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**Datasheet for the decision  
of 21 January 2013**

**Case Number:** T 0176/10 - 3.3.02

**Application Number:** 01972310.5

**Publication Number:** 1324752

**IPC:** A61K 9/16, A61K 9/50, A61K 9/22

**Language of the proceedings:** EN

**Title of invention:**  
Delayed release pharmaceutical formulations

**Applicant:**  
EURO-CELTIQUE S.A.

**Headword:**  
Delayed release pharmaceutical formulations/EURO-CELTIQUE S.A.

**Relevant legal provisions:**  
EPC Art. 123(2), 84, 111

**Keyword:**  
"Main request - allowability of amendments, clarity - (yes)"  
"Remittal - (yes): undecided issues"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 0176/10 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 21 January 2013

**Appellant:**  
(Applicant)

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**Representative:**

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**Decision under appeal:**

Decision of the Examining Division of the  
European Patent Office posted 24 July 2009  
refusing European patent application  
No. 01972310.5 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** A. Lindner  
L. Bühler

## **Summary of Facts and Submissions**

- I. European patent application No. 01 972 310.5 was refused by a decision of the examining division pronounced on 2 July 2009 and dispatched on 24 July 2009 on the basis of Article 97(2) EPC.
  
- II. The examining division decided that the main request as well as auxiliary requests I and VII lacked novelty over numerous documents cited in the search report. Regarding the functional features "disruption agent", "gel-forming", "delayed release" and "providing a lag in the delivery of a drug following administration", the examining division concluded that these terms were vague and therefore not suitable for establishing novelty. Regarding the latter two features, the examining division additionally raised objections under Article 84 EPC, as the original application did not define the conditions for measuring the delay and the lag. Auxiliary request II was not admitted into the proceedings and auxiliary requests III to VI and VIII to XI were not allowable under Article 123(2) EPC.
  
- III. The appellant (applicant) lodged an appeal against this decision. With the statement of the grounds of appeal, the appellant submitted a new main request and auxiliary requests I to XIII.
  
- IV. In the annex to the summons to oral proceedings issued by the board pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), the board in its preliminary opinion raised objections under Articles 84, 123(2) and 54 EPC. Regarding the requirements of Article 84 EPC, the board concluded

that the feature "providing a lag in the delivery of a drug following administration" lacked clarity.

V. At the oral proceedings of 21 January 2013, the appellant submitted a main request and auxiliary requests 1 to 3. Claim 1 of the main request reads as follows:

"1. A delayed release pharmaceutical composition, the composition being a multi-unit dosage form of multiparticulates, each unit of the composition comprising a core which includes a drug and a disruption agent and further comprising between 20% and 100% coating weight gain of a regulatory membrane coating on the core formed from a mixture of a water-soluble gel-forming polymer and a water-insoluble film-forming polymer."

VI. The appellant essentially argued the clarity objections raised in the decision under appeal and reiterated by the board in its annex to the summons to oral proceedings had been overcome by the amendments made in claim 1 of the main request.

VII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request submitted during oral proceedings on 21 January 2013.

### **Reasons for the decision**

1. The appeal is admissible.

2. Main request

2.1 Admission

These requests were not filed until the oral proceedings before the board. Their admittance is therefore at the board's discretion and depends upon the overall circumstances of the case under consideration (see Article 13 RPBA). The board notes that the amendments were made to overcome objections concerning Article 84 EPC. They were of a simple nature and did not complicate the proceedings. As a consequence, the board decided to admit these requests into the proceedings.

2.2 Article 123(2) EPC

Claim 1 concerns

- (a) a delayed release pharmaceutical composition,
- (b) the composition being a multi-unit dosage form of multiparticulates, each unit of the composition comprising
- (c) a core which includes a drug and a disruption agent and further comprising
- (d) between 20% and 100% coating weight gain of a
- (e) regulatory membrane coating on the core formed from a mixture of a water-soluble gel-forming polymer and a water-insoluble film-forming polymer.

Features (a), (c) and (e) have their basis in claim 1 of the application. Feature (b) is disclosed in the penultimate paragraph of page 6, which describes multi-unit dosage forms of multiparticulates forms as a preferred embodiment. The coating weight gain of

between 20% and 100% (feature (d)) has its basis in the first paragraph of page 9, which discloses a general range of 2.5% to 100% and a preferred range of 20% to 70% (see lines 2-4). As compared to the general range mentioned above, the claimed range was shortened by introducing the lower end (20%) from the preferred range. This shortening does not introduce subject-matter which extends beyond the content of the application of the original application. As a consequence, the subject-matter of claim 1 of the main request meets the requirements of Article 123(2) EPC.

### 2.3 Article 84 EPC

In the decision under appeal the examining division reasoned that the features "delayed release pharmaceutical composition", "disruption agent" and "gel-forming polymer" were vague and ill-defined. These features are functionally defined and therefore include any compound/composition having the function in question. As a consequence, each of the features cited above includes a large, possibly even an indefinite number of individual constituents, which, however, does not render the claim *per se* ambiguous. In the present case, the board notes that these features are commonly used in the art and therefore comprehensible to the skilled person. As a consequence, the requirements of Article 84 EPC are met.

### 2.4 Remittal to the examining division

The essential function of an appeal is to consider whether the contested decision 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 by the boards in cases where a first-instance department issues a decision against a party based upon certain issues only which are decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issues is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111 EPC).

The observations made above apply fully to the present case, where the examining division issued a decision which is solely based on Articles 123(2) and 54 EPC.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman

L. Fernández Gómez

U. Oswald