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D E C I S I O N
of 18 January 2000

Case Number: T 0435/97 - 3.3.3

Application Number: 88810548.3

Publication Number: 0304401

IPC: C08L 3/02

Language of the proceedings: EN

Title of invention:
Shaped articles made from pre-processed starch

Patentee:
NOVAMONT S.p.A.

Opponent:
Bio-tec Biologische Naturverpackungen GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 54(1), (2)

Keyword:
"Novelty - prior disclosure - implicit features (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0435/97 - 3.3.3

D E C I S I O N
of the Technical Board of Appeal 3.3.3
of 18 January 2000

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 21 February 1997 concerning maintenance of European patent No. 0 304 401 in amended form.**

Composition of the Board:

Chairman: C. Gérardin
Members: A. Däweritz
A. Lindqvist

Summary of Facts and Submissions

I. The grant of European patent No. 0 304 401 in respect of European patent application No. 88 810 548.3 filed on 12 August 1988 and claiming priority of 18 August 1987 of an earlier application in Great Britain (8719485), was announced on 2 March 1994 (Bulletin 94/09) on the basis of 27 claims.

Claim 1 as granted reads as follows:

"1. A process of forming shaped articles from starch comprising the steps of:

(a) heating a solid starch composition comprising starch and water, wherein said starch is selected from the group consisting of chemically non-modified starch composed mainly of amylose and/or amylopectin and physically modified starch, and in which the water content is in the range of from 10 to 20% by weight with respect to that of the composition, in a screw barrel of an injection molding machine or an extruder, to a temperature of from 80°C to 200°C, and at a pressure of from zero to 150 x 10^5 N/m^2, thereby to form a melt;

(b) transferring the melt to the mold while maintaining the water content in the range of from 10 to 20% by weight with respect to that of the composition; and

(c) cooling the melt in the mold to a temperature below its glass transition temperature to form a solid shaped article,

characterized in that

the solid starch composition of step a) has been obtained by previously heating said starch being selected from the group consisting of chemically non-modified starch composed mainly of amylose and/or amylopectin and physically modified starch, and in which the water content is in the range of from 10 to 20% by weight with respect to that of the composition, in a closed volume to a temperature within the range of 120°C to 190°C, at a pressure corresponding to the vapour pressure of water at the used temperature and up to 150 x 10^5 N/m^2, whereby the melt so obtained has been extruded, cooled to solidify and granulated."

Claims 2 to 23 concern preferred embodiments of the process according to Claim 1.

The patent as granted additionally contained product Claims 24 to 27 relating to shaped articles and to the melt as obtained in or during the process according to the preceding claims.

II. On 19 November 1994 and 25 November 1994, Notices of Opposition were filed by two Opponents in which revocation of the patent in its entirety was requested on the grounds of lack of novelty within the meaning of Article 54(1) and (2) EPC and inventive step within the meaning of Article 56 EPC. Opponent I additionally raised the objection of insufficiency of disclosure under Article 100(b) EPC, but withdrew its opposition by letter dated 15 November 1996.

The objections were supported essentially by the

following documents:

D1: translation of JP-B-53-019645 into English, and

D4: EP-A-0 118 240.

III. By interlocutory decision announced orally on 13 December 1996 and issued in writing on 21 February 1997, the Opposition Division held that the grounds of opposition did not prejudice the maintenance of the patent in amended form, the amendments consisting in the deletion of Claims 24 to 27 and minor adaptations of pages 2 and 3.

(i) In substance, the Opposition Division took the view that the claimed subject-matter was novel over D4, because the citation disclosed a one-step process and the cooling and granulation of an intermediate solid product was not disclosed.

Novelty was also accepted vis-à-vis Example 1 of D1 which lacked two essential features of Claim 1. Contrary to the requirement in the characterising part of Claim 1 under dispute, the starting material for the process described in Example 1 of D1 contained more than 20% of water. As calculation showed, the total amount of water in the composition was 44.2%. Moreover, D1 did not disclose the formation of a melt as required in the claimed process.

(ii) D4 was regarded as representing the closest prior art and as being concerned with precisely the same type of problem as the patent in suit,

namely the production of shaped articles by subjecting starch to heat and pressure, while controlling the water content, in an extruder or injection molding machine. Starting from this document, it was not considered obvious to convert the known one-stage process into a two-stage process by inserting the steps of cooling, solidifying and granulating in accordance with the requirements of the patent in suit in order to improve the physical properties of the known molded destructurised starch products.

Figure 7 of the patent in suit showed that under otherwise identical conditions, the molten starches processed according to Claim 1 had lower melt viscosities than starches processed according to D4. Lower melt viscosities were associated with lower sensitivity to residence time and shear rate, leading to improved process stability and a more reproducible product. This effect could not have been predicted, and there was no obvious reason why the skilled person should have been led to modify the known process in the way as done by the Patentee in the expectation of producing this desired effect. Consequently, an inventive step of the process according to Claim 1 was acknowledged.

Since all the remaining Claims 2 to 23, being dependent on Claim 1, were further limitations of that process, they also embodied an inventive step.

(iii) The objection under Article 100(b) EPC, which

had been raised by Opponent I only, was not founded since the patent specification contained sufficient information for a skilled person, using routine optimisation of process parameters, to carry out the claimed invention.

IV. On 18 April 1997, a Notice of Appeal was lodged by the remaining sole Opponent II (Appellant) against this interlocutory decision with simultaneous payment of the prescribed fee.

In the Statement of Grounds of Appeal filed on 19 June 1997, the Appellant maintained its objection of lack of novelty. To that end it relied mainly on D1 and

D8: a declaration of Dr. I. Tomka from the Institut für Polymere - Polymertechnologie of the ETH Zürich, dated 17 June 1997.

In that document, reference was made to an article having the title

D9: "Thermally Induced Structural Transitions in the Starch/Water System" by R.W. Willenbücher, I. Tomka and R. Müller.

According to D8, this article was published in "Carbohydrates in Industrial Synthesis": Proc. Symp. Div. Carb. Chem. Am. Soc., Verlag Dr. A. Bartens, Berlin, 1992, pages 93 to 111.

In substance, it argued essentially as follows:

(i) Example 1 of D1 (pages 3 and 4) literally

anticipated Claim 1 in its entirety.

1. In pre-stage (1) a starch material was pretreated with glycerol and distilled water resulting in a chemically non-modified or physically modified starch as used in the patent in suit as a starting material. According to D8, this starting material had a maximum water content of 17.9 % by weight at the end of pre-stage (1).

2. In stage (2), this physically modified starch was fed to an extruder corresponding to the closed volume in the patent in suit.

3. The starch composition was processed at a temperature within the range of from 120 to 150°C and at a pressure of 100 kg/cm^2.

4. In view of D8 (answer to question 2), the processing of the material in stage (2) of D1 must have inevitably taken place in molten state.

5. At the end of stage (2) the starch was formed into pellets and their water content was adjusted to about 13 % by weight.

6. In subsequent stage (3) a second extrusion step was carried out, the above pellets having a water content of about 13 % by weight being fed into the extruder. The temperature in this stage was 120 to 150°C at a pressure of 150 kg/cm^2.

7. It was evident from D8 (answer to question 3) that in stage (3) the composition was present as a melt and was formed into capsules, i.e. "solid shaped articles".

(ii) The assumption in the decision under appeal (cf. reasons, point 3.4) that a water content of 10 to 20 % by weight at the begin of stage (2) in D1 would be speculative, was not accepted. Contrary to the statement of the Respondent (Proprietor) in the opposition proceedings and as shown in D8 (answer to question 1), the water content would not be significantly above 20 % by weight.

(iii) Answer 2 in D8 provided evidence by means of X-ray diffraction that the presence of a melt in stage (2) was not a speculative assumption, contrary to the finding of the Opposition Division.

(iv) Similarly, the presence of a melt in stage (3) of D1 would not be speculative either.

(v) On page 2, second paragraph, lines 3 and 4, of D1 a number of different native starches was mentioned, thus anticipating Claim 2.

(vi) Example 1 of D1 also anticipated the water content of 12 to 19 % by weight as defined in Claim 3.

(vii) The process features in the further dependent claims were known to a large extent from D1.

(viii) D4 differed from the claims only in that it did not disclose a two-stage process, which was however known from D1 (point 2.2).

V. In its Counterstatement of Appeal, received on 12 May 1998, the Respondent (Proprietor) supported the findings of the decision under appeal substantially as follows:

(i) The technical significance of D8, which was allegedly based on a repetition of D1, was objected to (points 6 to 6.2.1 and 6.4 to 6.5.1), because it did not contain any particulars of the experiments, but appeared to be based on assumptions resulting from theoretical and speculative answers to some questions raised by the Representative of the Appellant. The data submitted could not thus be considered to be based on true repetitions of Example 1 of D1, but to result from wilful modifications of that example.

(ii) The Respondent referred to its statements submitted in its letter dated 14 August 1995 during the opposition proceedings.

(iii) Additionally, it reiterated these previous arguments and emphasised the complexity of the process as described in Example 1 of D1 (points 4 to 4.5.8). Thus, after heating starch, glycerol and water to form a sol having a water content of 44%, pouring the sol on a cooling belt to form a film and crushing the film to small particles, which were then pressed by

means of a screw type extrusion molding machine into molds to form small rods, the rods were formed into pellets having a water content of about 13% in a rotary dryer. These rods were then aged for 24 h and subsequently subjected to an extrusion molding process to form the desired capsules.

(iv) Further arguments were based on the molding pressure in D1 (150 kg/m^2), which indicated that it was an extrusion instead of an injection molding as carried out in the patent (600 to 3000 kg/m^2), and on the wall thickness of the final products inferring that the material present in the extrusion was not native destructurised starch, but a material having very low molecular weight which gave extremely low melt viscosity fluids.

(v) To further substantiate this statement an experimental report (Annex A) was submitted to demonstrate that sols could only be obtained in the first step of Example 1 if short chain polysaccharides comparable to maltodextrins, i.e. chemically modified starch, were used (points 6.3 to 6.4.1).

VI. With effect from 9 November 1999 the patent was transferred to Novamont S.p.A. (Respondent) for all the designated Contracting States.

VII. Oral proceedings, which had been requested by both parties as an auxiliary measure, were scheduled to take place on 18 January 2000. Together with the summons to

the hearing, a communication was issued on 9 August 1999 indicating the general principles according to which novelty and inventive step would be decided upon by the Board. In particular, it was pointed out that novelty of the claimed process would be acknowledged if the presence of at least one distinguishing feature between the subject-matter of Claim 1 and the disclosure of any document could be demonstrated clearly and unambiguously either in terms of starting compounds or in terms of processing conditions.

VIII. By letter of 29 November 1999, the Appellant informed the Board that it would not attend the hearing on 18 January 2000 and requested that a decision be issued based on the state of the file; by letter of 30 November 1999, it also withdrew its request for oral proceedings.

IX. By letter received on 17 December 1999, the Respondent confirmed its auxiliary request for oral proceedings.

X. In view of these facts, the hearing was cancelled on 22 December 1999.

XI. The Appellant requested that the interlocutory decision under appeal be set aside and that the patent be revoked in its entirety.

The Respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Procedural Matter*

2.1 To support its arguments in the Statement of Grounds of Appeal, the Appellant referred to two new documents not considered by the first instance, first a declaration D8, which contains a technical opinion followed by an experimental report, secondly an article D9.

As the Respondent offered detailed comments on both the technical opinion and the experimental report of D8, there is no obstacle to the introduction of that document into the proceedings.

D9, by contrast, which bears no date of publication, but of which D8 says that it was published in 1992 (cf. page 4, lines 17 to 24), i.e. after both the priority and the filing dates of the patent in suit, does not form part of the state of the art and will therefore be disregarded.

2.2 The Counterstatement of Appeal contains a detailed discussion of the points raised in the Statement of Grounds of Appeal and further experimental data. Despite the long period of time available since its submission and the indication by the Board of the features essential for the issue of novelty (cf. communication annexed to the summons dated 9 August 1999), the Appellant has not presented any further arguments, but only requested that a decision based on the state of the file be issued.

2.3 It is thus evident that the Appellant has had ample opportunity to comment on the grounds and evidence on which the present decision is based and that the

issuance of this decision on the basis of the written arguments is thus possible (Article 113(1) EPC).

3. *Wording of the Claims*

No objections under Article 123(2) and (3) EPC were raised with respect to the deletion of product Claims 24 to 27 and the consequential amendments on page 2, lines 3 and 57, nor to the minor amendment on page 3, line 1 (as annexed to the interlocutory decision). Since the Board also concurs with the view that these amendments comply with the requirements of Article 123 EPC, there is no need to consider this issue in further detail.

4. *Novelty*

4.1 The Board concurs with the finding of the Opposition Division in the decision under appeal, which was not disputed by the Appellant, that the subject-matter of Claim 1 relates to a process including two separate stages, whereas D4 concerns a one-stage process (see the patent in suit, page 2, lines 14 to 36; the last page of the Statement of Grounds of Appeal, lines 8 to 12; and the interlocutory decision, point 3.3). Hence, the process according to Claim 1 is novel with respect to this prior art disclosure.

4.2 In the Statement of Grounds of Appeal, however, the Appellant mainly relied on Example 1 of D1 and D8 to substantiate its objection of lack of novelty.

4.2.1 The Appellant's assumption, that the starch material ("Stärkematerial") used in the example as a starting

material was a chemically non-modified or physically modified starch (Statement of Grounds of Appeal, page 2, lines 7 to 11), has been disputed by the Respondent (Counterstatement of Appeal, points 4.5.3 to 4.5.7). According to the Respondent, the evidence (i.e. D8) and the interpretation of D1 based thereon as presented by the Appellant were not conclusive, because D8 was not based on a true repetition of Example 1 of D1 but on unjustified modifications thereof resulting from theoretical considerations and assumptions (see point V.i), above).

4.2.2 In fact, the reaction conditions are indicated in D8 (points 2 to 2.2) only in very general terms, which do not include all the necessary details of the processing steps carried out. In particular, the exact conditions are not given under which the starch was solubilised ("aufgeschlossen"; 2.1) and formed to a sol ("Behandlung"; 2.2), respectively. The "native starch" used as a starting material is not identified either. The passage on page 2, second paragraph, lines 3 and 4, referred to in the Statement of Grounds of Appeal, mentions "various kinds of starch, grain flour of wheat, rice, etc.", but does not provide the necessary information to identify the starting material either.

4.2.3 In the absence of specific processing features which would allow to identify the experiments in D8 as valid comparative tests with respect to D1 and the patent in suit, respectively, the spectra, diagrams and photographs included in D8 are of no substantive value to support the Appellant's case. Moreover, although they provide evidence of the identical properties of the products, they do not allow any conclusion

regarding the identity of the processes used to prepare them (see D8, last page: "in other words, the two processes 2.1 and 2.2 result in identical starch materials", which processes - in D8, page 2, chapter 2 - are said to represent the patent in suit and D1, respectively). This is a crucial defect in the Appellant's arguments, since the claims concern a process characterised by a combination of proper process features defining steps (a) to (c) with the product-by-process features of the composition used in step (a) (see the Counterstatement of Appeal, point 6.1).

4.2.4 In Annex A submitted with the Counterstatement of Appeal, the Respondent provided a detailed experimental report which shows that sols are only formed from mixtures of 100 parts by weight of a starch material, 5 parts by weight of glycerol and 60 parts by weight of distilled water (i.e. the ingredient ratios as used in Example 1 of D1) under processing conditions in accordance with the first step of Example 1 of D1, if maltodextrins, i.e. starch chemically degraded by acid hydrolysis, are used as the starting starch material. The other starch materials used in the experiments, such as different native corn starches or amylose, obtained by precipitation with butanol from an aqueous solution of corn starch, give "gummy aggregated starch granules" which cannot be poured to form films as described in that example.

Additional measurements giving further details about the drying of films obtained from one of the maltodextrin sols show that significant timely effort is necessary to reduce the water content from more than 30 % by weight to 20 % by weight, 20 % by weight being the upper limit of the water content defined in Claim 1.

This experimental evidence has not been disputed by the Appellant, which as the Opponent has the onus of proof for lack of novelty in opposition/appeal proceedings.

4.2.5 In points 4.3 and 4.4 of the Counterstatement of Appeal, the process steps in Example 1 of D1 are discussed in detail. After the preparation of a sol which is then cast to a film, the film is crushed to obtain small particles which are subsequently pressed into a mold by means of a screw type extrusion molding machine to yield small rods of the same size as the mold. These rods are then dried in a rotary drier, until a water content of approximately 13 % is achieved, and at the same time formed into pellets (D1, page 4, paragraph 1). After aging for 24h these pellets are molded to capsules.

4.2.6 According to Claim 1, the solid starch composition having a water content of 10 to 20 % by weight and to be used in the processing to shaped articles in steps (a), (b) and (c) has been obtained by heating in a closed volume under specific temperature and pressure conditions to form a melt. The melt is extruded, cooled to solidify and granulated.

4.2.7 Granulation is a processing step generally known in

this field of art. Reference can e.g. be made to Saechtling, International Plastics Handbook for the Technologist, Engineer and User, Second Edition, Hanser Publishers, Munich, 1987, page 47, "3.1.4. Plastics Compounding, 3.1.4.1. Thermoplastic compounds": "For molding and extrusion, most thermoplastic resins require admixture of auxiliary and additives (...) and processing to compounds in the form of pourable pellets or granules. ... The hot compound extruded through a perforated die plate is granulated either by action of a dieface cutter and then cooling the lens-shaped granules in water or by cooling first and then cutting into thick cylindrical pellets about 2 to 5 mm in length."

4.2.8 The process according to Claim 1 does not include a molding step to form small rods which are subsequently formed into pellets in a rotary drier upon reduction of the water content to 13%, as described in Example 1 of D1 (see point 3.2.5). The claimed process does not include the process steps as disclosed in a more general way on page 2, last complete paragraph of D1 either: "pelletising ... coarse powder under heat". On the contrary, it requires the cooling of the extrudate prior to the granulation.

4.3 In view of these objective differences, the Board concludes that the process as defined in Claim 1 is novel over D1.

4.4 For these reasons, the novelty requirement of Article 54(1) and (2) EPC is met by Claim 1.

5. *Inventive step*

5.1 In the Statement of Grounds of Appeal, the Appellant has not presented any arguments to support the objection to inventive step of Claim 1 initially raised during the opposition proceedings. In addition to the arguments dealing with novelty of Claim 1 vis-à-vis D1, a short reference to D4 was made at the end of point 2.2 dealing with the dependent claims, indicating that, except for the two-stage nature of the claimed process, all other features were known from D4.

5.2 The Board concludes from these facts that the Appellant has not intended to object to the reasons on which the Opposition Division based its decision to acknowledge an inventive step. Moreover, it does not see any reason by itself either to take a different position in this respect.

5.3 It follows that - for the reasons given in the decision under appeal (points 4 to 4.10) - the process of Claim 1 would not be obvious to a person skilled in the art having regard to the prior art documents relied upon by the Appellant, whether considered in isolation or in combination and, therefore, involves an inventive step.

6. Claims 2 to 23, which relate to preferred embodiments of the process according to Claim 1, are supported by the patentability of the main claim and thus also allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

E. Görgmaier C. Gérardin