous mass, example 4 disclosed that the mass was to be ground, dried according to example 1, and sifted. Therefore, the appellant concluded, the method disclosed in example 4 did not relate to the blending of pigment and polymer followed by the addition of atomized water. Additionally, the appellant cited paragraph [16] of the patent in suit.

With respect to inventive step, the appellant stated that document (7) represented the closest prior art. Document (7) disclosed a dry edible film coating composition comprising polymer, pigment and plasticizer. Water was not mentioned among the many plasticizers disclosed in document (7). Document (7) aimed to eliminate the problem of shipping of pigment dispersions containing aqueous or non-aqueous solvents and thereby to eliminate the problems caused by solvents, *inter alia* warehousing problems. The solution proposed by document (7) related to a non-dusting dry powder containing a plasticizer, but document (7) was silent about adding water or amounts of water.

The appellant defined the problem as how to provide a product for coating suspensions which is stable and dissolves more easily than the prior art products.

The solution, in the appellant's view, was the provision of a method in which a pigment-polymer blend was formed, followed by addition of water in atomized form, to produce a dustless free flowing product which is advantageous over the products of the closest prior art.

The appellant referred to the comparative test results shown in Annex 2 filed with its letter of 20 December 2004.

In the appellant's opinion, the addition of water in atomized form was directly linked to the advantageous product behaviour over the known products, since the pigment-polymer blend was preconditioned and made more hydrophilic and hence could accept additional water more easily.

The appellant further stated that the existence of document (18) did not change anything in its inventive step analysis, since the said document related to common general knowledge about agglomeration of powder formulations in several technical fields. Page 88 taught about avoiding powder dusting by superficially wetting the powder with liquid, but this was a very general teaching not directly linked to coating compositions. The skilled person starting from document (7), which taught that water should be avoided completely, would have no incentive to combine this

teaching with the teaching of document (18) and so arrive at the claimed invention.

The appellant stated that "document (7) teaches away from the claimed invention". The skilled person was aware (as also shown by document (9)) of the great advantages of dry pigment compositions in comparison to liquid pigment suspensions and hence he would not have considered the addition of water to the compositions for coating. Furthermore, in the appellant's view, document (18) also "taught away" since the products were dried after the wetting step.

The appellant stressed that the patent in suit related to a very specific technical field, namely that of the production of coating compositions where a polymer is the main component together with a pigment. In the light of the cited prior art, the skilled person would have tried to omit water and to obtain further dry compositions. There was not the slightest incentive for the skilled person to look at a general book for the addition of water. Furthermore, there were many other ways to add water than atomization. Document (18) referred to spray as a possible way, but did not mention the kind of material. The skilled person would have considered that the material could be a powder for tabletting, but not necessarily a powder for coating containing a polymer.

The appellant further stated that in document (7) no granules would be obtained due to the presence of the plasticizer. Therefore, there was no reason to combine the teaching of document (7) with that of document (18).

In respect of claim 1 of auxiliary request 5 the appellant argued that, by modifying the claim wording, any possible drying step was excluded. Document (18) disclosed a drying step. Moreover, it did not state the physical nature of the powder as a polymer and a pigment. The material prepared by the method claimed in claim 1 of auxiliary request 5 was a fluffy material, dust-free and good flowable.

XVII. The respondent contested the admissibility of the main request (set of claims as granted), since this set of claims was deemed to have been abandoned by the appellant. Moreover, auxiliary requests 1 and 3 to 5 were not admissible since the amendment relating to the deletion of the expression "modified starches" was not made to overcome an opposition ground (Rule 57(a) EPC) but to put into conformity the subject-matter claimed with the contents of the earliest priority document.

The respondent stated that document (1) disclosed a method corresponding to the mixing of the components (pigment, polymer and plasticizer) and to the addition of water. The mixing of the components could be performed in two steps. The question to be raised was whether adding water in atomized form was indeed a characterising process feature. The respondent pointed out that wet powders corresponded to small-size granulates. Moreover, the respondent stated that the patentee's commercialized products were sold as granulates.

With respect to inventive step, the respondent stated that document (7) represented the closest prior art. The problem to be solved lay in the provision of improved powder dispersions suitable for coating.

In the respondent's view the skilled person would have tried to look for further plasticizers to those already disclosed in document (7). As shown by document (8), water was known as plasticizer in the field of coating for tablets. To use water in atomized form was a common technique in the field of pharmaceutical technology and process engineering.

The respondent argued that the term powder used in the claims of the patent in suit meant agglomerates of elementary powders of polymer and pigment particles. To improve the dispersion behaviour of agglomerates in water the skilled person would have seriously contemplated the teaching of document (18) which shows the addition of water and how this is done.

The respondent also stated that the passages in document (7) cited by the appellant dealt with the avoidance of the commercially negative aspects of shipping and warehousing of liquid suspensions for coating. In order to improve the dispersion behaviour in water of the dry powders of document (7) the skilled person would have tried to modify the dispersing agent.

With respect to claim 1 of auxiliary request 5, the respondent stated that the method consisting of the two steps lacked inventive step. It was not compulsory to perform the drying step mentioned in document (18). The skilled person could stop in the preparation of the wet

powder and to do so would not confer an inventive step on the obvious process.

XVIII. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of one of the auxiliary requests 1, 2, 3 or 5 filed with letter dated 28.06.2005.

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

Reasons for the decision

1. The appeal is admissible.

2. *Admissibility of the late-filed auxiliary requests and document (18)*

2.1 The main request (set of claims as granted) is considered admissible since it was filed as a direct response to the board's comments in the communication sent as an annex to the invitation to oral proceedings. Moreover, since this is the set of claims against which the respondent filed its opposition, the respondent is deemed to be prepared for putting forward arguments concerning this request.

Auxiliary requests 1 to 3 and 5 are a clear and direct response to the board's communication sent as an annex to the invitation to oral proceedings. Moreover, auxiliary requests 2, 3 and 5 are admissible, since they basically relate to the deletion of claims from

the granted version. Additionally, the amendment introduced in claim 1 of auxiliary request 1 was to be expected, since the incorporated features are reflected in claim 6 as granted. Finally, the deletion of the expression "modified starches" was made in response to the board's comments made in the communication of 14 June 2005. This amendment was made in order to deal with the inventive step objection in relation to document (1), which was, after the amendment, prior art under Article 54(3) EPC only.

Therefore, in view of the above, the main request and auxiliary requests 1 and 2 to 3 and 5 are admissible.

However, auxiliary request 4 is not admissible since the method claim 1 (initially drafted as independent method claim 9 in the granted version) does not incorporate features from the dependent method claims of the granted version. The amendment made in claim 1 relates to the inclusion of a further method step (c) only partly reflected by the description and hence prima facie not allowable under Article 123(2) EPC. Therefore, the filing of auxiliary request 4, where a shifting of the invention takes place, cannot be justified at such a late stage since it extends unexpectedly the framework of the discussion.

2.2 Document (18) filed with the respondent's letter of 3 June 2005 is admitted into the proceedings since it merely represents common general knowledge in the field of powders and agglomerates engineering.

3. *Main request and auxiliary requests 1 to 3*

3.1 Claim 9 of the main request relates to a method of making a wet powder comprising the steps of blending powdered pigment particles and a film-forming polymer, and **applying water** onto the pigment-polymer blend **in atomized form**. Neither document (1) nor documents (7) and (8) disclose a method comprising the step of applying water in atomized form. Therefore the method claimed is novel over the cited prior art.

In conclusion, applying water in atomized form is a novelty bringing, characterising feature for the method claimed in claim 9 of the main request.

3.2 Document (7) represents the closest prior art. Document (7) discloses "a dry edible film coating composition for use in pharmaceuticals, confectionery and food, comprising a mixture including polymer particles, pigment particles, and a polymer plasticizer." (column 1, lines 53-56).

Document (7) discloses that "The polymer may be methylcellulose, hydroxypropylmethylcellulose, hydroxypropyl cellulose, ... or other film forming polymer used for coating tablets and the like" (column 7, lines 3-9).

Document (7) further discloses that "Any of the pigments heretofore used in making coating dispersions for coating tablets and the like may be used in the dry coating mixture of this invention. Examples are FD&C and D&C lakes, titanium dioxide, ..." (column 2, lines 10-17).

Examples of the polymer plasticizer are given in column 2, lines 22-32, of document (7). Water is not disclosed among these options for the plasticizer.

Document (7) discloses that "a preferred plasticizer is a liquid such as polyethylene glycol 400" (column 2, lines 35-36).

Document (7) further discloses that "A method of making a dry edible film coating composition for use in pharmaceuticals, confectionery and food, comprises the steps of mixing a polymer powder and pigment particles in a blender, adding a plasticizer to the blender containing the polymer-pigment mix, and mixing until the combined mix is thoroughly blended" (column 1, lines 59-64).

Example 16 of document (7) illustrates the method comprising the blending of powdered hydroxypropyl methylcellulose (film-forming, water-dispersible, edible polymer) and a powdered pigment (titanium dioxide) in a V blender, a P-K blender with an intensifier bar. Then the plasticizer (polyethylene glycol) is added to the blender and thoroughly mixed with the mixture of hydroxypropyl methylcellulose and titanium dioxide to form a coating mixture. "The resulting mixture is then passed through a grinder in order to reduce it to a **fine powder** which is adapted for shipping in dry form to a pharmaceutical manufacturer where it is **dispersed in water** to form a coating dispersion that is applied to tablets and dried to form a uniform film coating on the tablets." (column 4, example 16) (*emphasis added*).

Document (7) discloses that "One advantage of the dry edible film coating system of the invention is that it breaks down and disperses out the polymer so that when you add the dry coating mixture to a solvent, the polymer does not agglomerate and form fish eyes or lumps." (column 8, lines 7-11).

Document (7) further teaches that "Also, the plasticizer seems to have surfactant properties which aid in the thorough dispersion of the dry coating mixture into the liquid dispersion." (column 8, lines 18-20).

Furthermore, "Another advantage of the dry system is that it reduces the amount of dust that usually is connected with the use of lakes because the plasticizer acts as a non-dusting coat on the pigment particles." (column 8, lines 50-53).

3.3 In the light of the prior art, the problem to be solved is the provision of a method for the production of a powder suitable for forming coating suspensions with improved dispersion behaviour.

3.4 The solution relates to applying water in atomized form onto the pigment-polymer blend.

3.5 The board is satisfied that the problem has been plausibly solved in the light of the comparative test results shown in Annex 2 filed with the appellant's letter of 20 December 2004.

3.6 Therefore, it has to be assessed whether the proposed solution appears to be obvious in the light of the prior art.

As becomes apparent from the analysis of the contents of document (7) made in point 3.2 above, the said document teaches adding a plasticizer in order to improve the dispersing behaviour of the pigment-polymer powder blend. This is achieved, according to document (7), by a modification of the surface of the pigment-polymer powder blend.

Therefore, starting from document (7), the skilled person searching for a method relating to improvements in the dispersing behaviour of the pigment-polymer powder blend would seriously contemplate, in the light of the teaching of document (7), further modifying the nature of the plasticizer to be added.

The skilled person working in the field of pharmaceutical technology is aware of document (8) which discloses the preparation of compositions for the coating of tablets, comprising a polymer, a plasticizer and a pigment (claims 1, 6 and 8). Water is disclosed as an alternative to polyethylene glycol which is, as already mentioned, the preferred plasticizer of document (7) (page 2, line 7, claim 6).

Therefore, the skilled person has an incentive to try water as an alternative to polyethylene glycol. The plasticizer is added according to the method of document (7) after forming a pigment-polymer powder blend. Therefore, the question left is how the skilled

person starting from the method disclosed in document (7) (cf. example 16) would add the water.

Correspondingly, the skilled person would make use of its general knowledge in pharmaceutical technology and process engineering. Document (18) is a well-known encyclopaedia in these technical fields.

Document (18) expressly recommends powder clustering to "**improve behaviour of the original powder in flow, wetting, dispersion or dissolution**." (page 88, last paragraph) (emphasis added).

Document (18) further discloses that "agglomeration is accomplished **by superficially wetting the feed powder**; **often with less than 5% of bridging liquid in the form of a spray**, steam, mist, etc. The wetting is carried out in a relatively dry state in standard or specialized powder mixers in which the mass becomes moist rather than wet or pasty." (page 88, last paragraph) (emphasis added).

Document (18) also teaches that "The dry powder falls in a narrow stream and between two jet tubes **which inject the agglomeration fluid in a highly dispersed state**. Steam, **water**, solvents, or a combination of these are used." (page 89, first paragraph) (emphasis added).

Accordingly, the skilled person in the light of his general knowledge in process engineering would have added small proportions of water in atomized form in order to achieve the purpose of improving the pigment-polymer powder blend dispersing behaviour.

The tests submitted by the appellant relate to the addition of specific water amounts falling within the range of water mentioned in the claim. However, finding the appropriate water amounts for achieving better results over the compositions of document (7) merely requires a routine optimization which does not involve inventive skills.

3.7 Consequently, the subject-matter of claim 9 of the main request lacks an inventive step (Article 56 EPC), since it results from an obvious combination of the prior-art knowledge, in the light of the general knowledge of the technical field.

3.8 The board agrees with the appellant that the skilled person was aware, in the light of the contents of document (7) (column 8, lines 59-64), also reflected by document (9) (cf. column 2, lines 20-26), of the great advantages for shipping and warehousing of dry pigment compositions in comparison with **liquid suspensions**.

However, this would have not deterred the skilled person from using water as plasticizer (or surface modifier) for preconditioning purposes in relation to the pigment-polymer powder blend of document (7), since the amounts of water required are small (document (18) teaches amounts of less than 5%).

Moreover, claim 9 of the main request explicitly indicates "said composition containing between **1%** and 30% by weight of water".

With respect to the appellant's argument that document (18) teaches away from the proposed solution, since it discloses a drying step after the wetting step (cf. page 89, end of first paragraph), the following has to be said: the claim wording does not exclude an after drying, since the method is defined as "comprising the steps of…".

As regards the appellant's argument that the skilled person faced with the technical problem underlying the invention will discard document (18) since it relates to other technological fields and is of a very general nature, whereas the invention relies upon a very specific technical field, that of coating compositions, the following has been considered: As shown in document (7) the coating compositions are suitable for use in **pharmaceuticals, confectionery and food** (column 1, lines 53-56) (emphasis added). The skilled person involved in production methods of powder blends and powders in general has to have a general knowledge of process engineering. Document (18) represents a general consulting encyclopaedic work in that field.

Concerning the appellant's argument that the teaching of document (18) would refer to tablet feeds but would not necessarily apply to pigment-polymer blends due to their specific nature suitable for use in coating, the following has to be said: claim 9 remains silent about the actual chemical nature of the pigment which is merely defined as "powdered pigment particles" and defines very broadly the polymer as "a film-forming, water-soluble or water-dispersible, edible polymer". The technical problem faced by the skilled person is how to improve by means of the preparation method a

certain dispersing behaviour of powder blends, and the solution is a method step to further modify their surface. Whether the powders are suitable for use in coating or in feeding tablets is secondary, since the rheological problems, relating to the dispersing behaviour, are analogous. Moreover, powder materials having an analogous physico-chemical behaviour are also suitable as components of tablet feeds.

As regards the appellant's argument relating to a lack of incentive for the skilled person to combine the teaching of documents (7) and (18), it has to be said that document (8) teaches that water is a suitable plasticizer for coating compositions comprising a film-forming polymer and a pigment. Hence, it is only logical that the skilled person will make use of his general knowledge in process engineering to look at methods of adding water in order to improve the dispersing behaviour of powders.

3.9 Claim 9 of the main request, claim 8 of auxiliary request 1 and claim 1 of auxiliary requests 2 and 3 are identical. Therefore, the analysis made for claim 9 above applies identically to the corresponding claims of auxiliary requests 1 to 3.

3.10 Consequently, the main request and auxiliary requests 1 to 3 fail for lack of inventive step (Article 56 EPC).

4. *Auxiliary request 5*

4.1 Claim 1 of auxiliary request 5 merely differs from claim 9 of the main request in that the expression

"comprising the steps of" has been replaced by the expression "consisting of the steps".

4.2 It has not been contested by the respondent that this amendment meets the requirements of Article 123 EPC and the board sees no reason to differ.

4.3 The analysis made in point 3 above with respect to the novelty and inventive step of the subject-matter of claim 9 as granted applies mutatis mutandis to claim 1 of auxiliary request 5.

The only further argument put forward by the appellant in respect of auxiliary request 5 is that an after-drying step is excluded from the claim wording and hence document (18) is no longer relevant.

It may be true that the claim wording for the method of auxiliary request 5 does not include an after drying step, but the claim relates to a method of making a wet powder "**for use** in coating tablets and capsules". Therefore, it is left open whether the product prepared by the method claimed has to be suitable for direct dispersion in water, or is merely an intermediate which may still undergo a further step such as after-drying before dispersion.

Consequently, claim 1 of auxiliary request 5 lacks an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

U. Bultmann U. Oswald