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# Datasheet for the decision of 29 January 2015

**Case Number:** T 2263/10 - 3.3.07

**Application Number:** 05824409.6

**Publication Number:** 1833464

**IPC:** A61K9/14

**Language of the proceedings:** EN

**Title of invention:**
SOLID PHARMACEUTICAL COMPOSITION COMPRISING VALSARTAN

**Applicant:**
KRKA, tovarna zdravil, d.d., Novo mesto

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

**Keyword:**
Amendments - added subject-matter (no)

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**Case Number: T 2263/10 - 3.3.07**

# D E C I S I O N
# of Technical Board of Appeal 3.3.07
# of 29 January 2015

| | |
|---|---|
| **Appellant:** (Applicant) | KRKA, tovarna zdravil, d.d., Novo mesto<br>Smarjeska cesta 6<br>8501 Novo mesto (SI) |
| **Representative:** | Hoffmann Eitle<br>Patent- und Rechtsanwälte PartmbB<br>Arabellastraße 30<br>81925 München (DE) |
| **Decision under appeal:** | **Decision of the Examining Division of the European Patent Office posted on 30 June 2010 refusing European patent application No. 05824409.6 pursuant to Article 97(2) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | D. Semino |
| **Members:** | R. Hauss |
| | P. Schmitz |

## Summary of Facts and Submissions

I. The appeal by the applicant (appellant) lies from the decision of the examining division, pronounced on 8 June 2010 and posted on 30 June 2010, refusing European patent application No. 05824409.6.

II. The impugned decision was based on six sets of claims filed as main request and first to fourth auxiliary requests with the letter dated 7 May 2010, and as fifth auxiliary request during oral proceedings on 8 June 2010.

The examining division found that neither claim 1 of the main request nor claim 1 of any of the first to fourth auxiliary requests fulfilled the requirement of Article 123(2) EPC.

Pursuant to Rule 137(3) EPC, the fifth auxiliary request was not admitted into the proceedings because firstly, as claim 1 required a two-fold selection from the text of the application as originally filed, it did not meet the requirement of Article 123(2) EPC and secondly, the claims were of much broader scope than those of the higher ranking main request and auxiliary requests. Objections concerning lack of novelty and inventive step had already been raised against a similar request. The assessment of (even) the novelty of the new set of claims would require further investigations which could not be carried out during oral proceedings.

III. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal the appellant submitted a main request and auxiliary requests 1 to 3. The main request was identical to the fifth auxiliary request filed during oral proceedings before the examining division.

IV. With the letter of 15 October 2014 the appellant filed new sets of claims as auxiliary requests 2 and 3 to replace those previously on file, designating the latter as auxiliary requests 4 and 5 respectively.

V. In a communication issued in preparation for oral proceedings, the board indicated inter alia that if any of the appellant's requests were found to meet the requirement of Article 123(2) EPC, the board would be inclined to remit the case to the department of first instance, since that department had not yet decided on the issues of novelty and inventive step.

In the board's communication it was mentioned that in the year 2012, European patent No. 2033629 was granted based on a divisional application of the present application and that granted claim 1 of said patent was nearly identical with claim 1 of the pending main request of the present appeal proceedings.

VI. With the submission of 5 December 2014, the appellant withdrew the main request and auxiliary requests 1, 4 and 5, previous auxiliary request 2 becoming the new main request and previous auxiliary request 3 remaining as the only auxiliary request.

VII. The sole claim of the main request reads as follows:

"*1. A process for preparing a pharmaceutical composition containing valsartan which comprises the following steps:*

- *providing valsartan particles having a maximum diameter of 1100 µm*
- *granulating a mixture of valsartan and excipients using water as granulation liquid to obtain a granulate,*
- *adding further excipients to said granulate to give a compression mixture,*

- *compressing the compression mixture to the desired form, and*
- *optionally, applying a coating,*

*wherein the excipients include at least one disintegrant that is selected to be cross-linked carboxymethylcellulose sodium,*

*wherein the pharmaceutical composition containing valsartan is a solid pharmaceutical composition containing valsartan particles characterized in that the* $D_{50}$ *of said valsartan particles is 150 µm or below and that the valsartan particles have a maximum diameter of no more than 1100 µm, as determined by electron microscopy, and/or*

*wherein the pharmaceutical composition containing valsartan is a solid pharmaceutical composition comprising 30-70 wt.-% of valsartan, 10-70 wt.-% of a diluent, 1-20 wt.-% of a disintegrant, 1-20 wt.-% of a binder and 1-10 wt.-% of a lubricant."*

VIII. The board cancelled the oral proceedings scheduled for 11 December 2014.

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

The sole claim of the new main request was based on the text passage on page 7, line 33 to page 8, line 10 together with the text passages on page 5, lines 25 to 28, page 6, lines 1 to 5 as well as page 14, lines 13 to 15 and 23 to 36 of the application as filed.

The statement on page 7, lines 33 to 36 contained a cross-reference to the "*pharmaceutical composition as defined in any of the above aspects*", thereby providing support for the claimed combination of process and product features. The two alternative aspects of the composition characterised in the claim of the main

request were the only two "independent" aspects cross-referenced on page 7 of the application as filed.

It did not take a two-fold selection of features from lists to arrive at the claimed combination of technical features, because cross-linked carboxymethylcellulose sodium was clearly the most preferred disintegrant, to be used with any of the process embodiments of the application, in particular in a process including a wet granulation step.

X. The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance.

The case was to be examined on the basis of the claims of the main request or the auxiliary request, filed with the letter of 15 October 2014 as auxiliary requests 2 and 3 respectively.

## Reasons for the Decision

1. Amendments (Article 123(2) EPC) - main request

1.1 The specific process embodiment in which a granulate is prepared which includes valsartan, the granules are mixed with further excipients and the resulting mixture is compressed to a desired form is disclosed on page 7, line 33 to page 8, line 10 and in claim 18 of the application as filed. Here, in the feature relating to the granulation step of the process, it is specified that a mixture of valsartan particles and excipients is granulated "using water or an aqueous dispersion as granulation liquid".

1.2 The process defined in the claim of the main request differs from this embodiment in that the use of "an aqueous dispersion" as granulation liquid has been

deleted, and it has further been specified that "the excipients include at least one disintegrant that is selected to be cross-linked carboxymethylcellulose sodium". Furthermore, the claim has been further limited by reference to specific technical features of the pharmaceutical composition to be prepared, namely certain valsartan particle size parameters and/or the specific percentages of valsartan, diluent, disintegrant, binder and lubricant contained therein (see the last two paragraphs of the claim).

1.2.1 With respect to the first difference, the feature "using water as granulation liquid" merely requires the presence of water to moisten the mixture during the granulation step. Such wording does not exclude embodiments wherein said water is added to the granulation mixture in the form of a pre-mix which is an aqueous dispersion of an excipient.

Hence, the use of water as granulation liquid encompasses the use of "an aqueous dispersion" as granulation liquid, so that in fact by means of the deletion the generic embodiment is maintained and a more specific embodiment is deleted.

1.2.2 As far as the second difference is concerned, the original description (page 14, lines 1 to 26) explains that cross-linked carboxymethylcellulose sodium, as a disintegrant which can advantageously be used both intra- and extragranulary, is preferable to crospovidone (used in the prior art) in the formulation of valsartan by wet granulation with water. Cross-linked carboxymethylcellulose sodium and starch are the preferable disintegrants. In the light of the process examples however, all but one of which employ cross-linked carboxymethylcellulose sodium as disintegrant and none of which employ starch, it becomes clear that the

former is the most preferred disintegrant according to the originally filed application. Said process examples use the process embodiment according to present claim 1 wherein valsartan is included in the granules.

1.3 Combining one embodiment of the preparation process with the most preferred excipient is a combination which the skilled person would extract without any doubt from the application as originally filed.

1.4 With respect to the technical features defining the pharmaceutical composition which is to be prepared (claim 1, last two paragraphs), original claim 18 makes reference to a process for preparing "a pharmaceutical composition according to any of the preceding claims". Original independent claims 1 and 8 define a solid pharmaceutical composition containing valsartan particles having a $D_{50}$ of 150 µm or below and having a maximum diameter of no more than 1100 µm as determined by electron microscopy (claim 1), or a solid pharmaceutical composition comprising certain specific percentages of valsartan, diluent, disintegrant, binder and lubricant (claim 8).

Furthermore, the process defined on page 7, line 33 to page 8, line 10 is defined as being "a process for preparing the pharmaceutical composition as defined in any of the above aspects". The "aspects" in turn correspond to the combinations of features as defined in product claims 1 and 8 (see page 5, line 25 to page 6, line 18, and in particular page 5, lines 25 to 28, 33 to 35 and page 6, lines 1 to 5).

1.5 Thus there is no doubt that the process for preparing the pharmaceutical combination according to the claim of the main request is disclosed in the description as originally filed in direct association with the product features as defined in the claim.

1.6 As a consequence, the board has come to the conclusion that the requirement of Article 123(2) EPC is met by the claim of the main request.

2. Remittal (Article 111(1) EPC)

2.1 The impugned decision only concerns objections raised under Article 123(2) EPC.

2.2 Since the department of first instance has not yet decided on the issues of novelty and inventive step, the board deems it appropriate to remit the case, all the more so in view of the opposition proceedings concerning European patent No. 2033629, issued from a divisional application and containing claims similar to those under analysis in the present case (see point V. *supra*).

**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:

S. Fabiani D. Semino

Decision electronically authenticated