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Datasheet for the decision of 11 February 2021

Case Number: T 1510/18 - 3.3.07

Application Number: 06738862.9

Publication Number: 1885342

IPC: A61K9/48

Language of the proceedings: EN

Title of invention:
CRYSTALLIZATION INHIBITOR AND ITS USE IN GELATIN CAPSULES

Patent Proprietor:
Teva Czech Industries s.r.o.

Opponent:
Capsugel Belgium N.V.

Headword:
Crystallization inhibitor and its use in gelatin capsules / TEVA

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 100(a), 100(b), 100(c), 54, 56

Keyword:

Late-filed objection - admitted (no)
Amendments - added subject-matter (no)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)

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Case Number: T 1510/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 11 February 2021

Appellant: (Opponent)	Capsugel Belgium N.V. Rijksweg 11 2880 Bornem (BE)
Representative:	De Clercq & Partners Edgard Gevaertdreef 10a 9830 Sint-Martens-Latem (BE)
Respondent: (Patent Proprietor)	Teva Czech Industries s.r.o. Ostravska 29/305 747 70 Opava (CZ)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 April 2018 rejecting the opposition filed against European patent No. 1885342 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	E. Duval
	Y. Podbielski

Summary of Facts and Submissions

I. European Patent 1 885 342 (the patent) was granted on the basis of 16 claims. Claim 1 of the patent read as follows:

"A soft gelatin capsule, comprising:
a. a gelatin shell; and,
b. a capsule content, comprising: a water-insoluble active ingredient dissolved in an excipient, wherein the excipient, comprises: a crystallization inhibitor present in an amount of 2-10% w/w, with respect to the weight of the capsule content, wherein the crystallization inhibitor is selected from: a monoacylglycerol compound selected from the group consisting of glyceryl monooleate, glyceryl monolinoleate, glyceryl monopalmitate, glyceryl monostearate, glyceryl monolaurate, glyceryl monocaprylate, glyceryl monocaprate, and combinations thereof, and a hydrophilic solvent comprising ethanol."

II. In the present decision, reference is made to the following documents:

D1: US 5645856
D3: US 4388307
D9: Expert declaration of Dr. Caroline Bauer (Lonza), including references cited therein
D14: Data sheet of Maisine® 35-1, 1991, Gattefosse
D15: Data sheet of Maisine, 1990, Gattefosse
D16: EP 0539319 A2
D17: Experimental evidence filed with the appellant's statement of grounds of appeal
D18: Extract of US Pharmacopoeia (pages 1814-1815)

III. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed.

IV. The opposition division took the decision to reject the opposition.

V. In particular, the opposition division decided that:

(a) the claims as granted were based on a combination of claims 1-3 and 5, and paragraph [0018] of the original application, and therefore complied with the requirements of Article 123(2) EPC.

(b) The claimed subject-matter was sufficiently disclosed. In particular, the alleged non-achievement of the effect of stability of the compositions was not relevant to the issue of sufficiency of disclosure as this effect was not defined in the claims.

(c) The claimed subject-matter was novel over D1.

(d) The closest prior art was D3 rather than D1, since D3 was the only document on file dealing with the stabilisation of the composition by inhibiting phase separation. The distinguishing feature of the granted claims was the lower amount of monoacylglycerol. The technical problem was to provide a composition with increased stability against phase separation in gelatin capsules. In the absence of substantiated doubts, it was considered that the problem had been solved. The

claimed solution was not rendered obvious by the prior art.

VI. The opponent (appellant) lodged an appeal against the decision of the opposition division. With its statement setting out the grounds of appeal, the appellant filed D14-D18.

VII. With its reply to the appeal filed on 7 January 2019, the patent proprietor (respondent) defended its case on the basis of the patent as granted as the main request, and filed auxiliary request 1.

VIII. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA.

IX. On 5 February 2021, the respondent filed auxiliary requests 2-4.

X. Oral proceedings were held before the Board on 11 February 2021.

XI. The appellant's arguments can be summarised as follows:

(a) Admittance of the documents filed with the grounds of appeal (i.e. D14-D18) and of the objections based on example 6B of D1 and on D16

D14-D18 were submitted in response to new arguments and evidence presented during the oral proceedings before the opposition division, and supported the evidence already on file during the first-instance proceedings. Additionally, D16 was *prima facie* relevant for the aspect of novelty. Accordingly, the evidence and objections should be admitted under Article 12 RPBA.

(b) Article 100(c) EPC

Firstly, the feature regarding the presence of "a hydrophilic solvent comprising ethanol" resulted from an unallowable intermediate generalization from paragraph [0018] of the application as filed, where hydrophilic solvents were only disclosed in combination with further components.

Secondly, paragraph [0018] did not directly and unambiguously disclose the specific ethanol selection in combination with a crystallization inhibitor in an amount of from 2-10% w/w.

Accordingly, the main request contained added subject-matter.

(c) Article 100(b) EPC

Claim 1 was concerned with a soft gelatin capsule filled with a very broadly defined composition. As a result, the person skilled in the art could not, without undue burden, identify those compositions that could fulfill the goals of the opposed patent, i.e. to provide a soft gelatin capsule that could properly deliver the water-insoluble active ingredient while preventing phase separation or precipitation of the active ingredient in said capsule. The patent also gave no guidance as to what excipients were to be used and in what amount in order to dissolve the active ingredient. D17 (see formulations 180101 and 180098) illustrated the importance of the choice of the excipients for solubilising the active ingredient. Hence, the

subject-matter of claims 1 and 8 did not meet the requirements of sufficiency of disclosure.

(d) Article 100(a) EPC, novelty

Example 5 of D1 disclosed a soft gelatin capsule comprising a water-insoluble active ingredient, ethanol and 8.60 % w/w Maisine 35-1. D14 showed that Maisine 35-1 contained 33.3% glyceryl monolinoleate. This resulted in a content in pure glyceryl monolinoleate in example 5 falling within the claimed range of 2-10%.

Likewise, example 6 (formulation B) of D1 disclosed a formulation comprising a water-insoluble active ingredient, ethanol and 20% Maisine. As shown in D15 and D16, Maisine contained 30-40% glycerol mono-linoleate. Thus, formulation B of example 6 of D1 contained 6-8% monoacylglcerol, thereby also anticipating the subject-matter of claim 1 of the main request.

The additional presence of the component Inwitor 988 in both examples of D1 was allowed by the open expression "comprising" of claim 1. Additionally, the term "monoacylglycerol compound" was not defined in the patent and thus had to be interpreted broadly as covering not only pure monoglycerides but also mixtures containing it.

Consequently, claim 1 of the main request did not meet the requirements of novelty

(e) Article 100(a) EPC, inventive step

D3 had the same goal as the invention disclosed in the patent, and could be considered as closest prior art. D3 disclosed a formulation comprising cyclosporine (a water-insoluble drug), 72.3% glyceryl monooleate (GMO) and ethanol, encapsulated in a soft gelatin capsule (see claims 1 and 15, and example 6).

The subject-matter of claim 1 differed by the upper limit of GMO, being 10% w/w.

The technical effect of controlling the viscosity of the composition while at the same time preventing phase separation was not reached over the claimed scope. In particular, D17 showed several formulations falling within the claimed scope which did not solve the phase separation problem at 5% water levels.

The problem starting from D3 was the provision of alternative solutions to the problem of preventing phase separation.

The skilled person in the field of pharmaceutical formulations would have been aware that in order to reduce the viscosity of a formulation, the GMO would be an important factor to consider changing. Furthermore, the ratio of GMO to active ingredient needed to be taken into account. The amount of the lipophilic carrier GMO necessary to avoid phase-separation was logically higher in D3 than in the examples of the patent, because the amount of active ingredient was also higher. The ratio of GMO

vs. active ingredient in D3 fell within the range of the ratios claimed in the patent.

Additionally, the examples of the patent were closely related to example 6 of D3, since the only actual difference was the replacement of one lipophilic excipient composition having an HLB of below 10 (namely 72% GMO) with another lipophilic excipient composition having an HLB of below 10 (the excipient compositions exemplified in the patent). The skilled person would have considered this replacement, knowing that GMO was a very expensive excipient and in order to decrease the viscosity of the formulation.

Starting from example 6 of D3, the skilled person would have been able to determine the lower range of GMO still avoiding phase separation in said particular formulation, as outlined in D9.

Alternatively, D1 could be taken as closest prior art. D1 addressed the issue of bioavailability and thus shared a similar goal as the patent. The claimed subject-matter differed from the teaching of D1 by the amount of monoacylglycerol. It would have been obvious for the skilled person to remove Inwitor 988 from the formulations of examples 5 and 6B of D1, since this component was seen as lipophilic surfactant which could be exchanged with other lipophilic surfactants.

Accordingly, the claimed subject-matter did not involve an inventive step.

XII. The respondent's arguments can be summarised as follows:

(a) Admittance of the documents filed with the grounds of appeal and of the objections based on example 6B of D1 and on D16

None of the new documents filed with the grounds of appeal, or the new novelty and inventive step attack raised for the first time in the grounds of appeal, should be admitted into the proceedings under Article 12(4) RPBA. In particular, the appellant had provided no justification for raising the new objections based on D16 with its grounds of appeal only. These newly raised objections were not *prima facie* relevant. Additionally, an appeal was intended to review the correctness of a first-instance decision, and was not an opportunity to raise completely fresh sets of objections on which the opposition division did not have any opportunity to comment.

(b) Article 100(c) EPC

The appellant had not explained where the opposition division may have erred in its analysis under Article 123(2) EPC. The opposition division's analysis was correct. The main request did not contain added subject-matter.

(c) Article 100(b) EPC

The claims of the main request were directed to products and processes for making the products. There was no evidence that the claimed products could not be made or that the processes could not

be followed. The objections put forward by the appellant were rather objections under Article 84 EPC or related to issues of claim breadth to be addressed under Article 56 EPC.

(d) Article 100(a) EPC, novelty

In examples 5 and 6B of D1, not only the components Maisine or Maisine 35-1, but also Inwitor 988 comprised monoacylglycerol. There was no demonstration that the overall content in monoacylglycerol in these examples still fell within the claimed range of 2-10%. As a result, the claimed subject-matter was novel.

(e) Article 100(a) EPC, inventive step

D3 was the closest prior art since it was the only document on file dealing with stabilisation of compositions by inhibiting phase separation.

In example 6 of D3 the amount of monoacylglycerol compound was greater than 70% w/w. The distinguishing feature of claim 1 of the main request was that the amount of monoacylglycerol compound was 2-10%.

The technical effect associated with this difference was a reduced phase separation as shown by the data filed with the letter dated 26 May 2017. D17 did not prove that this effect did not arise.

The technical problem was the provision of a composition with increased stability against phase separation in gelatin capsules.

Starting from D3 as closest prior art the skilled person would not have reduced the amount of monoacylglycerol compound, or replaced most of it with another lipophilic excipient, in the reasonable expectation of solving the above mentioned technical problem. Moreover, the link between the amount of active ingredient and the amount of monoacylglycerol compound alleged by the appellant was not correct. The primary role of the monoacylglycerol compound was to increase the amount of water coming from the gelatin capsule that could be tolerated by the composition, without causing phase separation.

As to D1, it did not deal with the same problem as the patent. D1 mentioned the issue of bioavailability, as did the patent. However, bioavailability was an aspect common to many drug delivery systems. The patent was primarily and overwhelming concerned with reducing phase separation in gelatin capsule formulations. D1 did not address this problem and was not an appropriate starting point for the assessment of inventive step.

Accordingly, the criteria of inventive step were met.

XIII. The appellant requests that the decision under appeal be set aside and that the patent be revoked.

XIV. The respondent requests that the appeal be dismissed and the patent be maintained as granted or, as an auxiliary measure, that the patent be maintained on the basis of auxiliary request 1 filed with the reply to

the grounds of appeal on 7 January 2019 or one of auxiliary requests 2-4 filed with letter dated 5 February 2021.

The respondent also requests that the following documents/objections filed with the grounds of appeal not be admitted into the proceedings:
- documents D14-D18,
- novelty objection starting from of Example 6B of D1,
- novelty objection in view of D16, and
- inventive step objection starting from D16.

Reasons for the Decision

1. Admittance of D14-D18 and of the new novelty and inventive step objections into the proceedings

1.1 Together with its statement setting out the grounds of appeal, the appellant introduced documents D14-D18, and raised, among others, objections of lack of novelty over example 6B of D1, and objections of lack of novelty and lack of inventive step over the newly cited D16.

The respondent contested the admittance of these documents and objections into the proceedings.

1.2 In line with the opinion expressed in its communication pursuant to Article 15(1) RPBA (see paragraphs 1 and 1.1 to 1.4), the Board decided to admit these documents, including D16, and the novelty objection based on Example 6B of D1 into the proceedings, but not the novelty and inventive step objections based on D16. Considering that the Board comes to the conclusion that the appeal should be dismissed (see below), only the

non-admittance of the objections based on D16 needs to be discussed here.

1.3 The statement setting out the grounds of appeal was filed before 1 January 2020. Consequently, under the transitional provisions of Article 25(2) RPBA 2020, Article 12(4) to (6) RPBA 2020 does not apply. Instead, the question as to whether these new submissions should be admitted must be decided on the basis of Article 12(4) RPBA 2007, which gives the Board discretion not to admit, on appeal, facts or evidence which could have been presented in the opposition proceedings.

1.4 The Board considered the filing of document D16 with the grounds of appeal as a legitimate attempt of the appellant to fill in the gaps in its argumentation of lack of novelty over D1, namely as regards the composition of the component "Maisine" in example 6B of D1.

1.5 However, the admission of D16 as evidence of the composition of Maisine does not mean that any new objection of lack of novelty and inventive step over the rest of the disclosure of D16 should also be admitted.

The introduction of these new novelty and inventive step objections at the appeal stage is not seen as a reaction to any developments in the first-instance proceedings, but as a substantial change in the subject of the proceedings. The facts and evidence supporting these objections based on D16 could, and should, have been presented during the proceedings before the opposition division. Accordingly, and irrespective of their potential relevance, the Board decided under Article 12(4) RPBA 2007 not to admit the novelty and

inventive step objections based on D16 into the proceedings.

The Board adds that, contrary to the appellant's view, D16 is not *prima facie* relevant for the novelty of claim 1. The passages cited by the appellant either do not disclose soft gelatin capsules (see example 2 of D16) or do not comprise an amount of monoacylglycerol compound as claimed (see example 4, composition 8). The appellant did not identify in D16 any disclosure of a general range for the amount of monoacylglycerols, from which the claimed range of 2-10% would allegedly represent a non-novel sub-selection. The appellant did not show either why the features of claim 1 of the main request should be read in combination starting from the numerous alternatives recited in the general disclosure of D16 (see D16, claims 1, 6-17, 22-25, and page 5 line 42 to page 6 line 4).

2. Main request (patent as granted)

2.1 Article 100(c) EPC, added subject-matter

2.1.1 The appellant considers the feature of claim 1 pertaining to the "hydrophilic solvent comprising ethanol" to result from an intermediate generalisation from paragraph [0018] of the application as filed and to infringe Article 123(2) EPC.

The Board does not share this view. According to paragraph [0018], the excipient of the gelatin capsules of the invention *can* further comprise: (a) hydrophilic solvents (e.g., ethanol), (b) lipophilic solvents, (c) surfactants, *and* (d) lipophilic carriers. The word "can" expresses that the list of components (a)-(d) is an enumeration of possible ingredients and that not all

of these components (a)-(d) have to be simultaneously present. Accordingly, the application as filed provides basis for the addition of the hydrophilic solvent (here, ethanol) to the exclusion of the others excipients (b)-(d).

2.1.2 Regarding the combination of the feature relating to ethanol with the amount of crystallisation inhibitor (2-10% w/w), the Board agrees with the reasons given in the decision under appeal (see in particular paragraph 15.2.2). The decision identified claims 1-3 and 5 and paragraph [0018] of the application as filed as basis, and rightly observed that both the selection of ethanol as hydrophilic solvent and the range of 2-10% are disclosed as preferred in the application as filed, such that their combination does not introduce new subject-matter.

2.1.3 Accordingly, the ground for opposition under Article 100(c) EPC does not prejudice the maintenance of the patent.

2.2 Article 100(b) EPC, sufficiency of disclosure

2.2.1 According to the appellant, the desired result of preventing phase separation or precipitation cannot be achieved without undue burden. However, an objection of insufficient disclosure cannot legitimately be based on an argument that the patent would not enable a skilled person to achieve a non-claimed technical effect. The Board notes that the effect of preventing phase separation or precipitation is not a feature of claim 1. Any undue burden to achieve this effect is consequently not relevant to the issue of sufficiency of disclosure.

2.2.2 Claim 1 requires that the capsule content comprises a water-insoluble active ingredient dissolved in an excipient. D17 does not demonstrate the absence of solubility of the active ingredient in the excipient (see formulations 180098 and 180101). Furthermore, claim 1 does not exclude formulations further comprising undissolved water-insoluble active ingredient. In any case, the Board concurs with the opposition division that the solubility of a water-insoluble active ingredient in the excipient is not unlimited. Finding an amount of active ingredient in the capsule content which remains below this solubility limit does not represent an undue burden for the skilled person.

2.2.3 Accordingly, the ground for opposition of Article 100(b) EPC does not prejudice the maintenance of the patent.

2.3 Article 100(a) EPC, novelty

2.3.1 D1 discloses soft gel capsules (see example 5 and example 6, formulation B). In example 5, the capsule content comprises 8.60% w/w Maisine 35-1 and 25.79% w/w Imwitor 988. In example 6B, the capsule content comprises 20% Maisine and 11% Imwitor 988. According to D1 (see column 4, line 45), Imwitor 988 is a mixture of glycerol mono- and di-caprylate. However, the amount of monoacylglycerol in Imwitor 988 is unknown. As a result, it cannot be concluded that the overall amount of monoacylglycerol compounds present in the compositions of examples 5 or 6B falls within the claimed range of 2-10%. Thus, D1 does not directly and unambiguously disclose a soft gel capsule according to claim 1.

2.3.2 The appellant submitted that, in the capsule of claim 1, only the amount of crystallization inhibitor was limited to 2-10% w/w of the capsule content. The presence of other components, including further monoacylglycerols, was permitted by the open expression "comprising" of claim 1.

The Board does not agree. In claim 1, the amount of crystallization inhibitor in the capsule content is defined to be 2-10% w/w. This crystallization inhibitor is defined as a monoacylglycerol compound selected from glyceryl monooleate, glyceryl monolinoleate, glyceryl monopalmitate, glyceryl monostearate, glyceryl monolaurate, glyceryl monocaprylate, glyceryl monocaprate, and combinations thereof. Consequently, in any given capsule composition, all the recited monoacylglycerols qualify as crystallisation inhibitor in the sense of claim 1. Thus the range of 2-10% specified in claim 1 applies to the overall content of the listed monoacylglycerols.

2.3.3 Lastly, and contrary to the appellant's position, the patent does not justify that the expression "monoacylglycerol compound" be broadly interpretated so as to cover mixtures merely containing the monoacylglycerol as the main component, such as Maisine 35-1. In any event, this interpretation would not help the appellant's case, since the combined amounts of Imwitor 988 and Maisine or Maisine 35-1 in D1 exceed the upper limit of 10% specified in claim 1.

Hence, the subject-matter of claim 1 of the patent is novel.

2.4 Article 100(a) EPC, inventive step

2.4.1 The present invention relates to soft gelatin capsules comprising a water-insoluble active ingredient. Soft gel capsules are known to undergo a phenomenon known as syneresis, wherein water contained in the gel passes into the content of the capsules, leading to phase separation problems. The patent seeks to solve the problem of stabilising the water-insoluble active ingredient and preventing turbidity, formation of a coarse emulsion, and/or crystallisation of the active ingredient due to the presence of water from syneresis or other environmental changes inside the capsule (see paragraphs [0011] and [0012] of the patent).

2.4.2 D3 is considered as a suitable starting point for the assessment of inventive step by both parties.

D3 deals with the stabilisation of compositions by inhibiting phase separation (see column 1, lines 31-40). In example 6, D3 discloses a soft gelatin capsule containing cyclosporin A (a water-insoluble active ingredient), ethanol, and 72,3% w/w glyceryl mono-oleate.

2.4.3 The subject-matter of claim 1 differs from the teaching of D3 in that the amount of monoacylglycerol compound is in the range of 2-10% w/w.

2.4.4 The parties debated whether, and to what extent, the claimed compositions solved the problem of preventing phase separation in the presence of water. In particular, according to the appellant, D17 showed that some of the claimed compositions were not able to tolerate the amounts of water mentioned in paragraph

[0005] of the patent, namely 5% or 10%. Consequently, the claimed subject-matter would not solve the problem.

The Board does not agree. D17 shows that formulations falling within the scope of the claim are able to tolerate the presence of water to some extent and become turbid only when the amount of added water reaches at least 4% (see D17, formulation 180124, page 14) or 7% (see page 18, formulation 180125). The fact that some of the claimed formulations may not be able to tolerate the amounts of water indicated in the patent (e.g. 5%, see paragraph [0005] of the patent) is related to the extent of the effect, and not its existence.

For the reasons given below, the Board comes to the conclusion that the claimed subject-matter involves an inventive step, even if no improvement is demonstrated over the compositions of D3. Consequently, it is not necessary to assess whether the experimental data submitted with the respondent's letter of 26 May 2017 demonstrate an additional effect on viscosity.

2.4.5 Thus, the problem to be solved can be seen as the provision of further soft gelatin capsules in which phase separation is prevented.

2.4.6 D3 generally discloses pharmaceutical compositions comprising at least of one of several components (a), (b) or (c) (see column 1, lines 56-65), where component (c) is a mono- or di-glyceride such as GMO (see column 4, lines 34-39). The amount of component (c) is defined as a function of the amount of active ingredient (i.e. a peptide), such as 1 to 7 parts by weight of peptide (see column 4, lines 45-55 and 60).

However, the relevant question is not whether this ratio of GMO to active ingredient disclosed in D3 covers the ratio of monoacylglycerol to active ingredient in the formulations of the patent, but whether D3 considers lowering the amount of GMO from the 72% of example 6 to the claimed range of 2-10%. The Board finds that D3 does not give any incentive to consider changing the composition to such an extent and expect the composition to still tolerate the presence of some amounts of water. There is also no indication in D3 that the majority of monoacylglycerol compound could be replaced with another lipophilic excipient without compromising the properties of the capsule with respect to phase separation.

The appellant further argued that the skilled person starting from D3 would have been able to determine the lower range of GMO still avoiding phase separation, as outlined in D9. D9 pertains to the common use of phase diagrams in formulation. However, D9 does not show either that the skilled person would be led to consider the claimed amounts of monoacylglcerol to address the particular issue of water ingress in soft gelatin capsules.

2.4.7 The appellant further raised an objection of inventive step starting from D1. The Board concurs with the opposition division that D1 is more remote from the present invention as it does not address the problem of stability against phase separation gelatin capsule formulations and crystallisation upon exposure to water. The fact that D1 mentions the issue of bioavailability does not qualify D1 as closest prior art, considering that this issue is not central to the patent in suit but is rather common to most drug delivery systems. Furthermore, as discussed above (see

2.3), D1 does not disclose gelatin capsule formulations with a content comprising the claimed amounts of monoacylglycerol.

2.4.8 Consequently, the subject-matter of claim 1 of the main request involves an inventive step.

2.4.9 Claim 13 is directed at a process for the preparation of a soft gelatin capsule characterised by the same features as in product claim 1. Since claim 1 is found allowable, process claim 13 is also allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated