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**Datasheet for the decision
of 12 December 2013**

Case Number: T 1319/09 - 3.3.07
Application Number: 98932185.6
Publication Number: 1010423
IPC: A61K9/16, A61K9/50
Language of the proceedings: EN

Title of invention:

ORAL PHARMACEUTICAL PREPARATION COMPRISING AN ANTIULCER
BENZIMIDAZOLE DERIVATIVE, AND PROCESS FOR ITS PRODUCTION

Patent Proprietor:

Liconsá, Liberación Controlada de Sustancias
Activas, S.A.

Opponents:

KRKA, tovarna zdravil, d.d., Novo mesto
AstraZeneca AB

Headword:

-

Relevant legal provisions:

EPC Art. 100(c), 123(2), 84

Keyword:

Amendments - added subject-matter (yes)
Claims - clarity - auxiliary request (no)

Decisions cited:

Catchword:

-



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 1319/09 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 12 December 2013

Appellant: Liconsa, Liberacion Controlada de Sustancias
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 9 April 2009
revoking European patent No. 1010423 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman: J. Riolo

Members: R. Hauss

D. T. Keeling

Summary of Facts and Submissions

I. European patent No. 1 010 423 was granted on the basis of fifteen claims.

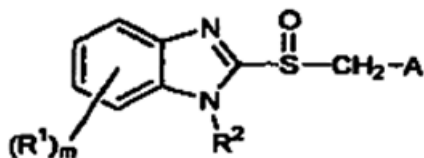
Independent claim 1 reads as follows:

"1. Procedure for making an oral pharmaceutical preparation consisting of

a) an inert nucleus;

b) a soluble active layer or layer which disintegrates rapidly in water, made from a single aqueous or hydroalcoholic solution-suspension which includes:

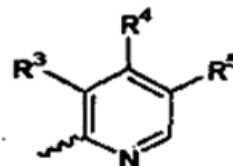
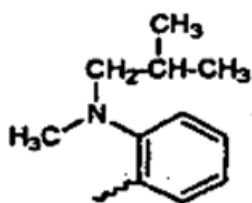
- an active ingredient of anti-ulcer activity of general formula I



I

in which:

A can be:



wherein:

R^3 and R^5 are the same or different, and may be hydrogen, alkyl, alkoxy, or alkoxyalkoxy;

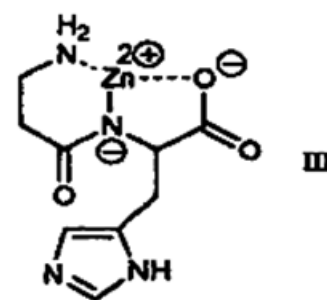
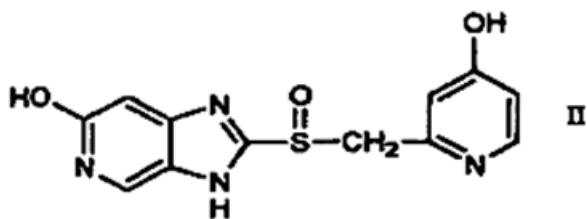
R^4 is hydrogen, alkyl, alkoxy which can optionally be fluorinated, alkoxyalkoxy, or alkoxyalkyl;

R^1 is hydrogen, alkyl, halogen, cyano, carboxy, carboalkoxy, carboalkoxyalkyl, carbamoyl, carbamoylalkyl, hydroxy, alkoxy, hydroxyalkyl, trifluoromethyl, acyl, carbamoyloxy, nitro, acyloxy, aryl, aryloxy, alkylthio or alkylsulfinyl;

R^2 is hydrogen, alkyl, acyl, carboalkoxy, carbamoyl, alkylcarbamoyl, dialkylcarbamoyl, alkylcarbonylmethyl, alkoxy carbonylmethyl or alkylsulfonyl; and

m is an integer from 0 a 4;

or of formula II or III,



- an alkaline reacting compound and
- at least one pharmaceutically acceptable excipient selected from the group which includes: a binder, a surface-active agent, a filling material and a disintegrating-swelling excipient;

and

c) a gastro-resistant outer coating made from a solution which includes:

- an enteric coating polymer; and
- at least one excipient chosen from the group which includes: a plasticizer, a surface-active agent, a pigment and a lubricant,

being the procedure characterized in that the following steps are carried out:

1) coating of the inert nucleus by spraying with a single aqueous or hydroalcoholic suspension-solution, which includes the active ingredient, the alkaline reacting compound and the pharmaceutically acceptable excipient or excipients;

2) drying the active layer formed in step 1;

3) coating of the charged nuclei by spraying a solution which contains the enteric coating polymer and the pharmaceutically acceptable excipient, in order to form the gastro-resistant external coating layer;

being all the steps performed in a single fluidized bed coater."

II. Two notices of opposition were filed in which the patent was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.

III. The documents cited during the opposition and appeal proceedings included the following:

D9: Pharmaceutical Pelletization Theory, editor Isaac Ghebre-Sellassie, New York 1989, 145-149

D13: Pharmaceutical Dosage Forms, vol. 3, ed. H.A. Lieberman & al., 2nd edition New York 1990, 138-150

D14: Int. J. Pharm. Tech. & Prod. Mfr. 2(4), 31-43 (1981)

D17: US 2 648 609

D20: Hunnius Pharmazeutisches Wörterbuch, 7th edition Berlin 1993, 924-925

D21: Int. J. Pharm. Tech. & Prod. Mfr. 3(1), 27-32
(1982)

IV. The appeal lies from the decision of the opposition division pronounced in oral proceedings on 11 March 2009 and posted on 9 April 2009, revoking the patent.

The impugned decision is based on the patent proprietor's main request, directed to the rejection of the oppositions, and on two sets of claims submitted during oral proceedings as first and second auxiliary requests.

The opposition division decided with regard to the main request that the subject-matter of claim 1 as granted extended beyond the content of the application as filed in respect of the term "fluidized bed coater" employed in said claim. In that context, the opposition division held that the application as filed disclosed neither explicitly nor implicitly that the fluidised-bed equipment to be used was, specifically, a coater. Nor did the application as filed provide support for extrapolation (or generalisation) from the more specific "'Wurster' type fluid bed" mentioned throughout to any type of fluidised-bed coater.

The patent proprietor's first auxiliary request was not admitted into the proceedings.

Claim 1 of the second auxiliary request was identical to claim 1 as granted, except that the term "*fluidized bed coater*" was replaced by: "*Wurster type fluid bed, in which the coating process is carried out*", based on the text of the application as filed, page 6, lines 11 to 12. The amended term was found to lack clarity within the meaning of Article 84 EPC, as its scope could not be determined with regard to apparatus requirements and with regard to the question of which

variations were possible within the scope of "Wurster type" configurations.

- V. The appellant (patent proprietor) lodged an appeal against that decision.

With the statement setting out the grounds of appeal, dated 19 August 2009, the appellant requested that the patent be maintained as granted and also submitted a first auxiliary request consisting of fifteen claims, identical to the former second auxiliary request dealt with in the opposition proceedings.

In a letter dated 12 November 2013 the appellant also requested that the case be remitted to the department of first instance should the board find one of the pending requests to meet the requirements of Articles 84 and 123 EPC.

- VI. With a submission dated 22 November 2013, the appellant filed another set of claims as its second auxiliary request.

The wording of claim 1 of the second auxiliary request is identical to the wording of claim 1 as granted, except that the expression "*fluidized bed coater*" is replaced by "*fluid bed, in which the coating process is carried out*".

- VII. With a letter dated 26 November 2013, respondent 2 (opponent 2) announced that it would not be represented at the oral proceedings scheduled for 12 December 2013.

- VIII. Oral proceedings before the board took place on 12 December 2013, in the absence of respondent 2.

- IX. The appellant argued as follows:

Main request, added subject-matter (Article 100(c) EPC)

While the term "fluidized bed coater" was not literally disclosed in the application as filed, a person skilled in the art would directly and unambiguously derive from the teaching of the application that the process steps were to be carried out in a fluidised-bed coater.

According to said teaching, fluidised-bed coating was carried out in steps 1) and 3) of the process by applying onto the inert nuclei a single solution or suspension which contained the active agent and excipients. In that way, breakage and abrasion could be minimised in comparison with abrasive coating techniques of the prior art which used a rotogranulating machine (which imparted shear forces to the particles, exercised by a rotary disc). Single-solution coating as required by the claimed process did not involve dusting the inert nuclei with a solid powdered material combined with an aqueous binder, as in a typical three-component granulation process. Hence it was implicit that a coater and not a granulator was to be used. It was furthermore mentioned in the patent in suit that all process steps were carried out in the same fluidised-bed equipment.

As far as the coating equipment was concerned, the application clearly did not intend to restrict the scope only to Wurster-type coaters. Rather, it was mentioned repeatedly that a "'Wurster' type fluid bed or the like", or a "'Wurster' type fluid bed or similar equipment" was to be used. A reader skilled in the art would infer that any fluidised-bed coating equipment could be used which was suitable for carrying out the process of the invention, said process involving single-solution coating steps to yield uniformly coated particles.

First auxiliary request, clarity (Article 84 EPC)

Taking into account the technical teaching of the patent in suit, the person skilled in the art would clearly understand that the "Wurster type fluid bed, in which the coating process is carried out", as defined in claim 1 of the first auxiliary request, was a Wurster-type fluidised-bed coater. The essential features of such a coater were universally known, as shown in documents D13 (page 139, figure 24) and D14 (figure 3). Hence, the person skilled in the art would have no doubt what equipment was to be used.

Even though documents D13 and D14 each contained a reference to document D17 (the patent describing the original Wurster design), both documents clearly indicated the technical features of the apparatus which were required. Well aware of the design of current coatiers as typically described in D13 or D14, the skilled person would disregard the much older disclosure of D17.

It was irrelevant to ask, as the respondents did, whether designs involving top-spray coating (such as disclosed in document D20 on page 925) or other designs which were described as "similar" to Wurster-type coatiers (such as disclosed in document D21 in figure 9) were included by the term: "Wurster type fluid bed, in which the coating process is carried out". All that mattered was that the single-solution spray coating process carried out in the coating apparatus had to result in the uniformly coated oral pharmaceutical preparation as defined in claim 1 of the first auxiliary request.

Second auxiliary request

In its written submissions, the appellant indicated the following passages of the application as the basis for the amendment introducing the term "*fluid bed, in which*

the coating process is carried out": page 6, lines 11 and 12, and page 10, line 18, to page 12, line 34.

In the oral proceedings, the appellant did not contest the board's statement that the scope of claim 1 of the second auxiliary request was the same as the scope of claim 1 of the main request, and that the issues to be dealt with were therefore the same.

X. The respondents argued as follows:

Main request, added subject-matter (Article 100(c) EPC)

The feature in claim 1: "being all the steps performed in a single fluidized bed coater" did not have a basis in the text of the application as filed.

The application consistently stated that all process steps were to be performed in a Wurster-type or similar fluidised-bed equipment. The term "Wurster type fluid bed" referred to a specific design and technique. That disclosure, even if including similar equipment, was therefore more limited in scope than the term "fluidized bed coater", which constituted an unwarranted generalisation.

The only passage in the application as filed which did not mention the limitation "Wurster type" was found on page 6, lines 29 to 34, stating that unlike what happened in the prior art, the entire process of the invention was carried out using a single piece of fluid bed equipment.

In the context of the application seen as a whole, that passage would not, however, be understood as an independent disclosure of fluidised-bed equipment in general, including other than Wurster-type equipment. Rather, it constituted a mere paraphrasing comment on the concept that all process steps were to be carried out in the same Wurster-type equipment.

The passage in question had been interpreted in that sense by the appellant itself throughout the examination and opposition proceedings.

Also, according to the teaching of the application as filed, the use of a Wurster-type fluidised-bed configuration was presented as the solution to the problem of avoiding disadvantages such as abrasion and breakage incurred by the use of rotogranulating machines employed in the prior art. Thus, rotogranulating machines were clearly not intended to be used in the claimed process, although such machines were, in fact, covered by the term "fluidized bed coater" since they employed a fluidised bed and were suitable for carrying out the required single-solution spray coating steps. The skilled reader would accordingly infer that the application was directed only to a process employing Wurster-type fluidised-bed equipment.

First auxiliary request, clarity (Article 84 EPC)

Since the term "Wurster type" did not have a well-defined meaning, its introduction into claim 1 contravened the requirements of Article 84 EPC.

The term "Wurster type" was not defined in the patent in suit. Comparing the respective disclosure of documents D13, D14, D17 and D20, it appeared that different combinations of technical features were presented in the prior art as essential to Wurster-type fluidised-bed apparatus. Hence, the term did not have a universally accepted meaning. Moreover, document D21 presented a design (D21: figure 9) said to present "many similarities to the Wurster principle" but lacking the inner coating partitions. With the available information, the person skilled in the art was not in a position to decide whether such equipment

was included in the scope of the term "Wurster type fluid bed, in which the coating process is carried out".

- XI. The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance on the basis of claims 1 to 15 as granted or, in the alternative, on the basis of claims 1 to 15 of the first auxiliary request filed with letter of 19 August 2009 or on the basis of claims 1 to 15 of the second auxiliary request filed with letter of 22 November 2013.
- XII. Respondent 1 (opponent 1) requested that the appeal be dismissed.
- XIII. Respondent 2 (opponent 2) had requested in writing that the patent be revoked, which is understood by the board as a request that the appeal be dismissed.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Analysis of terms
 - 2.1 As previously mentioned in a communication dated 20 November 2013 advising the parties of the board's preliminary opinion, the term "coater" employed in claim 1 of the main request is a purely functional description which, in the absence of other defining features, must be understood to designate any apparatus or equipment which is suitable for carrying out a coating process.

- 2.2 Accordingly, a "fluidized bed coater" is any apparatus suitable for coating a material, working with a fluidised-bed configuration.
- 2.3 "Fluid bed" is understood to have the same meaning as "fluidized bed".
3. Main request, added subject-matter (Article 100(c) EPC)
- 3.1 Claim 1 is directed to a process ("procedure") for making an oral pharmaceutical preparation. The definition of said process contains the requirement that all process steps are to be "performed in a single fluidized bed coater".
- 3.2 The process claims of the application as filed (former claim 14 and dependent claims 15 to 25) do not contain such a feature. The figures show coated pellets and do not provide any information about the equipment used.
- 3.3 Hence, it must be established whether the text of the description as filed provides adequate support for the amendment introducing the feature in question.
- 3.3.1 The term "fluidized bed coater" is not mentioned literally in the text of the application.
- 3.3.2 The application as filed mentions consistently in various passages on pages 4, 6, 11 and 12 that all process steps (i.e. the mandatory coating and drying steps) are to be carried out in "a 'Wurster' type fluid bed or the like". Variations of that wording which are also used are "a 'Wurster' type fluid bed or similar equipment" or "a fluid bed of the 'Wurster' type or the like".
- In particular, as stated on page 12, lines 30 to 34:
"From the time that charging of the inert nuclei starts

until the enteric coating is completed, the entire procedure is carried out on a single 'Wurster' type fluid bed or the like, unlike other procedures which take place on several different pieces of equipment".

The qualified term "'Wurster' type fluid bed or the like" is more restricted in scope than the general term "fluidized bed". Only a sub-group of fluidised-bed equipment is of the Wurster type, other fluidised-bed equipment is not of the Wurster type. The meaning of the additions "or the like" and "or similar equipment" has not been defined and cannot, in any case, serve to extend the scope of the term to include all equipment which is not of the Wurster type.

Consequently, the passages in the application as filed which refer to "'Wurster' type fluid bed" and to "similar" equipment cannot provide an adequate basis for the amendment in claim 1 of the main request employing the more general term "fluidized bed coater".

3.3.3 In addition to the above-cited references to "Wurster type" equipment, the following comment is found on page 6, lines 29 to 34: "Likewise, unlike what happened in the prior art (...), in which the manufacturing procedure was carried out using several different pieces of equipment, in the present invention the entire process is carried out using a single piece of fluid-bed equipment, thereby minimizing loss of time and of product, while more easily complying with Good Manufacturing Practice (GMP) for medicaments."

The cited passage refers to "fluid-bed equipment" without mentioning the limiting term "'Wurster' type" or the word "coater".

Since the process for which the equipment is to be used comprises two essential mandatory coating steps involving liquid-spray coating, combined with an

intermediate drying step, it is however already implied in the process requirements that the equipment used must be suitable for coating and hence that it is a coater in the sense explained in point 2.1 *supra*.

In order to determine whether the passage on page 6, lines 29 to 34, could serve as a basis for the feature "being all the steps performed in a single fluidized bed coater", the question to be answered is whether said passage would be understood by the skilled reader as an independent, general disclosure of any type of fluidised-bed equipment including non-Wurster-type, or whether it would be understood as a mere paraphrasing comment on the situation that the same Wurster-type fluidised-bed equipment is used for all process steps, as mentioned on page 12, lines 30 to 34 (see point 3.3.2 *supra*).

a) The passage on page 6, lines 29 to 34, of the application as filed, rather than expanding on the specific type of equipment, stresses the point that, in contrast to prior art processes, only one piece of equipment is needed for all process steps. In the immediate and general context of the passage in question, it cannot therefore be ruled out that nothing more than a reference to the more precisely designated Wurster-type equipment mentioned elsewhere in the text was actually intended.

b) Nor is that interpretation contradicted by the appellant's previous statements during opposition proceedings. On page 3 of a letter dated 2 July 2007 the appellant stated that the term "single piece of fluid-bed equipment" referred to the fluid bed coater of the "Wurster" type or the like mentioned in lines 11 to 12 on page 6 of the application as filed.

c) It is also mentioned in the description that the process of the invention, due to the avoidance of detrimental shear forces, is superior to prior-art processes using rotogranulating machines. As submitted by respondent 1, this may serve as a further indication of the intended meaning.

On page 3 of the description (lines 2 to 9) it is mentioned that the technique of using a rotogranulating machine, known from the prior art, is very abrasive. Apart from the abrasion of the particles against the walls of the machine due to the thrust of the air, a situation normal in any fluid bed, there is a shear force exercised by the rotary disc of the rotogranulating machine. All this often leads to problems such as breakage and abrasion of the granules.

It can be inferred from that passage, and also from document D13 which shows the design of a roto-granulating machine (see D13: page 142, figure 26 (c)), that a rotogranulating machine is suitable for coating and works with a fluidised-bed configuration. Hence, a rotogranulating machine is in fact a fluidised-bed coater.

It is however evident from the text of the application as filed that a different process was sought which did not involve the use of a rotogranulating machine, so as to avoid damage caused by excessive shear.

On page 4, lines 6 to 11, it is mentioned that "in the present invention a formulation and a working methodology in a fluid bed of the 'Wurster' type or the like have been developed. In it, negative factors which affected the methods described to date are eliminated and substantial changes introduced with respect to the methods of previous patents for pellets containing benzimidazole."

On page 6, line 11 to 13, it is mentioned that the "Wurster" type fluid bed or the like in which the coating process is carried out minimises the abrasion caused by rotogranulation and that it is therefore unnecessary to use a specially hard nucleus.

On page 12, lines 25 to 27, it is furthermore mentioned that "a fluid bed of the Wurster type or the like is used, this being much less abrasive than the rotogranulating machine which has to be used when a seeding nucleus is coated with an active powder and a binder solution."

It can be inferred from the cited passages that the use of a rotogranulating machine is to be avoided. Instead, it is presented as essential for the inventive process that a "Wurster" type fluidised-bed configuration "or the like" be used, as an alternative to a roto-granulating machine, to provide the advantage of avoiding abrasion and breakage caused by excessive shear.

Thus the process of the alleged invention was not actually intended to encompass the use of any type of fluidised-bed coaters, which would include rotogranulating machines, but is taught to be based on the use of "Wurster type" equipment "or the like", which is more restricted in scope.

For all these reasons, the board agrees with the respondents' view that the passage on page 6, lines 29 to 34, cannot be regarded as a direct and unambiguous disclosure of fluidised-bed coaters in general, i.e. all non-Wurster-type coaters in addition to Wurster-type coaters.

- 3.3.4 No other passage has been identified in the text of the application as filed on which the introduction of the

general term "fluidized bed coater" into claim 1 could be based.

3.4 Hence the board concludes that the text of the application as filed does not provide adequate support for the generalised term "fluidized bed coater". As a consequence, said term introduces into claim 1 subject-matter extending beyond the content of the application as filed.

4. First auxiliary request, clarity (Article 84 EPC)

4.1 Claim 1 of the first auxiliary request contains the feature "Wurster type fluid bed, in which the coating process is carried out".

That feature was not present in the claims as granted, but was taken from the description (see page 6, lines 11 to 12).

When substantive amendments are made to a patent, both the opposition division and the board of appeal have the power, conferred by Article 101(3) EPC, to deal with issues arising from those amendments, including issues under Article 84 EPC.

4.2 The issue in the present case was whether it was clear what restrictions, in terms of technical features, had been introduced into process claim 1 of the first auxiliary request by the term "Wurster type".

4.3 Most commonly, the term appears to refer to fluidised-bed equipment containing a cylindrical/tubular inner partition in the coating chamber and using a bottom-spray technique (see D9: page 151; D13: figures 24, 26b; D14: figure 3).

- 4.4 However, document D17 of 1953, the original Wurster patent, does not disclose the feature of an inner partition. Document D20 on the other hand presents a top-spray technique as a "Wurster" process (page 925, figure 2, and column 2, lines 5 to 11).
- 4.5 The differences in the cited prior-art disclosures raise some doubt as to which technical features are mandatorily implied by the expression "Wurster type".
- 4.6 The appellant's argument that the skilled person would simply disregard documents D17 and D20 is not convincing. In view of the lack of a universally recognised precise meaning, and in the absence of any indication in the patent of what is considered to be a "Wurster" fluid bed or a "Wurster type" fluid bed, it is in fact not possible for the skilled reader to determine the intended scope of claim 1. He would thus not in all cases be in a position to decide if a given process using some kind of fluidised-bed equipment met the qualification "Wurster type".
- 4.7 The appellant also argued that it was irrelevant whether top-spray or bottom-spray equipment or an inner partition was to be used and that only the structure and properties of the final product (the coated particles) should be taken into account to establish which equipment was suitable for preparing such a product. That argument cannot succeed, in view of the fact that claim 1 is directed to a process, defined by the indication of mandatory process steps and of the apparatus to be used for carrying out those steps. The indication of the equipment to be used, "Wurster type fluid bed", is part of the actual definition of the process. Therefore the skilled person should be able to determine the scope, in terms of the mandatory

features, of the equipment from the wording of the claim, which is not the case in the present instance.

4.8 As a consequence, the board finds that the definition of claim 1 is not clear within the meaning of Article 84 EPC with regard to the term "Wurster type fluid bed".

5. Second auxiliary request

5.1 The meaning and scope of the feature of claim 1: "being all the steps performed in a single fluid bed, in which the coating process is carried out" is the same as the scope of the corresponding feature of claim 1 of the main request: "being all the steps performed in a single fluidized bed coater". This has not been contested by the appellant.

5.2 Hence, the same objection applies as in the case of claim 1 of the main request, viz. the feature in question does not find an adequate basis in the text of the application as filed, for the same reasons as explained above in the context of the main request.

5.3 As a consequence, the subject-matter defined in claim 1 of the second auxiliary request extends beyond the content of the application as filed, in contravention of the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



L. Fernández Gómez

J. Riolo

Decision electronically authenticated