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**Datasheet for the decision
of 12 May 2009**

Case Number: T 1180/06 - 3.3.09

Application Number: 97900936.2

Publication Number: 0877562

IPC: A23L 1/275

Language of the proceedings: EN

Title of invention:

Water dispersible compositions containing natural hydrophilic, water-insoluble pigments, methods of preparing same and their use

Patentee:

Chr. Hansen A/S

Opponent:

GNT International B.V.

Headword:

-

Relevant legal provisions:

EPC Art. 54, 56

Keyword:

"Main request: Novelty (yes), Inventive step (no)"

"First auxiliary request: withdrawn"

"Second auxiliary request: Novelty (yes), Inventive step (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 1180/06 - 3.3.09

DECISION
of the Technical Board of Appeal 3.3.09
of 12 May 2009

Appellant: GNT International B.V.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office orally
announced 11 May 2006 and posted 19 June 2006
concerning maintenance of European patent
No. 0877562 in amended form.

Composition of the Board:

Chairman: P. Kitzmantel
Members: W. Ehrenreich
M-B. Tardo-Dino

Summary of Facts and Submissions

- I. Mention of the grant of European patent No. EP-B 0 877 562 in respect of European patent application No. 97 900 936.2 filed on 20 January 1997 as International application PCT/DK97/00026 in the name of CHR. HANSEN A/S and published on 31 July 1997 as WO-A 97/026803, was announced on 3 September 2003 (Bulletin 2003/36).

The patent entitled "*Water dispersible compositions containing natural hydrophilic, water-insoluble pigments, methods of preparing same and their use*" was granted with thirty claims.

Independent Claims 1, 2, and 11 were directed to the use of a water dispersible pigment composition for the preparation of an edible/food product (Claims 1, 2) or of a pharmaceutical product (Claim 11). Claims 3 to 10 were, either directly or indirectly, dependent on Claims 1 and 2. Claim 12 was dependent on Claim 11.

Independent product Claim 13, to which Claims 14 to 18 were appended, pertained to the ready-to-use water dispersible pigment composition itself.

Claims 19 and 20 concerned an edible product (Claim 19) or a pharmaceutical product (Claim 20) comprising the composition of Claims 13 to 18.

Independent Claims 21, 27 and 29 were directed to various methods of preparing the ready-to-use water dispersible pigment composition according to Claims 13-18 (Claim 21) or 14-18 (Claims 27, 29). Claims 22 to 26 were dependent on Claim 21; Claim 28

was dependent on Claim 27 and Claim 30 was dependent on Claim 29.

II. An opposition against the patent was filed by

GNT International B.V.

on 13 May 2004.

The opposition was based on the opposition grounds of Article 100(a) EPC, namely that the claimed subject-matter was not novel and did not involve an inventive step, and of Article 100(b) EPC, namely that the invention was insufficiently disclosed.

The objections under Article 100(a) EPC were based *inter alia* on the following document:

D2 DE-A 40 33 690.

With the letter of 2 February 2006 further documents, *inter alia* the document

D9 EP-A 0 498 824.

were submitted.

III. With its interlocutory decision, announced in the oral proceedings on 11 May 2006 and issued in writing on 19 June 2006, the Opposition Division maintained the patent in amended form on the basis of Claims 1 to 13 of auxiliary request 3 filed in the oral proceedings. The set of claims according to this request contained

independent Claims 1, 2, 10, 12 and 13 which read as follows:

"1. Use of a ready-to-use water-dispersible composition comprising

- a dispersion of a water-insoluble hydrophilic natural pigment insoluble in aqueous media at about neutral pH or below but soluble in aqueous media at pH values in the alkaline range;
- said pigment being in the form of bodies having an average size of at most 10 μm ;
- said bodies being dispersed in the absence of a surface-active substance in an aqueous phase comprising a hydrocolloid;
- the composition containing in excess of 10 weight % of water;

in the manufacturing of an edible product whereby the composition is dispersed in an aqueous phase of said product."

"2. Use of a water-dispersible pigment composition comprising

- a dispersion of a water-insoluble hydrophilic natural pigment insoluble in aqueous media at about neutral pH or below but soluble in aqueous media at pH values in the alkaline range;
- said pigment being in the form of bodies of an average size of at most 10 μm ;

- said bodies being dispersed in the absence of a surface-active substance in an aqueous phase comprising a hydrocolloid;
- the composition containing less than 5% by weight of water;
- subject to the limitation that when the pigment is carmine or spray-dried norbixin, the hydrocolloid is not gelatine;
- said composition, when it is added to a food product comprising multiple, separate compartments, whereby the composition is dispersed in one or more selected compartments, essentially does not migrate from said compartment(s) where it is dispersed into other compartments;

in the manufacturing of a food product whereby the composition is dispersed in an aqueous phase of said product."

"10. Use of a ready-to-use water-dispersible composition comprising

- i) a dispersion of a hydrophilic natural pigment insoluble in aqueous media at about neutral pH or below but soluble in aqueous media at pH values in the alkaline range;
- ii) said pigment being in the form of bodies of an average size of at most 10 μm ;
- iii) said bodies being dispersed in the absence of a surface-active substance in an aqueous phase comprising a hydrocolloid;
- iv) the composition containing in excess of 10% by weight of water;

in the manufacturing of a pharmaceutical product."

"12. A method of preparing a ready-to-use water dispersible pigment composition comprising

- a dispersion of a natural pigment insoluble in water at or below pH 7 but soluble in alkaline solutions;
- said pigment being in the form of bodies of an average size of at most 10 μm ;
- said bodies being dispersed in the absence of a surface-active substance in an aqueous phase comprising a hydrocolloid, and at least 5% by weight of water;
- the natural pigment being selected from the group consisting of a carmine metal chelate, a curcumin metal chelate, a porphyrin pigment and norbixin;
- the composition, when it is added to a food product, comprising multiple, separate compartments, whereby the composition is dispersed in one or more selected compartments, essentially does not migrate from said compartment(s) where it is dispersed into other compartments;

said method comprising the steps of:

- v) preparing an alkaline aqueous solution comprising a water-insoluble, hydrophilic natural pigment,
- vi) preparing an aqueous dispersion or solution of a hydrocolloid,
- vii) mixing the alkaline aqueous solution with the aqueous dispersion or solution of a hydrocolloid and

viii) if desired, adjusting the pH to a level which causes the pigment to precipitate,

to obtain the composition comprising the pigment in the form of a dispersion of pigment bodies having an average size of at the most 10 μm ."

"13. A method of preparing a ready-to-use water-dispersible pigment composition comprising

- a dispersion of a natural pigment insoluble in water at or below pH 7 but soluble in alkaline solutions;
- said pigment being in the form of bodies of an average size of at most 10 μm ;
- said bodies being dispersed in the absence of a surface-active substance in an aqueous phase comprising a hydrocolloid, and at least 5% by weight of water;
- the natural pigment being selected from the group consisting of a carmine metal chelate, a curcumin metal chelate, a porphyrin pigment and norbixin;
- the composition, when it is added to a food product, comprising multiple, separate compartments, whereby the composition is dispersed in one or more selected compartments, essentially does not migrate from said compartment(s) where it is dispersed into other compartments;

said method comprising the steps of:

- i) preparing an alkaline aqueous solution comprising a water-insoluble, hydrophilic natural pigment followed by decreasing the pH to a level which causes the pigment to

- precipitate, resulting in a dispersion of precipitated pigment,
- ii) preparing an aqueous dispersion or solution of a hydrocolloid,
 - iii) mixing the dispersion comprising the precipitated pigment of step i) and the dispersion or solution of the hydrocolloid of step ii),

to obtain the composition comprising the pigment in the form of dispersions of pigment bodies having an average size of at the most 10 μm ."

The Opposition Division saw no problem with sufficiency of disclosure and recognized the novelty of the subject-matter of all independent claims over the late-filed document D9, which was admitted due to its relevance.

In that respect the Opposition Division found

- with regard to Claims 1 and 2, that D9 did not disclose that the colorant composition was dispersed in an aqueous phase of an edible product;
- with regard to Claim 10, that the microcapsules of D9 contained a lesser amount of water, and
- with regard to the method Claims 12 and 13, that D9 failed to disclose the dissolution of the pigment in an alkaline aqueous medium.

Concerning inventive step, the Opposition Division considered D2, not D9, representative of the closest prior art for the subject-matter of Claims 1 and 2. In its view, there was however no reason for the skilled person to replace, as colorants for aqueous food products, the norbixin-hydrocolloid-complex solutions

of D2 by compositions containing the norbixin in the form of a dispersion.

For the subject-matter of Claims 10, 12 and 13 the Opposition Division considered D9 as the closest prior art. With regard to the use according to Claim 10 for the manufacture of a pharmaceutical product, it found that it was non-obvious to miss out the spray-drying step leading to a powder with a maximum of 10% water and instead turn to a dispersion containing water in excess of 10%. Similarly, it was not obvious to prepare the pigment particles by precipitation from an aqueous solution in accordance with Claims 12 and 13, instead of a milling process as used according to D9.

IV. An appeal against the decision of the Opposition Division was filed by the Opponent (hereinafter: the Appellant) on 29 July 2006. The Statement of the Grounds of Appeal was submitted 27 October 2006. The objections as to insufficiency of disclosure under the opposition ground according to Article 100 (b) EPC were no longer maintained.

Document D18 (DE-B 1 211 922) and, with the letter dated 14 April 2009, document D19 (DE-A 40 26 118) were cited for the first time in order to support the objections of lack of novelty and lack of inventive step.

V. With the letter dated 8 April 2009 the Patent Proprietor (hereinafter: the Respondent) filed a new main request and auxiliary requests 1 to 4. Modified claim versions of the main and auxiliary requests 1 and 2 containing a correction of typographical errors were submitted with the letter dated 6 May 2009. With the

same letter a signed declaration of Mr. Køhler was filed.

The Respondent further contested the admissibility of the late-filed documents D18 and D19.

The main request essentially corresponds to auxiliary request 3 as allowed by the Opposition Division. The process steps (v) to (viii) in Claim 12 were renumbered to (i) to (iv). In the process step (viii) of Claim 12 - now step (iv) - the wording "*if desired*" was deleted, making this step optional, in reaction to the Board's observation in this regard in its communication of 18 December 2008.

During the oral proceedings, held on 12 May 2009, auxiliary request 1 was withdrawn.

The set of Claims 1 to 10 of the second auxiliary request contains independent Claims 1, 8, 9 and 10 which read as follows:

"1. Use of a ready-to-use water-dispersible composition comprising

- a dispersion of a water-insoluble hydrophilic natural pigment insoluble in aqueous media at about neutral pH or below but soluble in aqueous media at pH values in the alkaline range;
- said pigment being in the form of bodies having an average size of at most 10 μm ;
- said bodies being dispersed in the absence of a surface-active substance in an aqueous phase comprising a hydrocolloid;

- the composition containing in excess of 10 weight % water;

in the manufacturing of an edible product whereby the composition is dispersed in an aqueous phase of said product, wherein the edible product comprises multiple, separated compartments whereby the composition is dispersed in one or more selected compartments, the composition in one compartment essentially not migrating to other compartments."

"8. Use of a ready-to-use water-dispersible composition comprising

- i) a dispersion of a hydrophilic natural pigment insoluble in aqueous media at about neutral pH or below but soluble in aqueous media at pH values in the alkaline range;
- ii) said pigment being in the form of bodies of an average size of at most 10 μm ;
- iii) said bodies being dispersed in the absence of a surface-active substance in an aqueous phase comprising a hydrocolloid;
- iv) the composition containing in excess of 10% by weight of water;

in the manufacturing of a pharmaceutical product, wherein the pharmaceutical product comprises multiple, separated compartments whereby the composition is dispersed in one or more selected compartments, the composition in one compartment essentially not migrating to other compartments."

"9. A method of preparing a ready-to-use water dispersible pigment composition comprising

- a dispersion of a natural pigment insoluble in water at or below pH 7 but soluble in alkaline solutions;
- said pigment being in the form of bodies of an average size of at most 10 μm ;
- said bodies being dispersed in the absence of a surface-active substance in an aqueous phase comprising a hydrocolloid; and at least 5% by weight of water;
- the natural pigment being selected from the group consisting of a carmine metal chelate, a curcumin metal chelate, a porphyrin pigment and norbixin;
- the composition, when it is added to a food product comprising multiple, separate compartments, whereby the composition is dispersed in one or more selected compartments, essentially does not migrate from said compartment(s) where it is dispersed into other compartments;

said method comprising

- i) preparing an alkaline aqueous solution comprising a water-insoluble, hydrophilic natural pigment,
- ii) preparing an aqueous dispersion or solution of a hydrocolloid,
- iii) mixing the alkaline aqueous solution with the aqueous dispersion or solution of a hydrocolloid and
- iv) [i]adjusting the pH to a level which causes the pigment to precipitate,

to obtain the composition comprising the pigment in the form of a dispersion of pigment bodies having an average size of at the most 10 μm ."

"10. A method of preparing a ready-to-use water-dispersible pigment composition comprising

- a dispersion of a natural pigment insoluble in water at or below pH 7 but soluble in alkaline solutions;
- said pigment being in the form of bodies of an average size of at most 10 μm ;
- said bodies being dispersed in the absence of a surface-active substance in an aqueous phase comprising a hydrocolloid; and at least 5% by weight of water;
- the natural pigment being selected from the group consisting of a carmine metal chelate, a curcumin metal chelate, a porphyrin pigment and norbixin;
- the composition, when it is added to a food product, comprising multiple, separate compartments, whereby the composition is dispersed in one or more selected compartments, essentially does not migrate from said compartment(s) where it is dispersed into other compartments;

said method comprising the steps of:

- i) preparing an alkaline aqueous solution comprising a water-insoluble, hydrophilic natural pigment followed by decreasing the pH to a level which causes the pigment to precipitate, resulting in a dispersion of precipitated pigment,

- ii) preparing an aqueous dispersion or solution of a hydrocolloid,
- iii) mixing the dispersion comprising the precipitated pigment of step i) and the dispersion or solution of the hydrocolloid of step ii),

to obtain the composition comprising the pigment in the form of dispersions of pigment bodies having an average size of at the most 10 μm ."

Auxiliary requests 3 and 4 are not discussed in what follows because, as will be seen, the patent is ordered to be maintained on the basis of auxiliary request 2.

VI. The arguments provided by the Appellant may be summarized as follows:

- (a) *Novelty of the method according to Claim 12 of the main request - which essentially corresponds to Claim 9 of the second auxiliary request - vis à vis D19*

According to examples 1 and 2 of D19 stable complexes of curcumin - a water-insoluble hydrophilic natural pigment - with a hydrocolloid were prepared by

- preparing an alkaline aqueous curcumin solution;
- preparing an aqueous solution of a hydrocolloid;
- mixing the curcumin solution with the solution of the hydrocolloid and
- decreasing the pH by adding phosphorous acid.

These process measures correspond to the effective process steps (v) to (viii) of Claim 12 of the main request and would therefore lead to a precipitation of the curcumin pigment. Hence, the subject-matter of Claim 12 was not novel over D19.

(b) *Inventive step of the subject-matter of Claims 1, 2 and 10 of the main request*

D9 was representative of the closest prior art. This document disclosed a water-dispersible pigment composition comprising:

- a dispersion of a water-insoluble hydrophilic natural pigment in the sense of the teaching of the patent, like norbixin, curcumin, chlorophyll or carmine;
- the pigment having a particle size not exceeding 10 μm ;
- the pigment being dispersed in the absence of a surface-active substance in an aqueous medium in the presence of a hydrocolloid.

Since according to column 5 the composition "may be dried to a residual water content of between 0 and 10" (emphasis by the Board) by "modified spray drying", spray-drying is an optional feature, and before spray-drying the composition could anyway have a water content in excess of 10%.

In column 6 it was stated that the composition can be used in pharmaceutical compositions, feeds and foodstuffs.

In view of the further disclosure in column 6 of D9 that the composition is redispersible in water

to form discrete microparticles, the measure according to Claim 1 of the main request to provide the pigment composition in the form of an aqueous formulation containing more than 10% of water and to disperse it in an aqueous phase of a food product was obvious from D9.

In a similar manner, and with regard to the spray-drying step disclosed in column 5 of D9 leading to a composition with a residual water content between 0 and 10%, the subject-matter of Claim 2 relating to a pigment composition containing less than 5% of water was also obvious.

In the light of the disclosure in D9 that the composition could be used in pharmaceutical compositions, the use of the composition for the manufacture of a pharmaceutical product in accordance with Claim 10 was also obvious.

(c) *Inventive step of the subject-matter of Claims 1 and 8 of the second auxiliary request*

The arguments provided under point (b) also applied to Claims 1 and 8 of the second auxiliary request because the additional feature that the edible product/pharmaceutical product "*comprises multiple, separated compartments ... the composition in one compartment essentially not migrating to other compartments*" was a functional feature, merely expressing a result to be achieved. Moreover, it was indicated in paragraphs [0011/12] of the patent specification itself that migration of colorants from one compartment of a food

product or pharmaceutical product to another was a well-known problem in the prior art, which a skilled person intending to provide colorants for food or pharmaceutical products would therefore automatically take into account.

(d) *Inventive step of the method according to Claims 9 and 10 of the second auxiliary request*

The process claimed in Claim 9 of the second auxiliary request differed from that disclosed in D9 essentially in that the pigment particles with an average size of at most 10 μm were prepared by precipitating the pigment from an alkaline aqueous pigment solution comprising the hydrocolloid, instead of milling the solid particles in an aqueous medium in the presence of a hydrocolloid in accordance with D9.

The solubility of certain natural pigments, such as norbixin, in an alkaline medium containing a hydrocolloid, and their precipitation by decreasing the pH of the solution with an acid was, however, known from D2.

Since the Respondent did not show any particular effect caused by precipitating the pigment from an alkaline solution, the process of Claim 9 merely represented an alternative method vis à vis the method of D9, which the skilled person would however take into account in view of the disclosure in D2.

The same consideration principally applied to the method of Claim 10 because it was within the

bounds of routine experimentation of a skilled person to precipitate the pigment before adding the hydrocolloid solution.

VII. The Respondent provided the following counterarguments (taking them in the same order):

(a)

The Appellant's argument that D19 disclosed the precipitation of the curcumin pigment from an alkaline solution was based on a misinterpretation of the document. According to Claim 10 in conjunction with page 4, lines 3 to 5 of D19 a curcumin/hydrocolloid complex in the form of a clear yellow solution was prepared which remained stable when left to stand and from which curcumin could not be removed by centrifuging.

The process step (viii) of Claim 12 of the main request was therefore not disclosed in D19. Hence, the claimed process was novel.

(b)

The use of a pigment composition containing more than 10% by weight of water for dispersing it in an aqueous phase of an edible product was not part of the teaching of D9.

Column 6, lines 17 et seq. only contained a very general disclosure referring to the possible use of the powdery pigment composition - obtained by spray-drying to a water content between 0 and 10% - for foodstuffs or pharmaceutical compositions.

This general disclosure, however, would not render it obvious to provide the pigment powder as a composition containing in excess of 10 % of water and to disperse it in this water-enriched form in an aqueous phase of a foodstuff. The use according to Claim 1 of the main request was therefore based on an inventive step.

The same argument applied to the use according to Claim 2 requiring dispersion of the pigment composition in its water-reduced form to an aqueous dispersion of a foodstuff, and to the use of the water enriched form of the pigment composition for the preparation of a pharmaceutical product according to Claim 10.

(c)

According to Claims 1 and 8 of the second auxiliary request the presence of several compartments in the edible product/pharmaceutical composition was mandatory, in which compartments the pigment was dispersed and should not migrate from one compartment into another.

This meant that the pigment composition had to fulfil certain criteria which made it suitable for solving the migration problem.

This problem was neither addressed in D9 nor was a teaching to be found therein indicating which one of the colorants listed in columns 4/5 of D9 would be suitable for the formulation of a pigment composition able to provide a solution to the

problem of migration of colorants from one compartment to another.

The use according to Claims 1 and 8 of the second auxiliary request was therefore based on an inventive step.

(d)

Both D2 and D9 failed to disclose the preparation of a pigment composition by precipitating the pigment from an alkaline aqueous solution. In particular, it was taught in D2 to keep the norbixin pigment in solution in the form of an adduct, a method leading away from the measure in Claims 9 and 10 of the second auxiliary request requiring precipitation the pigment. A combination of D9 with D2 would therefore not render the method of Claims 9 and 10 obvious.

VIII. The Appellant requested that the decision under appeal be set aside and that the patent be revoked.

IX. The Respondent requested that the appeal be dismissed and the patent be maintained on the basis of Claims 1-13 of the main request, or alternatively on the basis of Claims 1-10 of auxiliary request 2, both filed with the letter dated 6 May 2009, or alternatively on the basis of Claims 1 and 2 of auxiliary request 3 or the single claim of auxiliary request 4, both filed with the letter dated 8 April 2009.

The Respondent further requested that documents D18 and D19 be not admitted into the appeal proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. Admissibility of the late-filed documents D18 and D19

It appeared from the discussion during the oral proceedings that D18 and D19 were not more relevant than the documents already on file. As regards D19, which was cited by the Appellant in order to attack the novelty of the method claimed in Claim 12 of the main request, its disclosure concerning the preparation of a pigment formulation in the form of a pigment-hydrocolloid adduct from an alkaline aqueous solution does not go beyond the teaching of D2. Contrary to the Appellant's argument, D19 does not disclose a pigment precipitate but rather a solution.

In accordance with Article 114(2) EPC and Article 13 (1) of the Rules of Procedure of the Boards of Appeal (OJ 11/2007, 536-547) D18 and D19 are therefore not admitted into the appeal proceedings.

3. *Novelty*
 - 3.1 *Novelty of the use of the water-dispersible pigment composition for the preparation of an edible/food product according to Claims 1 and 2 of the main request and Claim 1 of the second auxiliary request*

The above claims all contain the essential feature that the composition is dispersed in an aqueous phase of the edible/food product. This feature is not disclosed in a clear and unambiguous way in any of the cited documents. The subject-matter of the above claims is therefore novel over the prior art.

3.2 *Novelty of the use of the water-dispersible pigment composition for the preparation of a pharmaceutical product according to Claim 10 of the main and Claim 8 of the second auxiliary request*

The relevant document for the consideration of novelty is D9, which discloses in column 6, lines 24 to 26, that (water dispersible) microcapsules can be used, *inter alia*, in pharmaceutical compositions.

In the Board's judgment and contrary to the argument of the Appellant, D9 does not disclose the use of a water-dispersible pigment composition in the manufacturing of a pharmaceutical product (emphasis by the Board). D9 discloses the preparation of hydrophilic/aerophilic solids that can be dispersed in water in the form of microparticles (column 2, lines 43 to 49). Natural colorants like norbixin, curcumin, chlorophyll, carmine etc. and drugs (pharmaceutically active compounds) like grisofulvin, ibuprofen or benzodiazepines are disclosed as hydrophobic/aerophilic materials in column 3, line 54 to column 4, line 6. Thus D9 relates to a method for the formulation of these solids in the form of microparticles, and it is in this context that the above mentioned passage in column 6 that "the microcapsules ... *can be used in pharmaceutical compositions, feeds and foodstuffs*" is to be understood,

namely as the possible provision of each of these materials in the form of microparticles. This disclosure does not comprise therefore the use of pigment containing microparticles for colouring pharmaceutical compositions.

The use claims of Claim 10 of the main request and Claim 8 of the second auxiliary request are therefore novel.

3.3 *Novelty of the method for preparing the water-dispersible pigment composition according to Claims 12 and 13 of the main request and Claims 9 and 10 of the second auxiliary request*

One essential feature of the above claims is the process step of causing the pigment to precipitate from an aqueous alkaline solution - either in admixture with the hydrocolloid solution (main request: Claim 12; second auxiliary request: Claim 9) or before mixing it with the hydrocolloid solution (main request: Claim 13; second auxiliary request: Claim 10).

A second essential feature of the above claims is that the pigment in the resulting dispersion is in the form of bodies having an average size of at most 10 μm .

The most pertinent document for the assessment of novelty is D2, which, however, does not disclose the precipitation of a pigment to form bodies with an average size of at most 10 μm . Although example 4 of D2 indicates that (too) quick a neutralisation of an alkaline norbixin/adduct solution leads to the (undesired) precipitation of norbixin in its free form,

nothing is said about the particle size of the precipitated particles.

The other relevant document, D9, arrives at the particle size of at most 10 μm by milling the pigment particles in an aqueous medium (column 2, lines 50 to 58) and not by precipitation.

The subject-matter of the above claims is therefore novel over D2 and D9.

Inventive step

4. The patent in suit

The contested patent is concerned with the use of ready-to-use water-dispersible compositions containing natural hydrophilic, water-insoluble pigments for colouring edible products and pharmaceutical products (patent specification, paragraph [0001] and a method for preparing them with the aid of a hydrocolloid and in the absence of a surface-active substance (paragraphs [0021] to [0023])).

The patent also deals with the well-known problem associated with water-dispersible colouring agents, i.e. their undesirable tendency to migrate from one compartment of a food product or pharmaceutical product to another (paragraphs [0011] and [0012])).

5. *Inventive step of the subject-matter of Claim 1 according to the main request*

Claim 1 of the main request is directed to the use of a ready-to-use water-dispersible composition for

colouring edible products and is characterized by the following features:

- (a) the composition comprises a hydrophilic natural pigment insoluble in neutral aqueous media but soluble in alkaline media;
- (b) the pigment is present in the form of particles having an average size of at most 10 µm;
- (c) the pigment is dispersed in an aqueous phase comprising a hydrocolloid in the absence of a surface-active agent;
- (d) the composition comprises in excess of 10% by weight of water;
- (e) the composition described in (a) to (d) is dispersed in an aqueous phase of the edible product.

5.1 *The closest prior art*

In the Board's judgment, D9 is representative of the closest prior art.

This document describes the use of water-dispersible microencapsulated colorant compositions in feeds and foodstuffs (column 6, lines 17 to 26). The composition is characterized by the following features:

- (a) the colorant can be a pigment like norbixin, curcumin, chlorophyll or carmine (column 3, line 54 to column 4, line 6). These pigments are hydrophilic and soluble in alkaline aqueous media in the sense of the invention (patent specification, paragraphs [0024] and [0026]);

- (b) the pigment has a particle size not exceeding 10 μm (column 1, line 23 to 26 and column 3, lines 44 to 48);
- (c) the pigment is dispersed in the aqueous phase of a hydrocolloid without the use of a surface-active agent (column 2, line 50 to column 3, line 43);
- (d) the composition is dried, e.g. by spray-drying, to a residual water content of between 0 and 10% (column 5, lines 26 to 31). According to column 2, lines 43 to 49 it is intended to disperse the solid in water in the form of discrete micro-particles without the aid of further additives to form a microencapsulated product having a concentration of up to 71 % of hydrophobic/aerophilic solid. This implies that the composition is used as colorant in its dispersed form having a water content of minimum 29 %, i.e. in excess of 10 % by weight as required by Claim 1 of the main request.

5.2 *The problem to be solved*

The claimed use differs from that disclosed in D9 only as regards feature (e), in that the composition is dispersed in an aqueous phase of an edible product. In the absence of any experimental evidences showing that this measure leads to a surprising non-predictable advantage, the problem to be solved is merely seen in a use of a water-dispersible colorant composition for colouring food products in an alternative way.

5.3 *Obviousness*

In column 1, lines 12 to 16, D9 points to the improved colouring effect and colour intensity of a pigment

dispersed in an aqueous medium by decreasing its particle size and increasing its dispersibility. This implies that the related benefit of the pigment microparticles provided by the method of D9 is only exploited to its full extent when they are brought into an aqueous medium. It follows that the skilled person wishing to make the most of D9's invention is prompted to use them for the colouration of foodstuffs comprising an aqueous phase.

Dispersing the colorant composition according to Claim 1 in an aqueous phase of an edible product is therefore obvious over D9.

As a consequence the entire main request is not allowable.

6. *Inventive step of the subject-matter according to the second auxiliary request*

6.1 *Use according to Claims 1 and 8*

Claims 1 and 8 of the second auxiliary request both require that the composition dispersed in one or more selected separate compartments which are present in the edible product or the pharmaceutical product does not migrate into other compartments.

In the Board's judgment, this desired property is to be regarded as a functional feature restricting the choice of pigments to those meeting this requirement. While the pigments norbixin, carmine and curcumin, all of which provide this property and which are preferred pigments of the present invention are included in the

list of materials which can be used for the microparticles of D9 (cf. paragraph bridging columns 3 and 4), this document does not address this property and no selection criteria are therefore at the skilled person's disposal for picking them out for the purpose of the present invention from this relatively heterogeneous list (including carotenoids not matching the solubility criteria of present Claim 1, like bixin, as well as drugs like benzodiazepins). Nor is there any information in that respect in the further citations.

It follows that the use according to Claims 1 and 8 is not rendered obvious.

6.2 *The method according to Claims 9 and 10*

One essential step of the method of Claims 9 and 10 is the precipitation of the pigment from an alkaline solution by adjusting (i.e. decreasing) the pH of the solution (features (iii) and (iv) of Claim 9 and feature (i) of Claim 10).

The closest prior art is again represented by D9, which describes the preparation of a water dispersible pigment composition wherein pigment bodies of a particle size of not more than 10 μm are dispersed in an aqueous medium in the presence of a hydrocolloid. According to D9 the pigment bodies are, however, formed by transferring the particles in an aqueous suspension in the presence of a hydrocolloid to a mill which is capable of milling the solid to a maximum particle size of 10 μm . This method by applying high shear forces to the particles is very different from the precipitation step of Claims 9 and 10.

The Appellant's argument that the measure of precipitating the particles from an alkaline solution was an alternative which was obvious from D2 because this document already taught the precipitation of norbixin by acidification is not convincing. D2, dealing with the preparation of stable, soluble norbixin/hydrocolloid pigment adducts from an alkaline norbixinate solution, indeed teaches the very slow decrease of the pH of the solution in order to keep the norbixin in solution and by this means avoid precipitation of free norbixin (column 3, lines 26 to 40 and column 4, line 52 to column 5, line 3). In this context, Example 4 of D2 furthermore indicates that precipitation of the norbixin by too quick an addition of the acid to the alkaline solution is undesirable because it leads to a considerably reduced colouring capacity of the pigment composition. D2 therefore leads away from the claimed process.

Consequently, a combination of D9 with D2 does not render the method of Claims 9 and 10 obvious.

6.3 Conclusion

The subject-matter of all independent claims of the second auxiliary request is based on an inventive step.

The second auxiliary request is therefore allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of Claims 1 to 10 of the second auxiliary request filed with the letter dated 6 May 2009, after any necessary consequential amendment of the description.

The Registrar

The Chairman

G. Röhn

P. Kitzmantel