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D E C I S I O N
of 3 November 1993

Case Number: T 0407/90 - 3.3.3

Application Number: 83301643.9

Publication Number: 0090600

IPC: A61J 3/07

Language of the proceedings: EN

Title of invention:
Method for molding capsules

Applicant:
Warner-Lambert Company

Opponent:
-

Headword:
-

Relevant legal norms:
EPC Art. 54, 56, 123(2)

Keyword:
"Novelty (affirmed) - no anticipation on correct interpretation of prior art"
"Inventive step (affirmed)"
"Original disclosure (affirmed) - objection dropped following amendment and argument"

Decisions cited:
G 0010/91, T 0150/82, T 0248/85

Catchword:
-



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Boards of Appeal

Chambres de recours

Case Number: T 0407/90 - 3.3.3

D E C I S I O N
of the Technical Board of Appeal 3.3.3
of 3 November 1993

Appellant: Warner-Lamber Company
(Proprietor of the patent) 201 Tabor Road
Morris Plains
New Jersey 07950 (US)

Representative: Mercer, Christopher Paul
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)

Respondent: -
(Opponent)

Representative: -

Decision under appeal: Decision of the Opposition Division of the
European Patent Office of 19 February 1990 and
issued in writing on 20 March 1990 revoking
European patent No. 0 090 600 pursuant to
Article 102(1) EPC.

Composition of the Board:

Chairman: F. Antony
Members: R. Young
F. Benussi

Summary of Facts and Submissions

I. The mention of the grant of European patent No. 0 090 600 in respect of European patent application No. 83 301 643.9, filed on 24 March 1983 and claiming a US priority of 26 March 1982 (Application No. 0 362 430) was announced on 22 July 1987 (cf. Bulletin 87/30).

II. Notice of Opposition was filed on 19 April 1988 on the grounds of Article 100(a) and (b) EPC. The Opposition was supported *inter alia* by the documents:

D5: US-A-4 076 846
D6: US-A-3 411 972,

and the later filed, but admitted documents:

D8: JP-B-53-19645, (in the form of a translation of its description into English), and
D9: US-A-4 216 240, which had already been cited in the description of the patent in suit.

III. By the time the case was up for decision by the Opposition Division, Claim 1 according to the then main request read as follows:

"A method for molding pharmaceutical capsule parts using an apparatus fitted with a screw plasticising unit comprising the steps of:

a) maintaining a molding composition comprising gelatin having a controlled water content of from 5 to 25% and which is acceptable as a capsule material by virtue of its properties under controlled conditions of temperature and pressure;

b) melting and dissolving in the water predetermined quantities of said gelatin and plasticizing the composition into a plasticized melt under controlled pressure conditions;

c) injecting a sufficient amount of the plasticized melt into a pharmaceutical capsule part mold; and

d) ejecting the capsule part from the capsule part mold."

There were also independent Claims 13 and 15 relating, respectively, to a moulded capsule and a moulding composition.

Furthermore there were two auxiliary requests containing disclaimers in the respective Claim 1.

IV. By a decision which was given at the end of oral proceedings held on 19 February 1990 and issued in writing on 20 March 1990 the Opposition Division revoked the patent because the subject matter *inter alia* of the independent Claims 1 and 15 did not involve an inventive step.

According to the decision, D5 disclosed a moulding composition of a starch material and a protein material together with water, plasticiser and lubricants, for the production amongst other things of pharmaceutical capsule parts. Since gelatin - and not just a gelatin salt - was disclosed as a protein ingredient, D5 disclosed a "moulding composition comprising gelatin". Predetermined quantities of this "gelatin" having a water content of 17% were dissolved in water (Example 5) and the composition plasticised into a plasticised melt under controlled conditions of temperature and pressure.

The composition could then be moulded into pharmaceutical capsule parts.

Since the means by which plasticisation was achieved in the context of the injection moulding application were not described, the only feature which could not be immediately deduced from the document was the use of a screw plasticiser in combination with an injection moulding machine. It was, however, well known in the field that the more modern type of injection moulding machine having a displaceable screw plasticiser was superseding the older ram operated type. Moreover, the Proprietor had failed to prove by published documents that there existed a general prejudice against using a screw plasticiser when injection moulding water-containing thermoplastic materials. On the contrary, D9 disclosed the use of such a machine when injection moulding water-containing protein materials.

Consequently, the use of the more modern type of machine was evident, and this difference failed to involve an inventive step. Since the process of Claim 1 did not involve an inventive step, the intermediate product of such a process (Claim 15) also failed to involve an inventive step.

V. On 12 May 1990 a Notice of Appeal against the above decision was filed, the appeal fee having been paid separately on 3 May 1990.

In the grounds of appeal filed on 25 July 1990 and in a subsequent submission filed on 14 September 1992, the Appellant (Patentee) argued essentially as follows:

- (i) D5 should not have been interpreted as disclosing a moulding composition comprising "gelatin" in the sense of the patent in suit.

Gelatin was amphoteric, and in its commercially supplied "normal" form (pH 5.2 to 6.0) had very different physical and chemical properties from in its fully neutralised form (pH 11.0); D5 disclosed only the latter form, even in Examples 30 and 33 where "normal" gelatin was completely neutralised *in situ* (see grounds of appeal, paragraphs 6.1.3 to 6.1.23 and Declaration of Cadé filed therewith; Affidavit of Kägi filed on 14 September 1992).

- (ii) D5 did not disclose the injection moulding of gelatin, since the only moulding material was a composition containing the reaction product of a gelatin **salt** with starch; moreover, although it mentioned a screw extruder, it did not refer to a screw injection moulding machine (cf. submission of 14 September 1992, page 13, paragraph 5.7).

- (iii) D6 taught no more than that it might be possible to use gelatin having a water content of 25% to 35% in a **ram** injection moulding process under mild conditions to produce low quality structural bodies such as containers for components and supplies used in space; there was no suggestion of suitability for the precision moulding of capsules, nor of the use of screw injection moulding, which was known to produce high temperature, pressure and shear processing conditions which would have denatured the gelatin; its teaching was therefore not combinable with that of D5, and even if it had been, would not have led to the claimed subject matter (cf. submission of 14 September 1992, paragraphs 2 and 5.13 to 5.15).

- (iv) D9 did not mention gelatin or allude to the production of capsules. Its purpose was to produce fibrous, meat-like materials. The use of a screw plasticiser, although described for injection moulding of protein materials, was for the purpose of conferring fibrous character on them. Its aim was thus incompatible, and its disclosure therefore also not combinable, with that of D5 (grounds of appeal, paragraph 6.2).

- (v) D8 pointed away from the patent in suit because the capsules it produced were made from a material which had to be other than gelatin and was in particular starch. Moreover, it was doubtful whether the process described was injection moulding (grounds of appeal, paragraph 6.3).

- (vi) The existence of a prejudice against the use of an injection moulding technique for making gelatin capsules did not need to be established by reference to published documents. It was the generally held view in the art. The evidence of two Experts had been adduced to show this. The position was not affected by D9 since this document demonstrated an unconventional use of an injection moulding machine (grounds of appeal, paragraph 7.9, 7.10; submission of 14 September 1992, paragraph 5.16). Further evidence was provided in the second Affidavit of Wippenbeck indicating the disadvantageous consequences of even small quantities of water in conventional compositions for injection moulding (cf. submission of 14 September 1992, paragraphs 5.17 to 5.22).

(vii) The Respondent evidently had no confidence in his own arguments that the subject-matter of the patent in suit lacked an inventive step, since he had himself prosecuted and obtained a German Patent, DE-C1-3 843 844 (D20), which effectively asserted, even as late as the end of 1988, that it was novel and inventive to subject a gelatin/water mixture to conditions of temperature, pressure and shear to produce a plastic material (see submission filed on 5 July 1991).

VI. The Respondent (Opponent) on the other hand argued, in a submission filed on 29 March 1991, essentially as follows:

(i) According to the patent in suit, gelatin was always subjected, as part of its preparation, in particular for adjustment of the pH, to a treatment with alkali, normally sodium hydroxide. This caused a proportion of the carboxyl group protons to be replaced by sodium. Thus "normal" or "commercially available" gelatin was always a gelatin salt, the terms being synonymous with one another, and also with "gelatin-sodium" in D5. The neutralisation according to D5 of the gelatin was in any case only a preferable feature (cf. paragraph 3.1 to 3.4; 5.2.4)

(ii) The Appellant's calculations of the degree of neutralisation of "normal" gelatin (cf. Declaration of Cadé) were flawed. In particular the calculation based on Example 30 of D5 neglected both the sparing solubility of calcium hydroxide and the presence of additional neutralisable groups in casein. Moreover, a calculation based on Example 33 of D5, where

gelatin was the only protein present, showed only partial (62.5%) neutralisation had taken place (paragraph 5.2.4).

- (iii) Claim 1 of the patent in suit was in any case not limited to gelatin but referred to a "composition comprising gelatin" and thus covered compositions containing, for instance, up to 95% of modified starch. D5 also concerned a composition containing, in addition to gelatin (or gelatin salt), a modified starch (cf. paragraph 5.1, 5.2).
- (iv) Although D5 did not expressly disclose the special combination of a screw preplasticiser unit with an injection moulding machine, e.g. in Example 1, it was clear that there were only two possibilities as to what sort of plasticising unit was to be used in the production of capsules, namely a ram or a screw plasticising unit, and a choice out of two possibilities could not involve the exercise of inventive ingenuity (cf. paragraph 5.4).
- (v) Even if one assumed that D5 did not teach the use of "normal" or "commercially available" gelatin, this was clearly shown in D6 (column 3, line 6 to column 4, line 10), which, apart from indicating that any conventional method of injection moulding could be applied, also stated that "containers" could be formed; the capsules of D5 were containers, however, and thus the combined features of Claim 1 were derivable from the two documents together (cf. paragraph 5.5).
- (vi) It was not sufficient for the Patentee simply to assert the existence of a prejudice, e.g. by an

expert opinion. No general prejudice in the sense of German jurisprudence (cf. Schulte, "Patentgesetz", 4. Auflage, § 4, page 107) or European jurisprudence (cf. Singer, "Europäisches Patentübereinkommen", pages 161/162) had been shown to exist in the art against use of a screw preplasticiser unit for the injection moulding of gelatin containing compositions. On the contrary, D5 spoke against such a prejudice, since it disclosed the use of a screw plasticiser for a hydrophilic polymer-containing composition, as did D8 and D9 (cf. paragraph 5.6).

- (vii) Formal objections furthermore arose concerning clarity and two part form of claim (paragraph 9).

VII. With the submission of 14 September 1992 the Appellant filed new sets of claims forming a main request and five auxiliary requests.

With a letter filed on 17 September 1992 the Respondent withdrew the Opposition for all designated States.

VIII. A communication was issued on 28 July 1993, informing the Appellant that the examination of the appeal was being continued under Article 114(1) EPC, and expressing certain reservations *inter alia* as to the formal acceptability of the amended claims.

Oral proceedings were held on 3 November 1993. At the oral proceedings the Appellant filed two further sets of claims replacing all previous requests and forming a main and an auxiliary request respectively. The main request consisted of a set of twelve claims, the independent Claims 1 and 10 of which are reproduced

below. The auxiliary request consisted of Claims 1 to 9 only of the main request.

Claim 1

"A method for injection moulding capsule parts using a reciprocating screw injection moulding device comprising the steps of:

- (a) maintaining gelatin, optionally containing up to 40% of pharmacologically acceptable plasticisers, up to 10% of pharmacologically acceptable lubricants and up to 10% of pharmacologically acceptable colouring agents, the gelatin having a water content of 5 to 25% by weight, under controlled conditions of temperature and pressure;
- (b) melting and dissolving the gelatin in the water and plasticising the composition into a plasticised melt under controlled pressure conditions in the screw injection moulding device;
- (c) injecting a sufficient amount of the plasticised melt into a capsule part mould;
- (d) cooling the injected, plasticised melt; and
- (e) ejecting the capsule part from the capsule part mould."

Claim 10

"A plasticised moulding composition characterised in that it is obtainable using a reciprocating screw injection moulding device by:

- (a) maintaining gelatin, optionally containing up to 40% of pharmacologically acceptable plasticisers, up to 10% of pharmacologically acceptable lubricants and up to 10% of pharmacologically acceptable colouring agents, the gelatin having a water content of 5 to 25% by weight, under controlled conditions of temperature and pressure; and
- (b) melting and dissolving the gelatin in the water and plasticising the composition into a plasticised melt under controlled pressure conditions in the screw injection moulding device."

- IX. The Appellant requests that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or the auxiliary request both submitted during the oral proceedings.
- X. On 10 November 1993 the Appellant filed a revised description corresponding to the claims of the main request.

Reasons for the Decision

- 1. The appeal is admissible.

Main Request

- 2. *Formal admissibility of the amendments*

- 2.1 Claim 1 is supported by Claim 17 of the application as originally filed, which set out in general terms steps (a) to (e). Regarding the reciprocating screw injection moulding device, the terminology is to be found in the

description of the application (see page 7, lines 6 and 7; references in this section to "the description" are references to the description as filed).

As regards step (a), the water content is supported by original Claim 20. The optional additives to the gelatin are supported by the description on page 29, line 21 to page 30, line 6.

Step (b) is based on the description on page 8, lines 17 to 20 and 25 to 29.

2.2 Claim 2 is based on original Claim 18 in conjunction with the description on page 10, lines 9 to 13.

2.3 Claim 3 is based on original Claim 25, the units having been amended for conformity with those given in Table 1 on page 12.

2.4 Claims 4 and 5 are based on the last sentence of the description on page 18. Claims 6 and 7 are based on the description at page 29, lines 26 to 33 and lines 34 to 38 respectively, and Claim 8 on the description on page 30, lines 1 to 6. Claim 9 is supported by the description on page 2, lines 8 to 11.

Consequently, and since Claim 1 is also narrower in scope than Claim 1 as granted, no objections to Claims 1 to 9 arise under Article 123(2) or (3) EPC.

2.5 Claim 10 is supported, as regards the feature of the "plasticised moulding material", by original Claim 17, step (b), read in conjunction with the repeated references in the description to "plasticized gelatin", which is disclosed as the material which is produced in the screw injection unit and which is injected into the mould (cf. the description on page 8, line 20, etc.).

As regards features (a) and (b) of Claim 10, these find the same support as do the corresponding features of Claim 1. In a similar manner, the features of Claims 11 and 12 find the same support as do the corresponding features of Claims 2 and 3 respectively (cf. sections 2.1, 2.2 and 2.3 above).

- 2.5.1 The Board had certain reservations as to whether the "plasticised moulding composition", to which Claim 10 was directed *per se*, had been originally disclosed **as part of the invention** and could therefore be allowed under Article 123(2) EPC. These reservations were expressed in the communication dated 28 July 1993 (see paragraph 3.1).
- 2.5.2 At the oral proceedings, the Appellant on the one hand defended the allowability of the amendment on the basis that it would have been clear to the skilled person that the plasticised state through which the gelatin necessarily passed in the screw injection unit was an essential feature of the invention, and on the other referred to the decision of the Enlarged Board of Appeal G 010/91 (OJ EPO 1993, 420). In the latter connection, although the claim in question had itself admittedly been filed during the appeal proceedings, nevertheless the essence of the amendment had already been present in the patent as granted. Furthermore, no objection under the opposition ground of Article 100(c) had been raised by the Respondent. Consequently, it was argued, the Board was not at liberty to raise the matter under Article 114(1) EPC.

In the absence of any refutation of this position, the Board chose not to pursue the matter further.

- 2.5.3 Although the term "obtainable" was used in Claim 10, instead of "obtained" as in the broadly corresponding

Claim 17 of the patent as granted, the interpretation of product-by-process claims according to the jurisprudence of the EPO attaches the same scope to such a claim regardless of whether the product is said to be "obtained" or "obtainable" by the process. Consequently this change cannot result in a difference in scope. Claim 10 is otherwise narrower in scope than Claim 17 of the patent as granted. Claims 11 and 12 are dependent on Claim 10.

Thus, no objection arose under Article 123(3) EPC and none was established under Article 123(2) EPC against Claim 10. The same considerations apply to Claims 11 and 12.

3. *The method of Claims 1 to 9; closest state of the art*

3.1 The patent in suit relates to a method for moulding capsule parts. Such a method is known from the state of the art as represented, for instance, by D5, on which the decision under appeal was essentially based (see Reasons for the Decision, paragraph 10.3). The Board is also of the opinion that this document is the closest state of the art for the method claims. It is in any case a closer state of the art than that presented as a starting point in the patent in suit, which utilised dip-moulding technology (cf. patent in suit, page 2, lines 31 to 40).

3.2 According to D5 there is provided a water-soluble, edible, thermoplastic moulding composition comprising a starch material, an alkali metal or alkaline earth metal salt of a protein material, water, an organic low-molecular-weight plasticizer, and a lubricant, all of these components being edible (column 1, lines 15 to 21). Shaped articles can be formed from the composition, e.g. by extrusion, compression, or injection (column 1,

lines 7 to 15). They can be used as capsule shells for pharmaceutical preparations (column 11, lines 65 to 68; Example 1).

- 3.2.1 The starch contains a high amount of amylose; the weight ratio starch/protein salt is from 30/70 to 70/30; the water content is 10 to 40 wt% based on the composition, and that of the plasticiser and lubricant 20 to 60 pbw and 1 to 11 pbw respectively per 100 pbw, in total, of the starch and protein salt (see Claim 1).
- 3.2.2 The protein salt is the salt of protein material, e.g. casein, albumin, gelatin, glue, gluten, etc., with an alkali metal or alkaline earth metal. It is prepared by neutralising in aqueous medium the protein material with an inorganic alkaline substance such as sodium hydroxide. It may be formed *in situ* by reacting the protein with a sufficient amount of an aqueous dispersion of at least one inorganic alkali substantially to neutralise the protein. In this case, the amount of alkali is preferably equivalent to the amount of free carboxyl groups so that free alkali may not be present in the composition (see column 4, lines 14 to 65).
- 3.2.3 It is not recommended to use a protein material itself in place of its alkali metal salt, because the composition yields a moulded article inferior in flexibility, water retentivity and mechanical strength. Instead of the protein salt, a mixture of protein material and its salt may be used, or the protein materials may be partly replaced by a protein rich grain powder, such as defatted soybean powder or by dried powders of an edible microorganism (column 4, line 66 to column 5, line 11).

- 3.2.4 Some degree of union has apparently been established between the starch and protein salt materials by chemical reaction. Such reaction is said to be desirable for the improvement of the moulded articles in appearance and in mechanical strength (column 6, lines 34 to 59).
- 3.2.5 In Example 5, a mixture of: high-amylose cornstarch (40 pbw); sodium caseinate (40 pbw); glycerol (60 pbw); gelatin-sodium (20 pbw) and lecithin (5 pbw) was adjusted to 20 wt% water content in a Henschel mixer to obtain a water-soluble and edible thermoplastic moulding composition in the form of fine granule. A translucent container, 0.5 mm in wall thickness, could be injection-blow moulded.
- 3.2.6 According to Example 30, a thermoplastic moulding composition (water content 17%) having comparable properties to that of Example 5 was obtained in the same manner, except that 40 parts of casein, 20 parts of gelatin, 10 parts of a 20-% aqueous solution of sodium hydroxide, and 5 parts of a 20-% aqueous dispersion of calcium hydroxide were used in place of 40 parts of casein-sodium and 20 parts of gelatin-sodium.
- 3.2.7 According to Example 33, in a composition containing a potato starch (see Example 24), 80 parts of gelatin and 10 parts of a 20-% aqueous solution of sodium hydroxide were used in place of 80 parts of gelatin-sodium.

3.3 Interpretation of D5

One of the main issues in the appeal was whether D5 disclosed "normal" or "commercially available" gelatin at all.

- 3.3.1 The document has to be interpreted, in the Board's opinion, in the light of the relevant submissions as to what the skilled person would have understood concerning gelatin, in particular the Declaration of Cadé, filed with the grounds of appeal, and the Affidavit of Kägi, filed on 14 September 1992. These both argue that the "gelatin-sodium" referred to in D5 is not gelatin itself, but a fully neutralised salt thereof, which has quite different properties, especially a different viscosity, and a capability, not present in "normal" gelatin, of reacting with starch materials in the manner described.
- 3.3.2 As regards the Declaration of Cadé, although the calculation of the degree of neutralisation of gelatin in Example 30 (paragraph 16) seems to contain an inaccuracy (calcium hydroxide is calculated as 5 parts and not 5 parts of a 20% dispersion), and the situation is complicated by the presence of casein, there nevertheless appears to be a sufficient amount of hydroxide ion present to neutralise all the gelatin to the salt form.
- 3.3.3 The Respondent's arguments that the sparing solubility of calcium hydroxide and additional phosphoric acid groups in the casein had not been taken into account are not convincing (see submission of 29 March 1991, paragraph 6.3). The undissolved calcium hydroxide would obviously pass into solution as this was consumed, and no evidence was submitted showing that the presence of phosphate would have been prejudicial to the complete neutralisation.

On the contrary, Example 30 must be read as it is presented in D5, namely as a re-run of Example 5, in which the gelatin and a neutralising amount of hydroxide

were added *in situ* instead of the ready formed salt as in Example 5.

- 3.3.4 The position of Cadé is supported by the Kāgi Affidavit filed on 14 September 1992. This Affidavit explains the distinction between "internal" and "external" salt formation in gelatin, the term "gelatin salt" referring to the latter kind of neutralisation, and contains a rigorous recalculation of the degree of neutralisation of the gelatin in Example 33, which is more critical than Example 30 since gelatin is the only protein present. This shows that the amount of hydroxide added is precisely enough to ensure that all the gelatin present is fully neutralised to the "external", i.e. sodium salt at pH 11 (cf. paragraph 8 of the Affidavit).
- 3.3.5 The only hint in D5 to the possibility of moulding a composition comprising gelatin would then be the general statement that "a mixture of the protein material and its salt may be used" (column 5, lines 3 to 4). It is not stated, however, that this would apply to the materials finally present in the resulting capsules (see submission of Appellant dated 14 February 1990, page 4, paragraph 16). In any case it does not mention gelatin specifically.

Consequently, D5 is held not to disclose the moulding of any composition comprising gelatin, let alone of gelatin itself.

4. *The technical problem and its solution*

Compared with the state of the art represented by D5 the technical problem could be seen in the desire to provide an alternative process for producing capsules hygienically at high speed and with minimal dimensional deviations.

The solution proposed according to Claim 1 of the patent in suit is to replace the moulding composition by gelatin having a water content of 5 to 25% by weight under controlled conditions of temperature and pressure and optionally containing a proportion of pharmacologically acceptable additives such as plasticisers, lubricants and colouring agents; melting and dissolving the gelatin in the water to form a plasticised melt under controlled pressure conditions using a reciprocating screw injection moulding machine; and then injecting a sufficient amount of the plasticised melt into a capsule part mould.

- 4.1 Although Claim 1 covers the possibility of less than 50% gelatin being present in the material moulded, by virtue of the optional features it specifies, nevertheless the optional additives are not themselves mouldable (see submission of 14 September 1992, paragraph 5.26).

Consequently, the claim is entitled, in the Board's view, to the interpretation that the material moulded must consist essentially of gelatin in the sense of having the moulding properties associated with gelatin itself.

- 4.2 Concerning the objections of the Respondent referred to in the submission filed on 29 March 1991 (see paragraph 9), originally raised before the Opposition Division in the submission dated 6 February 1990, paragraphs 11.1, 11.2 and 11.3, the following may be said:

- (i) the objection to the two part form (cf. paragraph 11.1) does not arise, since the present claims are in the one-part form.

- (ii) The objection concerning the clarity of the feature "under controlled conditions of temperature and pressure" in Claim 1 (cf. paragraph 11.2) is not sustainable, because the critical feature is the water content of the gelatin. The temperature and pressure conditions are those necessary to maintain the required water content in the injection moulding device and would be within the normal competence of the skilled person to determine, more particularly in view of the many examples given in the patent in suit.

- (iii) The statement that dissolution of the gelatin does not take place on plasticisation (cf. paragraph 11.3) is an assertion not supported by any evidence. Moreover, it does not correspond to the normal thermodynamic understanding of plasticisation and in any case appears to have no practical significance for the solution of the technical problem.

The measures claimed in Claim 1 provide a credible solution to the technical problem, as can be seen from the results of the examples in the patent in suit, according to which acceptable capsules were produced, and also from the samples produced in the Comparative Experiments provided during the Opposition Proceedings (cf. submission of the Appellant filed on 11 January 1989, page 6, and "Comparative Test Results" also filed with this submission).

5. *Novelty*

Novelty has not been contested in the present appeal.

5.1 D5 does not disclose the moulding of any composition comprising gelatin, or of gelatin itself (cf. section 3.3.5 above, last sentence). Claim 1 is therefore novel over D5.

5.2 According to D6 on the other hand, solid materials of construction comprising gelatin are obtainable by employing discrete, solid, finely comminuted gelatin containing 12% to 40% by weight of water. This is moulded at a temperature of about 100°C to about 160°C at from 50 to 3000 psi to obtain strong shaped solid objects, those of the products which have been moulded at above 125°C being less susceptible to water than those obtained at below 125°C (see column 1, lines 26 to 28; column 2, lines 18 to 26; column 9, lines 60 to 66).

The maximum content of moisture which may be present in the gelatin is limited only by the fact that the gelatin to be moulded must be in the solid state to permit moulding under heat and pressure (column 2, lines 61 to 62).

As the moisture content of gelatin in solid form is increased, the gelatin has an increasingly greater flow when subjected to heat and pressure. Injection moulding requires higher flow than does compression moulding. A solid gelatin which is most suitable for injection moulding may contain from 25% to 35% by weight of water. For compression moulding 13% to 16% will be more useful (column 3, lines 9 to 22).

The use of substances which are known to plasticise gelatin films or capsules, such as glycerine, may give products which are soft and rubbery rather than hard and tough. Polymeric compounds may be added, but may impair the properties of the gelatin (column 8, lines 28 to 42).

In Example 8, gelatin in the form of flakes was conditioned to a moisture content of 29 wt%. The cylinder of an injection moulding machine was loaded and tamped down with the conditioned gelatin, without further comminuting it, and the gelatin was moulded into test bars. Ram pressure used was 900 psi; the cylinder temperature was 130°C and the time of injection moulding cycle was 1 to 1.5 minutes. Clear, solid, smooth and glossy test bars were obtained.

According to Example 11, when the water content of the gelatin dropped below 12%, there was no gelatin flow and no lamination (cf. column 13, lines 43 to 47).

- 5.3 As with D5, the interpretation of D6 was the subject of controversy, in particular as to whether Example 8 thereof (the only example disclosing injection moulding) used a screw preplasticiser unit.

It is in any case clear that, although there is a disclosure of a "ram" (cf. reference to "Ram pressure", above) in D6, there is no explicit disclosure of a screw preplasticiser unit, nor indeed any reference to the use of shear. Furthermore, the reference to "tamping" the gelatin in the injection moulding machine (cf. Example 8) can in the Board's view only have any meaning in relation to the arrangement shown in Figure 1 on page 16 of the "Gutachten" of Prof. Woebcken, filed by the Respondent on 4 August 1989 - a "ram" type injection unit; the need to tamp the charge down in the cavity in front of the piston is quite clear, but it is not understandable why one should "tamp down" a charge on to a continuous screw. The remark in the same "Gutachten", that the low pressures used point to the use of an injection moulding machine with a screw preplasticiser unit as shown in Figure 2 (see page 6, second paragraph of the "Gutachten") on the other hand is not

convincing on its own, because other causes might equally well affect the moulding pressure.

Thus it cannot be said that there is any direct and unambiguous disclosure in Example 8 of D5, whether explicit or implicit, of the use of a screw preplasticiser.

Consequently Claim 1 has novelty also over the disclosure of D6.

- 5.4 The disclosure of D8 specifically excludes gelatin from its teaching, and that of D9 is neither concerned with gelatin, nor with capsules. Consequently, Claim 1 is novel over these disclosures also.

The remaining documents are more remote still.

Consequently, the subject-matter of Claim 1 is novel.

6. *Inventive step.*

- 6.1 There is no suggestion in D5 that normal gelatin is a suitable, or even possible replacement for the starch containing mixture with which this document is concerned. Even the presence of unneutralised protein material, although not excluded, is clearly not regarded as desirable (cf. section 3.2.3 above).

- 6.2 According to D6 on the other hand, solid materials of construction comprising gelatin are obtainable by moulding gelatin containing a specified content of water, in particular as taught in Example 8 (cf. section 5.2 above). Thus, the question arises as to what extent, if any, the skilled person might have been helped to find the solution to the technical problem arising from D5 by the knowledge that gelatin could be

ram-injection moulded at 29% moisture content to form a test bar.

6.2.1 There are in this connection a number of facts which need to be borne in mind in assessing the relevance of D6. These are as follows:-

- (i) D6 was published nearly nine years before D5, so that the inventors of D5 had presumably already been aware of the teaching of D6.
- (ii) Denaturation of the gelatin is stated to take place at processing temperatures of 125°C or above, leading to a much higher water insolubility in the product; this would be unsuitable for an edible capsule.
- (iii) The disclosure of D6 contains no reference to shear being necessary to achieve full plasticisation.
- (iv) The moisture contents taught as suitable are in essence quite different from those taught in the patent in suit. Not only is gelatin with a moisture content in the range below 12% taught to be unmouldable, but the range taught to be suitable for injection moulding (25% to 35%) overlaps the range claimed in the patent in suit at only one point (25%).
- (v) The use of plasticisers is taught to be disadvantageous (cf. column 8, lines 23 to 37).

In view of (i) and (ii) above, it is, therefore, not likely that the skilled person would have regarded the disclosure of D6 as being of value in his search for an alternative to D5.

Furthermore, in view of (iii), (iv) and (v) above, it is hardly credible that the phenomenon of "flowability" of gelatin, with which D6 is concerned, should correspond to the degree or type of plasticisation required for precision moulding of capsules in the sense of the patent in suit.

6.2.2 Crucial to the assessment of the relevance of D6, however, are the results of the "Comparative Tests", filed by the Appellant with the submission of 11 January 1989 (see page 6, and "Comparative Test Results" annexed to the Affidavit of Wippenbeck), according to which a re-working of Example 8 of D6 was completely unsuccessful when the shaped object was a capsule, even though a good test bar could be obtained. This was confirmed by inspection of the sample provided by the Appellant from Example 1 of "Comparative Tests" at the end of the "Wippenbeck" Affidavit, as well as the submission of Appellant filed on 15 January 1990, page 8, third paragraph, and Annex II of the same submission, page 7, first paragraph.

6.2.3 These results have not been convincingly refuted by the Respondent. In this connection, the suggestion of the Respondent that it could even be possible - accepting a certain loss of quality - to optimise the conditions of Examples 1 to 3 of the Appellant even using only a "torpedo" (as opposed to a reciprocal screw) for plasticising, to avoid the unusable capsules obtained by Wippenbeck (cf. "Gutachten" of Woebcken, filed on 4 August 1989, page 13, last paragraph) is a mere assertion unsupported by any concrete evidence. Furthermore, the criticism that the Appellant had omitted to carry out an experiment similar to Example 8 of D6, i.e. with the gelatin at 29% moisture, but using a screw preplasticiser unit (cf. same "Gutachten", page 11 penultimate paragraph) is irrelevant, since such

an experiment would have represented neither the subject-matter claimed nor the state of the art.

Thus any attempt to check the effectiveness, for preparing capsules, of the mouldability admittedly taught by D6, for instance by repeating the only relevant Example 8, would lead to failure.

- 6.2.4 Even if the matter were pursued beyond this failure, however, it is by no means clear how the disclosure of D6 could be combined with that of D5. The latter requires the presence of starch and that the gelatin be in salt form. Neither document discloses the use of a screw preplasticiser unit.

Therefore, not only is D6 on closer examination of doubtful relevance to the technical problem, but it evidently does not contain the elements necessary for a solution thereof.

Consequently, a combination of its disclosure with that of D5, if at all possible, would in any case not lead to the subject-matter of the patent in suit.

- 6.3 The disclosures of D8 and D9 are more remote, for the reasons given in section 5.4 above. The skilled person would thus be led away from the solution of the technical problem.

Thus the subject-matter claimed in the Claim 1 does not arise in an obvious way from the closest state of the art taken alone or in combination with the other documents in the proceedings.

- 6.4 It is consequently not necessary to decide whether there was a general prejudice in the art against injection moulding gelatin with a screw preplasticiser unit, nor

to consider the contents of the documents cited to this end in the Affidavit filed on 14 September 1992 (Wippenbeck II).

Thus the subject-matter of Claim 1 involves an inventive step. The subject-matter of Claims 2 to 9, which are directly or indirectly dependent on Claim 1, is by the same token also novel and involves an inventive step.

7. *The moulding composition of Claims 10 to 12*

Claim 10 is broader than the corresponding Claim 1 since it is directed to a plasticised moulding composition obtainable by a process involving steps (a) and (b) only of Claim 1. It is thus, according to the jurisprudence of the Boards of Appeal, to be interpreted as a claim to a moulding composition *per se*, characterised only by the features conferred upon it by the process (cf. the decisions T 0150/82, OJ EPO 1984, 309; T 0248/85, OJ EPO 1986, 261).

Crucial among these features is that the gelatin is "plasticised" through having been subjected to steps (a) and (b) of the process. According to the submission of the Appellant at the oral proceedings before the Board, the term "plasticised" referred to the quality of the gelatin of being injection mouldable to form thin-walled precision objects, such as pharmaceutical capsules. These require a high level of plasticity in the material being moulded.

8. *The closest state of the art*

To the extent that Claim 10 is directed to a plasticised composition *per se*, rather than to a capsule or a method of making a capsule, the closest state of

the art in respect of this subject-matter is considered on balance to be D6, rather than D5.

9. *The technical problem and its solution*

Compared with this state of the art, the technical problem could be seen as the search for a material of improved mouldability characteristics, to enable direct injection moulding of thin-walled precision objects, such as pharmaceutical capsules.

The solution was a gelatin corresponding to one which had been subjected, at a moisture content between 5% and 25% by weight, to high shear under controlled pressure conditions in a reciprocating screw injection moulding device, as defined in steps (a) and (b) above.

That the claimed features provide a credible solution to the technical problem is evidenced by the capability of the claimed process of producing acceptable capsules (cf. section 4.2 above, last sentence).

10. *Novelty*

It follows from the analysis of D6 given in sections 5 and 6 above, that this document not only fails to disclose the means for carrying out the step (b) above, but also that the gelatin material it exemplifies does not have moulding characteristics enabling it to be moulded to a thin-walled precision object (see especially sections 5.3.1; 6.2.2; 6.2.3).

Consequently, there is no ground for concluding that the gelatin material is inevitably "plasticised" in the sense of the patent in suit. Novelty is therefore given over the disclosure of D6.

The remaining documents being more remote (cf. section 5.4 above), hence the subject-matter of Claim 10 is novel.

11. *Inventive step*

The question to be addressed is whether the skilled person starting from Example 8 of D6 and wishing to improve the mouldability of the gelatin for obtaining precision moulded, thin-walled products such as capsule parts would, after the initial lack of success (cf. comparative experiments) realise that the difficulties could be overcome if he were (i) to adjust the moisture content to the bottom end of the range taught (25%), or below it, and (ii) substitute for the disclosed ram injection moulding machine a machine with a screw plasticising unit.

11.1 There is no hint in D6 itself, which would have caused the skilled person to modify the procedure described therein so as to make steps (a) and (b) of the solution to the technical problem and thus arrive at the claimed plasticised composition (cf. points (iii), (iv) and (v) in section 6.2.1 above).

11.2 Similar considerations apply to the other cited documents D5, D8 and D9 since these are not concerned with moulding gelatin at all (cf. sections 6.1 and 6.3 above). In particular the teaching of D5 is not combinable with that of D6 for the reasons given in section 6.2.4 above.

Consequently, the subject-matter of Claim 10 does not arise in an obvious way from the state of the art. It therefore involves an inventive step. Claims 11 and 12, being dependent on Claim 10, are also novel and inventive.

Claims 1 to 12 of the main request can therefore be maintained.

12. To the extent that the Appeal has been examined under Article 114(1) EPC, it is not considered necessary to enquire into any question arising from the Respondent's own patent (D20) (see section V(vii), above).

13. *Auxiliary Request*

In view of the conclusions reached in relation to the main request, it is not necessary to consider the auxiliary request further.

14. *Revised description*

Since the revised description was only filed on 10 November 1993, i.e. after the date of the decision of the Board, it cannot be taken into consideration in this appeal.

Order

For these reasons, it is decided that:

1. The decision of the Opposition Division is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of the main request as presented during the oral proceedings and a description yet to be adapted.

The Registrar:

The Chairman:

E. Görgmaier

F. Antony