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D E C I S I O N
of 11 June 2003

Case Number: T 1138/00 - 3.2.2

Application Number: 94902877.3

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IPC: A61J 3/07

Language of the proceedings: EN

Title of invention:
Encapsulation apparatus and process

Patentee:
R.P. SCHERER CORPORATION

Opponent:
Swiss Caps AG

Headword:
-

Relevant legal provisions:
EPC Art. 56, 83, 84, 123(2)

Keyword:
"Disclosure sufficiency (yes)"
"Amendments (supported)"
"Inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-



Case Number: T 1138/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 11 June 2003

Appellant 1: Swiss Caps AG
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Appellant 2: R.P. SCHERER CORPORATION
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Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 3 November
2000 concerning maintenance of European patent
No. 0 676 945 in amended form.

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
U. J. Tronser

Summary of Facts and Submissions

I. By interlocutory decision dated 3 November 2000 the Opposition Division decided to maintain the patent in a form amended during oral proceedings on the grounds that the skilled person would not be able to deduce from the prior art that an amount of lubricant on fresh capsules of less than 600 micrograms/gram would result in finished capsules which did not require a solvent wash step.

II. Both parties lodged an appeal against this decision.

Appellant 1 (opponent) filed a statement of grounds on 1 March 2001 along with a new document (D5b) for supplementing documents D5 to D9 already on file and cited in support of an alleged prior use. It contested the disclosure of the invention (Articles 83 EPC), the support for the amendments (Article 123(2) EPC) and the patentability of the invention (Articles 54 and 56 EPC) vis-à-vis the state of the art represented, in particular, by documents D4, D3 and the prior use. Further, objection arose against the decision of the Opposition Division refusing to hear witnesses offered for supporting the prior use.

Appellant 2 (patentee) filed a statement of grounds on 12 March 2001 along with new requests, of which re-establishment of the patent as granted (main request). New documents D9a, D9b were also filed in response to the opponent's arguments, in connection with the alleged prior use.

III. In a communication dated 24 January 2003 sent following a summons to attend oral proceedings, the Board objected against the various versions of the claims according to the different requests both on formal and substantive aspects and gave its provisional view as to an essential feature of the invention which was not represented in the main claims.

IV. Oral proceedings were held on 11 June 2003, at the end of which the requests of the parties were as follows:

Appellant 1 (opponent) requested that the decision under appeal be set aside and that the European patent be revoked or, as an auxiliary request that the case be remitted to the first instance to investigate the alleged prior use and to hear the witnesses offered.

Withdrawing all former requests, appellant 2 (patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form with claims 1 to 23 and description pages 1 to 7 as submitted at the oral proceedings, figures as granted.

V. The independent claims 1, 9 and 23 read as follows:

1. A gelatin encapsulation process comprising the steps of:

a. casting a continuous first gelatin ribbon (15) and a continuous second gelatin ribbon (15);

b. applying food-approved lubricant to a first side (11) of the first gelatin ribbon and to a first side (11) of the second gelatin ribbon;

c. applying food-approved lubricant to a second side (12) of the first gelatin ribbon and to a second side (12) of the second gelatin ribbon to give a lubricated first gelatin ribbon and a lubricated second gelatin ribbon;

d. uniting the lubricated first gelatin ribbon and the lubricated second gelatin ribbon to form gel pockets and injecting fill material into the gel pockets to give freshly formed gelatin capsules, the outsides of the capsules being formed by the second sides of the first and second gelatin ribbons;

e. finishing the freshly formed gelatin capsules to give finished gelatin capsules; and

f. recovering the finished gelatin capsules; characterised in that the amount of food-approved lubricant applied to the second sides of the first and second gelatin ribbons is controlled to give freshly formed gelatin capsules coated with less than 600 micrograms/gram of said food-approved lubricant, so that the freshly formed gelatin capsules and the finished gelatin capsules do not require a solvent wash step to remove lubricant, whereby the gelatin encapsulation process is a solvent-free process."

"9. A soft gelatin encapsulation apparatus comprising:

two opposing gelatin ribbon casting apparatuses for casting a first and second continuous ribbon (15) of gelatin;

a first pair of applicator means (20) respectively for applying a food-approved lubricant to a first side (11) of the first gelatin ribbon and a first side (11) of the second gelatin ribbon;

a second pair of applicator means (40) respectively for applying a food-approved lubricant to

a second side (12) of the first gelatin ribbon and a second side (12) of the second gelatin ribbon, the second sides of the first and second gelatin ribbons forming the outsides of the capsules; and

a die assembly (50);

characterised by means for controlling the amount of food-approved lubricant applied to the first and second gelatin ribbons so that freshly formed gelatin capsules and finished gelatin capsules do not require a solvent wash step to remove lubricant, and wherein the amount of food-approved lubricant applied to the second sides of the first and second gelatin ribbons (15) is controlled to give freshly formed gelatin capsules coated with less than 600 micrograms/gram of said food-approved lubricant."

"23. Lubricant applying apparatus for use with soft gelatin encapsulation apparatus, comprising first applicator means (20) for applying a food-approved lubricant to a first side (11) of a gelatin ribbon, and second applicator means (40) for applying a food-approved lubricant to a second side (12) of the gelatin ribbon, characterised by means for controlling the amount of food-approved lubricant applied to the first and second sides of the gelatin ribbon so that freshly formed gelatin capsules and finished gelatin capsules do not require a solvent wash step to remove lubricant, the outsides of the capsules being formed by the second side of the gelatin ribbon, and wherein the amount of food-approved lubricant applied to the second side of the gelatin ribbon is controlled to give freshly formed gelatin capsules coated with less than 600 micrograms/gram of said food-approved lubricant."

VI. Documents discussed during appeal proceedings and considered for the present decision:

D3: WO-A-92/15828

D4: US-A-2 663 129

D5: Company publication KAMATA Co, Ltd., Tokyo (JP)
"Machinery for soft capsule making"

D5a: 7 photographs of the lubrication device mounted on
KAMATA encapsulation machines

D5b: 2 photographs of the diaphragm pump type M-15 PRO-
PON used in the KAMATA machines according to D5a

D6: Letter dated 29 November 1989 from SWISS CAPS to
Eupharma GmbH

D7: Letter dated 25 October 1989 from SWISS CAPS to
FIS (Food Ingredients Spec. SA)

D8: Affidavit by Dieter W. Engle, 15 July 1998

D9a: Extracts (English translation) of a brochure about
the characteristics of PRO-PON diaphragm pumps

D9b: Inquiry from RP Scherer Corporation to Kyoritsu
Kiko Co. Ltd. and response, both dated 11 June
2001, concerning PRO-PON M-15 performance and
specification data sheet for the same (English
translation).

VII. Arguments presented by the parties.

(i) Appellant 1 (opponent)

- The size of the capsule and hence its outer surface may change substantially according to the medicament it is intended to contain. Consequently, the sole specification of a coating in micrograms of lubricant per gram of capsule is indefinite and not representative for the amount of lubricant to be applied and for thereby defining the level for eliminating a solvent wash step. Therefore, the invention as disclosed cannot be carried out by a person skilled in the art (Article 83 - 100(b) EPC).

- The amendments applied to the claims are not supported by the application as filed and lead to extension of its subject-matter (Article 123(2) - 100(a) EPC). In particular the original disclosure does not specify, contrary to what is now claimed, to exclusively control the amount of lubricant applied to the outer surface of the capsule (second side of the ribbons) but to both the internal and external sides of the ribbons.

- The subject-matter of claim 1 is obvious with respect to the combination of documents D4 and D3. D4 discloses control valves to control the amount of lubricant applied, separately, on each side of the ribbons. The skilled person is thus incited to adjust the flow rate of lubricant to a minimum value on the outside of the capsule to meet the

legal requirements of avoiding the use of toxic solvents and the performance of a subsequent washing step, as suggested by D3.

- The subject-matter of claim 1 is also disclosed by the public prior use of a Kamata encapsulation machine (evidence D5) equipped with a lubrication system using proportioning pumps PRO-PON M-15 (evidence D5a, D5b), the flow characteristics of which are well within the coating range as claimed. This relevant prior use should have been considered more thoroughly by the first instance, so that remittal of the case would be justified.

(ii) Appellant 2 (patentee)

- The encapsulation apparatus specified in Example 1 of the contested patent including indications of the machine type and of the lubricant flow rate expressed in micrograms/minute is suitable for producing capsules coated with amounts of lubricant in the range as claimed. For a given medicament of known density, the invention is, therefore, sufficiently disclosed to be carried out without undue burden by a person skilled in the art.
- The amendments made to the independent claims are fairly supported by both the patent specification and the application as filed, in particular the controlled amount of lubricant in the range as claimed and applied to the second sides of the ribbons (outside of the capsules) by the second pair of applicator means. The specification in the

characterising features of the second sides of the ribbons, therefore, does not lead to extension of the subject-matter of the application.

- Document D4 is silent about the amount of lubricant. Moreover, the control valves placed in the lubricant supplying lines would not be suitable to precisely control the delivery of lubricant at low flow rates. According to document D3, the capsules are coated with large amounts of lubricant, because the processing oil has to be removed by mechanical means after the encapsulation operation. Therefore the subject-matter of the main claims is not suggested by those documents, even when considered in combination.

- The alleged prior use of the Kamata encapsulation machine is technically irrelevant since the characteristics of the proportioning pumps (PRO-PON M-15) used for controlling the flow rate of lubricant would not allow for accurate control of lubricant in the low flow rates required by the patent.

Reasons for the Decision

1. The appeal is admissible.

2. *Disclosure of the invention (Article 100(b) EPC)*

It appears clearly from the description in connection with the figures that the lubricant is applied at a controlled low rate successively on both sides of the

ribbons by means of applicators 20 and 40 and that the amount of coating to be applied to the outer surface of the future capsule (the second sides of the ribbon) must be lower than the respective amount applied to the inner surface (cf. patent, page 3, lines 6 to 10). The application of a controlled minimum amount of lubricant to the second sides of the ribbons is performed by the applicator guide bar assemblies 40 just prior to capsule formation (cf. Figures 7 and 9; page 3, lines 15 to 18 and lines 29 to 31; page 5, lines 46 to 47). The amount of lubricant applied to the second sides of the ribbons is controlled by pump 21A, the output of which is connected to the applicator guide bar 40 (Figure 4; page 4, lines 54 to 57 and sentence bridging pages 4 and 5). Further, the flow rate of lubricant supplied by pump 21A is controlled by the speed of rotation of the drive shaft or by adjusting the pump stroke (page 5, lines 22 to 24). Since the pump is driven by a roller 22 associated with lubricant pump assembly 24, the flow rate of lubricant changes automatically as a result of the variation of the ribbon speed (page 4, lines 57 to 58 and page 5, lines 3 to 5). With this arrangement, a coating on the outer capsule surface of less than about 600 micrograms of lubricant per gram of freshly formed or green capsule, i.e. a capsule obtained before cooling and drying (page 3, lines 42 to 44 and page 6, lines 4 to 7), corresponds to a coating of less than about 400 micrograms/gram on the finished capsule (page 6, lines 24 to 27). These results are obtained (Example 1 and Table I, pages 6 to 7) using a R. P. Scherer Model 14 machine equipped with the above-mentioned applicators for applying the lubricant at a speed of 100 to 150 mg/min to the underside of the ribbons.

Since the Board has no reason to challenge these data, the invention as shown and reported in details can be carried out following the description. The Board does not share the opponent's view (see above point IX(i)) because a coating expressed in terms of micrograms of lubricant by gram of capsule is totally independent of the size or of the volume of the capsule as long as the medicament inside the capsule, i.e. its density, is not changed. The range as claimed does already account for minor variations of density. In addition, it must be observed that Rule 27(1)(e) EPC only requires disclosing one way of carrying out the invention, which is not necessarily the best mode. For all these reasons, the invention is sufficiently disclosed to be carried out by a person skilled in the art within the provisions of Article 100(b) EPC.

3. *Amendments (Articles 123(2) and 100(c) EPC)*

The precharacterising portion of claim 1 was amended by introducing in feature (d) the expression "the outsides of the capsules being formed by the second sides of the first and second gelatin ribbons". The application as filed specifies (page 3, line 36 to page 4, line 1) that less lubricant is applied to the sides of the ribbons which are to form the outer capsule surfaces, i.e. the outsides of the capsule. Knowing further (cf. page 4, lines 11 to 18; page 12, lines 25 to 28 and page 16, lines 17 to 19) that only a controlled minimum amount of lubricant is applied by the applicator guide bar on the second sides of the ribbons, there cannot be any doubt that said second sides of the ribbons are actually the outsides of the capsules, which is also confirmed by a detailed examination of Figures 3, 7 and 9. The added feature, therefore, is supported by the

original application.

The characterising portion of claim 1 was amended by some additional features such that the lubricant being applied to the "second sides" of the ribbons, by the amount of lubricant being controlled "to give freshly formed gelatin capsules coated with less than 600 micrograms/gram of said food-approved lubricant" and by the feature according to which as well the "freshly formed gelatine capsules" as the finished capsules do not require a solvent wash step to remove lubricant. All these amendments are fairly supported as set out in point 2 above with respect to the patent specification and also in particular by the following passages of the application as filed: page 5, line 34 to page 6, line 1; page 7, lines 11 to 17; page 8, lines 6 to 10 and page 14, line 28 to page 15, line 3.

Contrary to the opponent's assertion, the wording of claim 1 does not exclude that the first sides of the ribbons are also coated with lubricant, as recited in feature (b) of the precharacterising portion. The essential feature of the invention resides in controlling the amount of lubricant on the sides of the ribbon which are to form the outer surfaces of the capsules in order to avoid a subsequent solvent wash step (page 3, line 34 to page 4, line 1). This result applies in the same way to both the "freshly formed" and the "finished" capsules since it refers to capsules already formed and filled with medicament, i.e. after encapsulation. The subject-matter of claim 1, therefore, has not been extended beyond the original disclosure. The same conclusion applies to independent apparatus claims 9 and 23 which are concerned with identical or similar amendments made to provide

consistency with the process claim 1.

The introductory part of the description was adapted to the amended claims and document D4 was cited as additional relevant prior art, from which the present invention starts.

It results therefrom that the amendments made are not such as to extend the subject-matter of the application as filed, in accordance with the requirements of Articles 123(2) and 100(c) EPC.

4. *Inventive step*

- 4.1 The closest prior art is represented by document D4. This document discloses (Figures 1 and 11) a gelatin encapsulation process and apparatus comprising gelatin films or ribbons 302, 303 formed about casting drums and treating units 400, 401 consisting of a plurality of lubricating rolls 402, 403 supplied with mineral or vegetable oil from a reservoir 421. The lubricant is transmitted from the inner of the rolls to outer cylindrical felt surfaces 405, 433 surrounding the rolls (Figure 12). The ribbons are successively coated with oil on both sides when they pass between the lubricating rolls as shown on Figure 11. In contrast to the invention, the side of the ribbon which is to form the outer surface of the capsule is lubricated first, by roller 402 (cf. column 13, lines 19 to 23 and 33 to 44). The flow rate of lubricant applied to either side of each ribbon can be separately adjusted by means of valves 422, 432 placed in the supply lines (column 12, lines 54 to 62 and column 13, lines 11 to 18). Therefore according to document D4, the amount of lubricant applied to the outsides of the gelatin

ribbons is controlled, in conformity with the claimed invention.

Although in most of the known processes a solvent washing step is deemed to be necessary to remove the lubricant in excess, document D4 is silent about any subsequent lubricant removal operation with either chemical or mechanical means. The technical problem underlying the present invention of avoiding a solvent wash step, which necessarily follows a lubricating step provided to facilitate the fabrication process of the capsules, is neglected in document D4.

The invention solves this problem by precisely controlling the amount of lubricant applied to the sides of the ribbons which are to form the outer surface of the capsules at such low levels that a subsequent solvent washing usually performed for removing lubricant residues, is no more needed (cf. patent, page 4, lines 14 to 18 and 25 to 27). This result is attained when the freshly formed gelatine capsules, i.e. produced just after medicament filing, are coated with less than 600 micrograms/gram.

In document D4 there is no mention of any amount of lubricant applied to the ribbons prior to capsule formation. Minimizing the coating of lubricant on the outsides of the capsules is neither sought nor contemplated. The lubricating step there serves the purpose of rendering the surface of the ribbon less tacky as it is guided over the following rolls towards the capsule forming mechanism (column 13, lines 37 to 44). This does not imply any specific requirement as to the amount of lubricant applied to it. D4, therefore, does not suggest to reduce the amount of lubricant and

even less in the range as claimed. Moreover, it is unlikely that accurate control of very low amounts of lubricant could be achieved by simply manually adjusting values in the supplying lines.

- 4.2 Document D3, like the patent in suit, addresses the problem of eliminating the use of toxic solvents and chemicals for the removal of oils from the surface of the capsules (cf. page 6, lines 3 to 7). Although some oil may remain on the finished capsules, such low amounts would not be regarded as detrimental, at least for certain types of capsules, so that the use of solvents would still be eliminated (page 23, lines 20 to 23). According to D3 the lubricant is removed by mechanical means, preferably by placing the capsules within rotating baskets (cf. Figures 2 and 5) and contacting them with an absorbent material such as cloth materials, loose fibers, absorbent cellulose or synthetic materials, etc... .

However, even if the result is generally comparable with the one of the present invention, in that a thin but acceptable coating of lubricant may still remain on the surface of the capsules, this result is achieved in a completely different manner. While according to D3 the lubricant in excess is partially or totally removed by mechanical means **after** the encapsulation operation, the solution according to the invention controls the application of the lubricant such that only a small amount of it is applied **before** the capsule formation and filling. Document D3, therefore, could not suggest the basic idea of reducing the amount of lubricant applied to the appropriate sides of the ribbons before encapsulation since all the previous steps up to and including the formation of the capsules are not even

disclosed in this document.

It results therefrom that also by combining the teachings of documents D4 and D3 the skilled person would not have arrived at the subject-matter of claim 1. Neither document suggests to reduce the amount of lubricant down to a very low but still acceptable level, thereby avoiding the need of subsequent removal of lubricant by any means, either chemical or mechanical.

- 4.3 Appellant 1 (opponent) submitted that the invention was also suggested by the prior use of a plurality of encapsulation machines manufactured by the Japanese Company Kamata and sold to the firm Swiss Caps (the opponent) before 1985. The brochure Kamata (D5) does not refer to any lubricating system but the photographs (D5a, D5b) show a lubricant dosing system using proportioning pumps of the type PRO-PON M-15 and said to be fitting the Kamata machines. In addition, two letters from Swiss Caps (D6, D7) mention that the washing of the capsules is completely omitted since 1984.

Irrespective of the answer to the question, whether or not the alleged use had been available to the public, the first matter at issue was to examine whether the technical content of said alleged prior use was such as to change the above conclusion the Board arrived at on the basis of the published prior art documents.

Documents D9a, D9b provided by appellant 2 (patentee) in reply to the photographs D5a, D5b filed by appellant 1, give some information on the operating conditions and characteristics of the pumps PRO-PON

M-15. This piece of information originates from the Japanese manufacturer of the pumps, the translation of which into English was not contested by the parties. Examination of these documents reveals that pump PRO-PON M-15 is a diaphragm pump which lacks accuracy and reproductibility at low dial values. More specifically, the pump's range of use is 5-15 ml/min, i.e. about 500 to 1500 microgram/min (considering a density of 1 for the sake of simplification) to be compared with the far lower range of 100 to 150 mg/min given in Example 1 of the patent.

Moreover, the PRO-PON M-15 pump is said to have a stable operating range of about 30% to 100%, which contributes to further reducing the imparted operating performance. A dial setting of 1% corresponds to 0,15 ml/min, i.e. about 150 mg/min. It is, therefore, far from reality to accurately control flow rates having the same order of magnitude as the dial setting of the control pump. As a result the type of pump used in the machines according to the alleged prior use is not suitable and would not allow adjusting low amounts of lubricant in the range as claimed.

Furthermore, the above evidence is silent as to whether attempts had been made to reduce the amounts of lubricant on the outsides of the ribbons. Document D7 seems to prove even the contrary since, though a washing procedure was omitted, degreasing of the capsule surface using a mechanical process was considered to be necessary.

It results therefrom that on a mere technical aspect the alleged prior use is not more relevant than the published prior art documents previously considered. It

is, therefore, not suitable to challenge the allowability of the claimed invention. As a consequence, the Board deems it inappropriate to remit the case back for further investigations on this item and finds that the first instance's decision of refusing to hear the witnesses was justified and supported by the file as it stood.

- 4.4 For all these reasons the subject-matter of claim 1 as amended involves an inventive step with respect to the state of the art within the meaning of Article 56 EPC.

The same conclusion applies to other independent claims 9 and 23 which incorporate the same essential features as in claim 1. They are, therefore, also acceptable as well as the remaining claims appended thereto.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent in amended form with claims 1 to 23 and description pages 1 to 7 as filed at the oral proceedings, figures as granted.

The Registrar:

The Chairman:

A. Counillon

W. D. Weiâ