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**Datasheet for the decision
of 7 August 2006**

Case Number: T 1193/05 - 3.3.02

Application Number: 95901961.3

Publication Number: 0729353

IPC: A61K 9/50

Language of the proceedings: EN

Title of invention:

Preparation of biodegradable microparticles containing a biologically active agent

Patentee:

Alkermes Controlled Therapeutics, Inc.

Opponents:

Southern Research Institute
DrugAbuse Science, Inc.

Headword:

Preparation of microparticles/ELKERMES CONTROLLED THERAPEUTICS, INC.

Relevant legal provisions:

EPC Art. 111(2), 123(2)(3)

Keyword:

"Auxiliary request 1, Article 123(3) - no: deletion of the disclaimer increases the scope of protection vis à vis the claims as granted"

"Auxiliary request 2 - Article 123(3) - yes: scope of the disclaimer distinct from the scope of the restricted claims, so that its deletion does not effect its scope"

"Remittal - yes - unexamined grounds of opposition"

Decisions cited:

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Catchword:

-



Case Number: T 1193/05 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 7 August 2006

Appellant: Alkermes Controlled Therapeutics, Inc.
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 15 July 2005
revoking European patent No. 0729353 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: G. Rampold
Members: J. Riolo
K. Garnett

Summary of Facts and Submissions

- I. European patent No. 0 729 353 based on application No. 95 901 961.3 was granted on the basis of six claims.

Claim 1 as granted reads as follows:

"1. A method of preparing microparticles, comprising:
preparing a first phase, said first phase comprising an active agent and a polymer;
preparing a second phase;
preparing a quench liquid; and pumping said first phase and said second phase through a static mixer into said quench liquid thereby forming microparticles containing said active agent;
wherein the method is not:
a method of preparing spherules having one or more active alimentary or medicinal ingredients characterised in that in a first stage spherules are formed by controlled division of a primary oil-in-water emulsion consisting of an alimentary or medicinal ingredient, oil, a protein and water in a solvent immiscible with the water, then the obtained spherules are separated in a second stage."

- II. Oppositions were filed against the granted patent by respondents 1 and 2 (opponents O1 and O2). The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC because its subject-matter extended beyond the content of the application as filed.

III. The decision of the Opposition Division pronounced on 1 June 2005 revoked the patent under Article 102(1) EPC because its subject-matter contravened the requirements of Article 123(2) and (3) EPC.

Independent claim 1 of the main request filed with the patent proprietor's letter dated 3 June 2003, on which the decision of the Opposition Division is based, reads as follows:

"1. A method of preparing microparticles, comprising:
preparing a first phase, said first phase comprising an active agent and a polymer dissolved in a solution;
preparing a second phase which is substantially immiscible with the first phase;
preparing a quench liquid; and
pumping said first phase and said second phase through a static mixer into said quench liquid thereby forming microparticles containing said active agent;
wherein the method is not:
a method of preparing spherules having one or more active alimentary or medicinal ingredients characterised in that in a first stage spherules are formed by controlled division of a primary oil-in-water emulsion consisting of an alimentary or medicinal ingredient, oil, a protein and water in a solvent immiscible with the water, then the obtained spherules are separated in a second stage."

The Opposition Division considered that the introduction of the formulation "comprising a solution in which are dissolved an active agent and a polymer" in claim 1 of the main request filed with the patent

proprietor's letter dated 3 June 2003 contravened Article 123(2) and (3) EPC.

It also held that the disclaimer in claim 1 of that request did not fulfil the requirements of Article 123(2) EPC because it removed more than was necessary to restore novelty over (35) EP-A-618 001.

Moreover, under Rule 71a EPC the Opposition Division did not admit auxiliary requests 1 and 2 filed during the oral proceedings into the proceedings.

Accordingly, the Opposition Division revoked the patent in suit.

IV. The appellant lodged an appeal against the said decision and filed a main request and auxiliary request 1 together with its grounds of appeal dated 7 November 2005.

Claim 1 of the main request reads as follows:

"1. A method of preparing microparticles, comprising:
preparing a first phase comprising dissolving an active agent in a solution containing a polymer;
preparing a second phase which is substantially immiscible with the first phase;
preparing a quench liquid; and
pumping said first phase and said second phase through a static mixer into said quench liquid thereby forming microparticles containing said active agent;
wherein the method is not:
a method of preparing spherules having one or more active alimentary or medicinal ingredients

characterised in that in a first stage spherules are formed by controlled division of a primary oil-in-water emulsion consisting of an alimentary or medicinal ingredient, oil, a protein and water in a solvent immiscible with the water, then the obtained spherules are separated in a second stage."

Claim 1 of auxiliary request 1 reads as follows:

"1. A method of preparing microparticles, comprising:
preparing a first phase comprising dissolving an active agent in a solution containing a polymer;
preparing a second phase which is substantially immiscible with the first phase;
preparing a quench liquid; and
pumping said first phase and said second phase through a static mixer into said quench liquid thereby forming microparticles containing said active agent."

- V. Oral proceedings were held before the Board on 7 August 2006.

The appellant withdrew, at the start of the oral proceedings, the above main request filed on 7 November 2005 and requested that the patent be maintained on the basis of the auxiliary request filed on 7 November 2005 (auxiliary request 1 in the present proceedings).

In its introductory remarks at the oral proceedings, the Board indicated that the subject-matter of claim 1 of the first auxiliary request was identical to embodiment a) of claim 5 as granted, with the deletion of the disclaimer, which meant that claim 1 was limited to a specific object which was already claimed in the

patent as granted, so that the question of whether or not this subject-matter complied with Article 84 EPC was not at issue in the present case since, according to the consistent case law of the boards of appeal, Article 102(3) EPC does not allow objections to be based upon Article 84 EPC if they do not arise out of the amendments made.

During the oral proceedings, the appellant withdrew its main request and filed two further requests, namely auxiliary requests 2 and 3.

Claim 1 of auxiliary request 2 reads as follows:

"1. A method of preparing microparticles, comprising:
preparing a first phase by dissolving an active agent in a solution containing a polymer;
preparing a second phase which is substantially immiscible with the first phase;
preparing a quench liquid; and
pumping said first phase and said second phase through a static mixer into said quench liquid thereby forming microparticles containing said active agent."

VI. The appellant's submissions can be summarised as follows:

As claim 1 of all the requests was now restricted to the preparation of a first phase by "dissolving an active agent in a solution containing a polymer", i.e. a first phase in which the active agent and the polymer were dissolved to form a solution, the subject-matter of claim 1 was distinct from the process of the

disclaimer in which the first phase was a water-in-oil emulsion.

It followed that the disclaimer was no longer needed and that its deletion could not affect that part of the subject-matter which was originally in the claims as granted, so that Article 123(3) EPC was not infringed.

VII. The respondents contested these arguments.

They argued that the deletion of the disclaimer in claim 1 was not allowable under Article 123(3) EPC.

They mainly contended that because of the open wording of the claims, namely, the use of the term "comprising" in relation to the preparation of the first phase, the subject-matter of the disclaimer overlapped with the subject-matter of claim 1, so that its deletion infringed Article 123(3) EPC.

VIII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the Opposition Division for further prosecution on the basis of the first auxiliary request filed with the letter of 7 November 2005, alternatively on the basis of the second or third auxiliary requests filed during the oral proceedings.

The respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.
2. *Auxiliary request 1*
 - 2.1 Article 123(2) and (3) EPC
 - 2.1.1 The subject-matter of claim 1 differs from the subject-matter originally filed in that it has been restricted to claims 7 and 2 as originally filed.
 - 2.1.2 As claim 7 refers specifically to claim 2 as originally filed, all the amendments introduced into present claim 1 are adequately supported by the originally filed documents and comply in this respect with the provisions of Article 123(2) EPC.
 - 2.1.3 Compared with independent claim 1 (see paragraph I supra) as granted, the corresponding independent claim 1 as amended has been modified by the additional technical feature which requires that the method of preparing microparticules comprises a step of "preparing a first phase comprising dissolving an active agent in a solution containing a polymer", and, further, by the deletion of the disclaimer.

According to the claimed method, said first phase is mixed with a second phase which is substantially immiscible with it.

In particular, the disclaimer relates to "a method of preparing spherules (microparticles) having one or more active alimentary or medicinal ingredients (active

agent) characterised in that in a first stage spherules are formed by controlled division of a primary oil-in-water emulsion consisting of an alimentary or medicinal ingredient, oil, a protein (polymer) and water (first phase) in a solvent immiscible with the water (second phase), then the obtained spherules are separated in a second stage."

Thus, the key question here is whether the "first phase" of the disclaimer falls within the definition of the "first phase" of claim 1.

The "first phase" of the disclaimer is "a primary oil-in-water emulsion consisting of an alimentary or medicinal ingredient (active agent), oil, a protein (polymer) and water".

The "first phase" according to claim 1 of this request is prepared in a step "comprising dissolving an active agent in a solution containing a polymer".

Therefore, as a result of this open wording of the claim (ie use of the term "comprising"), even if "dissolving an active agent in a solution containing a polymer" would lead to a solution, for instance in water, the claim does not exclude further steps, and in particular steps wherein this solution could be emulsified as a water-in-oil emulsion.

Accordingly, the deletion of the disclaimer infringes Article 123(3) EPC, since claim 1 of this request encompasses embodiments, namely a first phase being an oil-in-water emulsion, which were excluded by the disclaimer.

2.1.4 The Board cannot accept the appellant's main argument that the sentence in claim 1 "preparing a first phase comprising dissolving an active agent in a solution containing a polymer" means "preparing a first phase **by** dissolving an active agent in a solution containing a polymer", which clearly excludes emulsions.

It is common practice in the patent field to use the term "comprising" as "open language" precisely in order to have a broader scope of protection.

It is therefore not correct to say that the two wordings are identical.

Auxiliary request 1 is thus rejected under Article 123(3) EPC.

3. *Auxiliary request 2*

3.1 Admissibility

This set of claims differs from the set of claims corresponding to the set of claims of auxiliary request 1 filed with the grounds of appeal on 7 November 2005 only in that "by" replaces the word "comprising" in claim 1.

Although auxiliary request 2 was only presented during the hearing before the Board and was, accordingly, filed late, the Board, exercising its discretionary power, considers that it should be admitted into the proceedings.

The appellant submitted that this request was prompted by the discussion in the oral proceedings and was reinforced by the weight given by the Board during the hearing to the question whether the embodiments covered by the disclaimer, namely emulsions, might still be encompassed by the open wording used in claim 1.

These assertions appear to be correct. Although the Board does not condone such lateness per se, the exact meaning and impact of the proposed small amendment in claim 1 of the second auxiliary request (see above) was immediately comprehensible to the Board and the parties. Coupled with the fact that the parties did not raise any further objections, beside its lateness, to the admissibility of this set of claims, the Board exercises its discretion in favour of the appellant.

3.2 Article 123(2) and (3) EPC

3.2.1 The subject-matter of claim 1 differs from the subject-matter originally filed in that it has been restricted to claims 7 and 2 as originally filed and in that "by" replaces the word "comprising" in claim 1.

3.2.2 As claim 7 refers specifically to claim 2 as originally filed and as there is *verbatim* support for the other amendment on page 8, lines 17 to 20, in the description as originally filed, all the amendments introduced into present claim 1 are adequately supported by the originally filed documents and comply in this respect with the provision of Article 123(2) EPC.

- 3.2.3 Compared with independent claim 1 of auxiliary request 1, the corresponding independent claim 1 of auxiliary request 2 is now modified in that "by" replaces the word "comprising".

In the light of this new wording, namely "preparing a first phase **by** dissolving an active agent in a solution containing a polymer", the first phase is now restricted to a solution, since the active agent and the polymer are dissolved to form a solution.

Accordingly, this subject-matter, which was encompassed by the subject-matter as granted, is distinct from the subject-matter of the disclaimer requirement of a water-in-oil emulsion as a first phase.

It follows that the deletion of the disclaimer does not affect this restricted subject-matter and that auxiliary request 2 thus fulfils the requirements of Article 123(3) EPC.

- 3.2.4 The Board does not agree with the respondents that claim 1 of the second auxiliary request still encompasses the embodiments of the disclaimer because of the term "comprising" in claim 1 in relation to the method of preparing microparticules, i.e. "a method of preparing microparticules, comprising: ...".

In fact, claim 1 requires that "**said** first phase", namely the first phase prepared "by dissolving an active agent in a solution containing a polymer", which is a solution, is mixed with the second immiscible phase.

On the contrary, in the disclaimer the first phase, which is mixed with the second immiscible phase, is a water-in-oil emulsion.

As this distinguishing feature is not affected by the term "comprising" present in claim 1 of this request, the above conclusions remain unchanged.

As to the other objections raised by the respondents concerning the fact that "dissolving an active agent in a solution" could be understood as meaning that the active agent is only partially dissolved, and that a "solution containing a polymer" might be an emulsion or a suspension of the polymer, the Board considers that the skilled person would always read a claim sensibly, unless the description leads to a different understanding of the terms used in the claims.

In the present case, the Board has no reason to think that in the present patent a "solution" means anything other than a mono-phase liquid in which a substance has been dissolved, and that "dissolving" means that the product becomes fully dissolved in the liquid.

Accordingly, if only part of a solid active agent were dissolved in a solution or if the polymer were not dissolved in the solution, as contended by the respondents, the skilled person would then use different terms to describe the physical state of the obtained mixture (suspension, emulsion, gel etc.) since the word solution would not be correct anymore.

Under these circumstances, the Board concludes that auxiliary request 2 fulfils the requirements of Article 123(3) EPC.

4. *Remittal to the first instance*

4.1 Although Article 111(1) EPC does not guarantee the parties an absolute right to have all the issues in the case considered at two levels, it is recognised that any party should, if possible, be given the opportunity to two hearing on the important elements of the case. The essential function of an appeal in *inter partes* proceedings is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally referred back, if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is considered appropriate by the boards in cases where a first instance department issues a decision solely upon one particular issue which is decisive for the case against a party and leaves other issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first instance department for consideration of essential undecided issues.

4.2 The observations and comments made above apply fully to the present case. The Opposition Division decided that claim 1 was not patentable because it contravened Article 123(2) and (3) EPC, but left outstanding the issues of novelty (Articles 52(1) and 54 EPC) and

inventive step (Articles 52(1) and 56 EPC) and the grounds of insufficiency of disclosure (Article 83 EPC). These issues, however, form, *inter alia*, the basis for the requests of the respondents that the patent be revoked in its entirety and must therefore be considered as essential substantive issues in the present case.

- 4.3 Thus, in view of the above considerations the Board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit the case to the Opposition Division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division for further prosecution on the basis of the second auxiliary request filed during the oral proceedings.

The Registrar:

The Chairman:

C. Eickhoff

G. Rampold