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**Datasheet for the decision
of 15 November 2016**

Case Number: T 2369/13 - 3.3.07

Application Number: 09176701.2

Publication Number: 2158902

IPC: A61K9/32, A61K47/30

Language of the proceedings: EN

Title of invention:

Ion binding compositions

Applicant:

Relypsa, Inc.

Relevant legal provisions:

EPC Art. 76(1), 123(2), 111(1)

Keyword:

Divisional application - added subject-matter (no)

Amendments - added subject-matter (no)

Appeal decision - remittal to the department of first instance
(yes)



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Case Number: T 2369/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 15 November 2016

Appellant: Relypsa, Inc.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 28 June 2013 refusing European patent application No. 09176701.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: A. Usuelli
P. Schmitz

Summary of Facts and Submissions

- I. The appeal of the applicant (appellant) lies from the decision of the examining division to refuse European patent application No. 09176701.2, which was filed as a divisional of application No. 05731099.7, published as WO 2005/097072.
- II. The decision of the examining division was based on a main request and four auxiliary requests. Claim 1 of each request related to a core-shell particle comprising a core containing poly-2-fluoroacrylic acid beads and a shell.

The examining division came to the conclusion that none of the requests on file complied with the requirement of Article 76(1) EPC. In particular, it considered that the parent application provided a basis for claims directed to core-shell particles comprising a core based on poly-2-fluoroacrylic acid beads only within the limits of the disclosure of example 8, i.e. only for particles in which the shell material was the co-polymer prepared by copolymerization of N-N'-dibutyl acrylamide and N-N'-diethylaminoethylmethacrylate (DBA-DEAEMA).

In relation to auxiliary request 3, the examining division furthermore considered that the requirement of Article 84 EPC was not met on account of the use of registered trademarks in claims 1, 5 and 6.

- III. With the statement setting out the grounds of appeal dated 8 November 2013, the appellant requested that the decision under appeal be set aside and a patent be granted on the basis of a main request or on the basis of one of four auxiliary requests.

The main request corresponded to auxiliary request 3 which formed part of the basis of the appealed decision.

- IV. In a communication pursuant to Article 15(1) RPBA issued on 15 September 2016, the Board expressed the view that the subject-matter of the main request fulfilled the requirements of Article 76(1) EPC and 123(2) EPC. In relation to Article 84 EPC, the Board substantially agreed with the conclusion of the examining division that the use of trademarks in a claim posed a problem of clarity. The Board furthermore informed the appellant about its intention to remit the case to the examining division for further prosecution, should one of the requests be found to comply with Articles 123(2), 76 and 84 EPC.
- V. With letter of 10 November 2016, the appellant submitted a new main request and auxiliary requests 1 and 2. Claim 1 of the main request read as follows:
- "1. Core-shell particle comprising a core consisting of poly-2-fluoroacrylic acid beads, and a shell comprising an enteric coating."
- VI. Oral proceedings were held on 15 November 2016 in the absence of the appellant.
- VII. In its written submissions, the appellant essentially argued that poly-2-fluoroacrylic acid beads were disclosed in example 7 of both the application as filed and the parent application. This disclosure was independent from example 8, wherein these beads were coated with the copolymer DBA-DEAEMA. The skilled artisan would have understood from the general

disclosure of the original application and the parent application that the poly-2-fluoroacrylic acid beads could be combined with any shell material disclosed in the description, such as the shells based on enteric coatings disclosed in paragraph [0053].

- VIII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request or one of auxiliary requests 1 or 2, filed with letter of 10 November 2016.

Reasons for the Decision

Main request

1. Article 76(1) EPC
- 1.1 The subject-matter of claim 1 relates to core-shell particles wherein the core consists of poly-2-fluoroacrylic acid beads, and the shell comprises an enteric coating.

The parent application (reference is made to publication WO 2005/097072) provides a general basis for core-shell particles comprising a core component and a shell component, for instance in paragraphs [0009] and [0026].

Information concerning the composition of the shell component is disclosed in paragraphs [0050] to [0053] of the parent application. Paragraph [0053] relates in particular to a generic class of shell components which comprise an enteric coating, which is made for instance of Eudragit acrylic polymer. Core-shell particles in which the shell component comprises an enteric coating

are also referred to in claim 23 of the parent application.

As to the composition of the cores, the information provided by the parent application is mainly contained in the examples. In the context of the present case, particularly relevant is example 7, which relates to the preparation of poly-2-fluoroacrylic acid beads, i.e. the core material of claim 1.

- 1.2 The beads of example 7 are used in example 8 to prepare core-shell particles having a specific shell material, namely the copolymer DBA-DEAEMA. However, in the Board's view, there is no indication in the parent application that the poly-2-fluoroacrylic acid beads of example 7 are to be used exclusively in combination with the shell material of example 8.

The parent application indicates that both the core-component and the shell-component influence the capacity of the particle to bind "target solutes", i.e. substances such as ions or toxins which may be at the origin of various disorders. Yet the application does not establish any link between core-component and shell-component on the basis of their composition.

Thus, the Board sees no reason to consider that the disclosure of the core-shell particles of example 8, implies that the poly-2-fluoroacrylic acid beads can be used as core component only when the copolymer DBA-DEAEMA is used as material for the shell component. Such a restrictive reading of example 8 has no support in the general description of the parent application and is at odds with the fact that poly-2-fluoroacrylic acid beads are disclosed, not only in example 8 as

components of specific particles, but also in example 7 "as such", i.e. without any shell coating.

- 1.3 The person skilled in the art reading the parent application would therefore understand that the poly-2-fluoroacrylic acid beads of example 7 can be used with any shell component described in the application, including the generic group of shell components comprising an enteric coating, which is disclosed in the embodiment of paragraph [0053]. The Board concludes therefore that the subject-matter of claim 1 can be directly and unambiguously derived from the disclosure of the parent application.

Hence, claim 1 meets the requirements of Article 76(1) EPC.

- 1.4 Claims 2 to 10 also have a basis in the parent application. In particular, claims 2, 3 and 10, which specify that the enteric coating contains a polymer of the Eudragit type, have a basis in paragraphs [0053] and [0066]. The therapeutic applications recited in claims 4 and 6 are disclosed in paragraph [0010]. The pharmaceutical composition of claim 5 has a basis in paragraph [0009]. Finally, the methods of claims 7 and 9 and the use of claim 8 can be derived from the disclosure of paragraphs [0052] and [0053] in combination with example 7.

Thus, claims 2 to 10 also comply with Article 76(1) EPC.

2. Article 123(2) EPC

- 2.1 The description of the application in suit as originally filed contains the description of the parent

application (paragraphs [0001] to [00173]) and additionally six pages of further embodiments (embodiments 1 to 53) corresponding to the 53 claims of the parent application as filed. In other words, the present application as originally filed incorporates the whole parent application.

Thus, in view of the considerations set out in paragraphs 1.1 to 1.4 above, claims 1 to 10 also have a basis in the application as filed.

The requirements of Article 123(2) EPC are therefore met.

3. Article 84 EPC

3.1 In the appealed decision, the examining division objected under Article 84 EPC to the use of some registered trademarks in the claims (see point II above).

The claims of the main request do not include these trademarks and the Board is satisfied that the claims comply with the requirements of Article 84 EPC.

4. Remittal

4.1 The primary function of an appeal is to consider whether the decision issued by the first-instance department was correct. Hence, a case is normally remitted 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 by the boards in cases where a first-instance department takes a decision against a party having regard to only some issues decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issues addressed is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111(1) EPC).

- 4.2 The observations above apply in full to the present case, since the examining division did not decide on fundamental issues such as novelty and inventive step.

Under these circumstances, the Board finds it appropriate to remit the case to the examining division for further prosecution (Article 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated