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**Datasheet for the decision  
of 20 March 2019**

**Case Number:** T 0072/17 - 3.3.07

**Application Number:** 12160674.3

**Publication Number:** 2502622

**IPC:** A61K9/48

**Language of the proceedings:** EN

**Title of invention:**

Pharmaceutical formulation comprising inositol

**Applicant:**

LO. LI. Pharma S.r.l.

**Headword:**

Inositol/ LOLI

**Relevant legal provisions:**

EPC Art. 123(2), 56

**Keyword:**

Amendments - allowable (yes)  
Inventive step - (yes)



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Case Number: T 0072/17 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 20 March 2019**

**Appellant:** LO. LI. Pharma S.r.l.  
(Applicant) Via dei Luxardo 33  
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**Representative:** Grünecker Patent- und Rechtsanwälte  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 29 July 2016  
refusing European patent application No.  
12160674.3 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** J. Riolo  
**Members:** A. Usuelli  
Y. Podbielski

## Summary of Facts and Submissions

I. The appeal of the applicant (hereinafter: the appellant) lies from the decision of the examining division to refuse European patent application No. 12 160 674.3. The decision was based on a set of claims filed on 8 July 2016. Claim 1 of this set of claims read as follows:

"1. A swallowable soft capsule composed of a gelatin-based shell that contains a filling consisting of inositol and excipients or a filling consisting of inositol, excipients and at least one further active principle; wherein said further active principle is selected in the group consisting of folic acid, cocoa polyphenols, genistein, L-arginine, vitamin E, selenium, N-acetylcysteine, and melatonin; wherein said filling is in a liquid or semi-liquid vehicle, together with supplementary excipients as necessary; said vehicle comprising gelatin, glycerol or mixture thereof."

II. The following documents were among those cited in the decision:

D1: US 2007/243211

D2: The New England Journal of Medicine, 1999,  
1314-1320

The decision also referred to an experimental report on stability filed by the appellant on 30 May 2016.

III. The examining division considered that the subject-matter of claim 1 covered the following two separate embodiments:

- (a) - inositol as the only active ingredient
- (b) - inositol in combination with other active ingredients

With regard to embodiment (a) the examining division held that the original application did not provide a basis for a composition consisting of inositol and excipients. With regard to embodiment (b) it came to the conclusion that the combination of inositol with the specific active ingredients recited in claim 1 could not be derived directly and unambiguously from the original application. Thus, both embodiments (a) and (b) were considered to offend against Article 123(2) EPC.

Document D1, relating *inter alia* to compositions in form of softgel capsules, was the closest prior art for the assessment of inventive step. The compositions defined in embodiments (a) and (b) differed from the disclosure of D1 essentially in the nature of the active ingredient(s). In the absence of any technical effect achieved over the whole scope of claim 1 the technical problem was the provision of alternative softgel formulations. The examining division held that embodiments (a) and (b) were obvious solutions of this problem having regard to the teaching of D1 alone.

- IV. With the statement setting out the grounds of appeal filed on 8 December 2016, the appellant submitted a main request and eight auxiliary requests.

The main request was identical to the request forming the basis of the decision under appeal. Auxiliary request 1 differed from the main request in the corrections of some errors in dependent claims 4 and 9.

- V. In a communication pursuant to Article 15(1) RPBA issued on 21 January 2019, the Board expressed the view that the main request complied with Articles 123(2) and 56 EPC. It further took note of the corrections made to the main request in auxiliary request 1 and informed the appellant that it intended to remit the case to the examining division with the order to grant a patent on the basis of auxiliary request 1.
- VI. In a letter dated 8 March 2019 the appellant asked that auxiliary request 1 filed on 8 December 2016 with the statement setting out the grounds of appeal be considered as the new main request. It requested to set aside the decision of the examining division and to grant a patent on the basis of the new main request.
- VII. By letter of 15 March 2019 the Board informed the appellant that the oral proceedings originally scheduled for 8 April 2019 were cancelled.
- VIII. In the statement setting out the grounds of appeal the appellant argued that embodiment (a) of claim 1 had a basis for instance on page 7, lines 9 to 10, of the original application. Page 8, lines 8 to 18, disclosed the active ingredients used in combination with inositol according to embodiment (b) of claim 1. Thus, both embodiments covered by claim 1 had a basis pursuant to Article 123(2) EPC in the original application.

As to inventive step, the appellant observed that the formulations defined in claim 1 were stable and provided an improved bioavailability of inositol. D1 could not be regarded as the closest prior art since it did not relate to the same purpose as the invention underlying the present application. The conclusions of

the examining division were therefore based on an *ex post facto* analysis. The subject-matter of claim 1 was in any case inventive over D1 considered alone or in combination with the other cited documents.

## **Reasons for the Decision**

Main request (filed on 8 December 2016 as auxiliary request 1)

1. Article 123(2) EPC

1.1 As stated by the examining division in the decision under appeal claim 1 covers two groups of compositions, namely:

(a) compositions containing inositol as the only active ingredient, and

(b) compositions containing inositol in combination with other specific active ingredients.

1.2 Page 7, lines 6 to 10 of the application as filed indicates that the soft capsules of the invention may be composed of a shell that contains inositol and excipients. This disclosure provides a basis for the compositions containing inositol as the only active ingredient (embodiment a).

1.3 The combination of inositol with the specific active ingredients recited in claim 1 (embodiment b) finds a basis on page 8, lines 17 to 20 of the application as filed. This passage reads as follows:

*"The composition of the invention preferably also comprises at least one active principle different from inositol, for example, folic acid, cocoa polyphenols,*

*genistein, L-carnitine, L-arginine, vitamin E, selenium, N-acetylcysteine, and melatonin."*

The examining division saw a problem in considering this passage of the original description as a proper basis for embodiment (b) of claim 1 since the list of active ingredients to be used in combination with inositol is not exhaustive, due to the presence of the expression "for example".

The Board cannot follow this conclusion of the examining division. The wording "for example" suggests that the original description contemplated the possibility of combining inositol also with other active ingredients different from those listed in current claim 1. The fact that this possibility is not covered by claim 1 simply means that the passage of page 8 is broader than the scope of claim 1. This does not imply, however, that page 8 does not provide a proper basis pursuant to Article 123(2) EPC for the subject-matter of embodiment (b). The relevant question in this regard is whether the combination of inositol with the specific active ingredients recited in embodiment (b) can be derived directly and unambiguously from this passage. This is clearly the case since the passage explicitly mentions this combination.

- 1.4 It follows that both embodiments covered by claim 1 have a basis in the original application.
- 1.5 Dependent claims 2 to 10 have a basis in the claims of the original application. Thus, the subject-matter of the main request complies with Article 123(2) EPC.

2. Inventive step

2.1 The invention addresses the problem of providing compositions containing inositol, possibly in combination with other specific active ingredients, which are stable and provide high plasma concentration of inositol. These compositions are used in the treatment of polycystic ovarian syndrome (PCOS).

2.2 Closest prior art

2.2.1 D1, selected by the examining division as the closest prior art, concerns compositions that comprise a combination of substances belonging to four different classes of active ingredients (see [0009]). Inositol is not included in any of these classes but it may be present in the composition as an optional ingredient (see [0019]). The compositions are used in the regulation of disorders related to metabolism. D1 does not address the issue concerning the stability of inositol or the problem of providing compositions containing high plasma concentration of this substance. Nor does D1 relate to compositions useful in the treatment of PCOS.

Moreover, starting from the compositions of D1, in order to arrive at the subject-matter of claim 1 it would be necessary to modify the compositions by removing some active ingredients. This would be against the teaching of D1 that describes these substances as essential components of the composition.

For all these reasons, the Board concludes that D1 cannot be regarded as a suitable starting point for the assessment of inventive step.



2.2.2 Document D2 relates to a clinical study on the efficacy of orally administered inositol in the treatment of PCOS. The Board considers that this document is the closest prior art for the assessment of inventive step.

2.2.3 D2 does not provide any detail as to the composition of the inositol formulation used in the clinical study. Thus, the subject-matter of the main request differs from the disclosure of D2 mainly in that inositol is formulated in swallowable soft capsules as defined in claim 1.

### 2.3 Technical problem

2.3.1 The application discloses experimental data on the stability of the formulation of claim 1 (Table 1) and on the plasma concentration of inositol after administration of this formulation (Figure 1). These data are compared with those obtained from a formulation in powder form of inositol. Further experiments on the stability had been submitted by the appellant in an experimental report filed during the proceedings before the examining division on 30 May 2016.

The data on the stability in the application indicate that the loss of inositol in the formulation in powder form over 12 months is much larger than the corresponding loss in the capsules of claim 1 over the same duration (7.5% vs 0.8%).

The data on the plasma concentration (Figure 1 and paragraph [0025]) demonstrate that the capsules provide a better bioabsorption of inositol than the powder form. Indeed the administration of soft capsules containing a total amount of 6.6g of inositol results

in a serum concentration of inositol which can be achieved only by the administration of 20g of inositol in powder form.

2.3.2 D2 does not disclose any specific inositol formulation and therefore also not the inositol powder formulation used in the comparative tests discussed above (see also point 2.2.3 above). Hence, these experiments do not represent a comparison with the closest prior art. Nevertheless, they still provide valuable data with regard to the properties of the compositions of claim 1 and an indication that not any inositol composition possesses these properties. In other words they are an indication that the soft capsules defined in claim 1 have not been arbitrarily chosen.

2.3.3 In the light of the above considerations, the technical problem can be defined as the provision of inositol formulations which are stable and provide good results in terms of bioavailability of the active ingredient.

2.4 Obviousness

2.4.1 D2 fails to provide any hint towards providing inositol formulations in form of softgel capsules. D1 describes softgel capsules that may optionally comprise inositol. However, the skilled person would have no reason to consider the teaching of this document in combination with the teaching of D2 since the documents concern different pharmaceutical compositions and address different problems.

2.5 Hence, the subject-matter of the main request meets the requirements of Article 56 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 with the order to grant a patent on the basis of the main request (filed on 8 December 2016 as auxiliary request 1) and a description to be adapted.

The Registrar:

The Chairman:



B. Atienza Vivancos

J. Riolo

Decision electronically authenticated