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**Datasheet for the decision  
of 28 November 2012**

**Case Number:** T 0385/08 - 3.3.04

**Application Number:** 98500119.7

**Publication Number:** 884054

**IPC:** A61K 38/55

**Language of the proceedings:** EN

**Title of invention:**

Fixed-dose association of an angiotensin-converting enzyme inhibitor and of a calcium channel antagonist for the treatment of cardiovascular illnesses

**Patentee:**

Ferrer Internacional, S.A.

**Opponent:**

MEDICAMED Produtos Médicos e Farmacêuticos S.A.

**Headword:**

Fixed-dose association/FERRER INTERNACIONAL

**Relevant legal provisions:**

EPC Art. 56  
RPBA Art. 12(4)

**Keyword:**

"Main request - inventive step (no)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0385/08 - 3.3.04

**DECISION**  
of the Technical Board of Appeal 3.3.04  
of 28 November 2012

**Appellant:** MEDICAMED Produtos Médicos e Farmacêuticos S.A.  
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**Respondent:** Ferrer Internacional, S.A.  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 30 November 2007  
rejecting the opposition filed against European  
patent No. 884054 pursuant to Article 101(2)  
EPC.

**Composition of the Board:**

**Chairman:** C. Rennie-Smith  
**Members:** B. Claes  
R. Morawetz

## Summary of Facts and Submissions

- I. The appeal was lodged by the opponent (appellant) against the decision of the opposition division to reject the opposition against European patent No. 0 884 054 entitled "*Fixed-dose association of an angiotensin-converting enzyme inhibitor and of a calcium channel antagonist for the treatment of cardiovascular illnesses*", which was granted on European patent application 98500119.7.
- II. Claim 1 of the granted patent reads:
- "1. Fixed-dose association of an angiotensin-converting enzyme inhibitor and of a calcium channel antagonist, characterized in that said association comprises a dose of (a) enalapril in the form of sodium salt and another dose of (b) nitrendipine micronized, the dose of enalapril being from 2.5 to 20 mg and the dose of nitrendipine being from 5 to 20 mg, and in that it is to be administered in single-dose galenic form."
- III. The opposition had been filed on the grounds in Article 100(a) EPC (lack of inventive step pursuant to Article 56 EPC) and Article 100(b) EPC (lack of sufficiency of disclosure). The opposition division decided that none of these grounds were allowable. It decided in particular that the claimed subject-matter involved an inventive step in view of the effects of the claimed subject-matter shown in additional "comparative examples" which were filed by the applicant with a letter dated 16 July 2002 during the examination proceedings. The opposition division had furthermore not admitted into the proceedings one

document filed by the opponent shortly before the oral proceedings.

- IV. With the statement of the grounds for appeal, relating to objections on inventive step and sufficiency of disclosure, the appellant submitted seven further documents, including the document which the opposition division had not admitted into the proceedings and another document pertaining to new experimental evidence on comparative dissolution profiles.
- V. The respondent (patent proprietor) replied to the appellant's appeal with a letter dated 18 December 2008. With a further letter dated 29 July 2011, the respondent filed a new test report in reaction to the appellant's new experimental evidence on comparative dissolution profiles (see section IV, above).
- VI. Oral proceedings were held on 28 November 2012. At these oral proceedings the appellant, although duly summoned, was absent.
- VII. Reference is made to the following documents in this decision:

D1: US-A-4 703 038

D2: EP-A-0 545 194

D3: US-A-5 573 780

D4: WO 95/08987

D8: "Modern Pharmaceuticals", 3rd Edition, revised and expanded, Banker & Rhodes (Eds.), Drugs and the Pharmaceutical Sciences, Vol. 72, Marcel Dekker, Inc., 1996

VIII. The appellant's arguments, in as far as they are relevant for the present decision and relate to claim 1 of the patent, can be summarised as follows:

*Inventive step (Article 56 EPC)*

- Document (D1) represented the closest prior art. The subject-matter of claim 1 differed from the disclosure in document (D1) in that enalapril in the form of its sodium salt was combined with nitrendipine in the micronized form. These differences achieved an improved stability of enalapril and an improved solubility of nitrendipine. This led to two distinct problems i.e. a first problem to increase the stability of enalapril and a second problem to increase the dissolution rate of nitrendipine.
  
- The "comparative examples" as filed with the applicant's letter dated 16 July 2002 were not suitable for showing a synergistic effect because not all the galenic formulations compared could be prepared according to the patent in suit because they would then all have enalapril in the form of sodium salt. Moreover, further ingredients might be present in the compared compositions, such as a wetting agent which, as acknowledged in the prior art, also had an effect on the dissolution properties of nitrendipine. There was thus no

functional interaction between the features which achieved a combined technical effect which was different from the sum of the technical effects of the individual features (synergistic effect) and the subject-matter of claim 1 was merely an "aggregation or juxtaposition of features". It was thus sufficient to show that the individual features were obvious to establish that the aggregation of features did not involve an inventive step.

- The preparation of a stable enalapril compound in the form of a sodium salt was known in the art from both documents (D2) and (D3), whereby the process described in document (D3) was in fact identical to the process used in the patent in suit. The skilled person would therefore apply these teachings to the formulations of document (D1), when addressing the first problem.
  
- Document (D4) disclosed the common knowledge of using micronization for improving solubility of a compound. It explicitly states on page 1, in paragraph 3, that "*... the most suitable solution in connection with the too slow dissolution rate is represented by the pharmaceutical-technological approach being realized in the simplest way by micronization.*" The remainder of the paragraph was merely a general statement about 1,4-dihydropyridines but did not specifically address the solubility of nitrendipine as such. Therefore, document (D4) did not teach away from using micronization to achieve good solubilisation of nitrendipine. Document (D8) taught furthermore

that the solubility of micronized particles which have air adsorbed on their surfaces can be increased by using water-soluble agents having surface-active properties in combination with the respective particles. Similarly, dissolution agents, such as polyvinylpyrrolidone and sodium lauryl-sulphate, might be added to further improve the solubility of the micronized particles. Therefore, the skilled person expected that micronization resulted in an improved solubility of a drug, possibly in the presence of a dissolution agent which in fact was also used in the patent in suit.

- The subject-matter of claim 1 was therefore obvious and, hence, lacked an inventive step under Article 56 EPC.

IX. The respondent's arguments in as far as they are relevant for the present decision and relate to claim 1 of the patent can be summarised as follows:

*Admissibility of the documentary evidence filed during the appeal proceedings*

- The seven documents filed by the appellant with the statement of the grounds of appeal were late filed. The new experimental evidence on comparative dissolution profiles related to arguments which had already been dealt with during the opposition proceedings and could therefore have been filed earlier. The remaining documents did not add anything relevant over the disclosure in the documents on file.

- The respondent was aware of the consequence for the admissibility of its own new test report filed with letter dated 29 July 2011 if the board would not admit the appellant's documents, including the appellant's new experimental evidence on comparative dissolution profiles, into the proceedings.

*Inventive step (Article 56 EPC)*

- The opposition division had correctly ruled that, starting from document (D1) as closest prior art, any combination of cited prior art documents with this document failed to teach the skilled person a solution to the objective technical problem of providing a new association formulation of enalapril and nitrendipine with increased stability of enalapril and increased solubility of nitrendipine. Indeed the "comparative examples" provided with the letter of 16 July 2002 proved a synergistic effect on the solubility rate of the micronized nitrendipine by the combined use with the sodium salt of enalapril which was not derivable from the prior art.
- Furthermore, document (D4) disclosed that micronization of nitrendipine was not the processing method of choice to achieve improved solubility thereof in a medicament and the skilled person would rather consider the preparation method of document (D4), i.e. spraying, in order to improve its solubility. Document (D4) therefore led away from the claimed subject-matter.



- Figures 1 and 2 of the patent in suit showed that the formulations of both examples 1 and 2 provided a near to full dissolution of both enalapril and nitrendipine after 30 minutes. When taking this effect into account for assessing inventive step and taking into account the "comparative examples" provided with the letter of 16 July 2002, then the objective technical problem to be solved was the provision of a fixed-dose association formulation containing enalapril and nitrendipine with a faster dissolution of nitrendipine so that it dissolves as fast as enalapril. An obvious solution for this problem was not available from the cited prior art.
  
- When solely taking the data of the "comparative examples" provided with the letter of 16 July 2002 into account, then the objective technical problem to be solved by the claimed subject-matter was the provision of a fixed-dose association containing enalapril and nitrendipine having an improved dissolution rate of nitrendipine. The claimed invention solved this problem by two factors, i.e. the use of the sodium salt of enalapril and the use of nitrendipine in a micronized form. Also when this problem was taken into account, the prior art did not provide an obvious solution.
  
- The subject-matter of claim 1 involved therefore an inventive step.

- X. The appellant (appellant) requested in writing that the decision under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the appeal be dismissed.

### **Reasons for the Decision**

1. The appeal is admissible.

#### *Admissibility of the documentary evidence filed during the appeal proceedings*

2. The appellant has submitted seven further documents with its statement of the grounds for appeal (see section IV, above). The board sees no reason why these documents could not have been filed during the first instance proceedings (Article 12(4) RPBA). The board considers furthermore that none of the seven documents add any relevant technical detail beyond the content of the cited documents which are on file already. The documents are accordingly not admitted into the proceedings.
3. The board notes furthermore that the appellant has not challenged the decision of the opposition division not to admit into the opposition proceedings the document filed very late in those proceedings (and which is one of the seven further documents filed on appeal). Accordingly, the board sees no necessity to examine whether or not the opposition division properly

exercised its discretion in relation to the admission of that document.

4. The respondent has filed a new test report with its letter dated 29 July 2011, i.e. some three years into the appeal proceedings and more than two and a half years after filing its reply to the grounds for appeal. The new test report includes new experimental evidence. The board does not admit this document into the proceedings because it is both very late filed and is irrelevant in view of the fact that the appellant's experimental evidence (to which the respondent's test report was a response) filed in the appeal is not admitted into the proceedings (see point 2, above).

*Inventive step (Article 56 EPC)*

5. Claim 1 relates to a fixed-dose association of a dose of 2.5 to 20 mg enalapril in the form of sodium salt and of a dose of 5 to 20 mg nitrendipine micronized for administration in single-dose galenic form.
6. For assessing whether or not a claimed invention meets the requirements of Article 56 EPC, the boards of appeal apply the "problem and solution" approach, which requires as a first step the identification of the closest prior art. In accordance with the established case law of the boards of appeal, the closest prior art is a teaching in a document conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications to arrive at the claimed invention.

*The closest prior art*

7. The opposition division considered document (D1) to represent the closest prior art and neither of the parties have disputed this. The board also concurs with this finding. It discloses a combination of enalapril and nitrendipine for the treatment of cardiovascular illnesses, in particular arterial hypertension, whereby the preferred doses for oral administration to human patients are 2.5 to 15 mg per day of enalapril and 10 to 20 mg per day of nitrendipine (see column 6, lines 32 to 37).
8. It has not been disputed by the respondent that the subject-matter of claim 1 differs from the association disclosed in document (D1) in that the claimed association specifies that enalapril is in the form of sodium salt and that nitrendipine is in a micronized form.

*The objective technical problem*

9. The aspect of the formulation of the appropriate objective technical problem to be solved by the subject-matter of claim 1 starting from the teaching of document (D1) is considered by the board to be the pivotal issue for dealing with this appeal. This aspect therefore received considerable attention during the oral proceedings before the board.
10. Examples 1 and 2 of the patent in suit relate to two particular associations of enalapril and nitredipine in the form of pharmaceutical formulations which fall

within the ambit of claim 1 (see paragraph [0033] of the patent in suit). The associations are defined in these examples in relation to their quantitative composition and a manufacturing method. Besides varying amounts of enalapril maleate (10 mg vs. 20 mg) and micronized nitrendipine (10 mg vs. 5 mg), the associations contain a number of further compounds, equally in varying concentrations, such as sodium bicarbonate establishing during manufacturing the presence of enalapril in the form of sodium salt (5 mg vs. 10 mg), but also sodium lauryl-sulphate (2 mg vs. 7.5 mg) and polyvinylpyrrolidone (8 mg vs. 11.2 mg). The board notes that the latter compounds are not part of the definition of the subject-matter of claim 1.

11. In paragraph [0030] the patent states that: "*[t]he instability of enalapril maleate and the considerable insolubility of nitrendipine are known. For this reason a method has been developed, and forms the object of this invention, for preparation of a gallenic formulation which achieves good stability of the enapril, in the form of sodium salt, and good solubility of the nitrendipine, thereby achieving rapid release of the enalapril-nitrendipine association.*" Subsequently the same paragraph explains the method for preparation of the formulation. It is stated that: "*[f]ollowing drying of the granulate a mass with a highly hydrophilic environment is obtained, which, linked with the action of the humectant (sodium lauryl-sulphate) favours dissolving the nitrendipine. The agluttin and wetting agent (polyvinylpyrrolidone and sodium lauryl-sulphate) can as an option be incorporated into the granulating solution.*" Tables 3 and 4 of the patent in suit relate to the stability

profiles of enalapril and nitrendipine of the associations of examples 1 and 2 in the function of time at various temperatures. Tables 5 and 6 (and Figures 1 and 2) of the patent in suit show the dissolution profiles for enalapril and nitrendipine of the associations of examples 1 and 2 in the function of time.

12. The board notes that as such the patent does not emphasise explicitly any improved features of the claimed association as compared to the prior art formulation. The technical effect obtained by the claimed invention is described in the patent as to achieve good stability of the enapril (i.e. in terms of overcoming the known instability of enalapril maleate) and a good solubility of the nitrendipine (i.e. to overcome the known considerable insolubility). Accordingly, in view of the disclosure in document (D1) the objective technical problem to be solved is the provision of a fixed-dose association formulation containing enalapril and nitrendipine with good stability properties for enalapril and good dissolution properties for nitrendipine.
  
13. In its decision the opposition division considered the problem to be solved to be "*the provision of a new formulation which shows an increased stability of enalapril and a better dissolution rate of nitrendipine*" (see point 4.3 of the decision). Although the opposition division did not specify any reference point for either of the aspects "increased stability" or "better dissolution rate" it must be assumed that this reference point is the formulation of enalapril and nitrendipine as disclosed in document (D1).

14. When judging inventive step the opposition division has made reference in its decision (see point 4.4) to "comparative examples" which had been provided during the examination proceedings by the applicant with a letter dated 16 July 2002. The data were considered to demonstrate a synergistic effect on the solubility rate of the micronized nitrendipine when the sodium salt of enalapril was used. The respondent has likewise referred to these data during the appeal proceedings when formulating arguments in support of inventive step.
  
15. The respondent has furthermore referred to the data as summarised in Figures 1 and 2 of the patent in suit and argued that these figures demonstrate that the formulations of both examples 1 and 2 provide a near to full dissolution of both enalapril and nitrendipine after 30 minutes. When taking this effect into account for assessing inventive step and considering the "comparative examples" provided with the letter of 16 July 2002, then, as it was argued by the respondent, the objective technical problem to be solved was the provision of a fixed-dose association formulation containing enalapril and nitrendipine with a faster dissolution of nitrendipine so that it dissolves as fast as enalapril. Alternatively, it was argued by the respondent that, when the data of the "comparative examples" were considered alone, the objective technical problem to be solved by the claimed subject-matter was the provision of a fixed-dose association formulation containing enalapril and nitrendipine having an increased stability of enalapril and an improved dissolution rate of nitrendipine. The latter improvement was thereby achieved by two measures, i.e.

- the choice of the micronized form of nitrendipine and the simultaneous use of the sodium salt of enalapril.
16. In patent law terms, the existence of a combination of features, i.e. of a "combination invention", is to be viewed differently from the mere existence of partial problems, i.e. of an aggregation of features. In accordance with the established jurisprudence of the boards of appeal, partial problems exist if the features or sets of features of a claim are a mere aggregation of these features or sets of features (juxtaposition or collocation) which are not functionally interdependent, i.e. do not mutually influence each other to achieve a technical success over and above the sum of their respective individual effects, in contrast to what is assumed in the case of a combination of features (see Case Law of the Boards of Appeal of the EPO, 6th Edition, I.D.8.2.2). Such a situation of "aggregation or juxtaposition of features" would exist if the problem as defined in point 11, above, would be considered for the assessment of inventive step.
17. For formulating the above two more ambitious objective technical problems to be solved by the subject-matter of claim 1 (see point 15, above), the respondent, similar to the opposition division, has relied on the data contained in the "comparative examples" as submitted with its letter dated 16 July 2002, which it contended demonstrate a synergistic effect of the use of the sodium salt of enalapril on the solubilisation of micronized nitrendipine. Accordingly, these two problems start from the premise that the "comparative examples" demonstrate that the combined use of the



micronized form of nitrendipine and sodium salt form of enalapril lead to an unexpected and advantageous synergistic improvement of the solubility of nitrendipine. The claimed invention is therefore a "combination invention" of two "functionally interdependent" features in accordance with the case law.

18. The "comparative examples" as submitted with the letter dated 16 July 2002 show two sets of data. The first set of data compares the dissolution rate of micronized nitrendipine compared with that of conventional nitrendipine in an otherwise identical galenic formulation as in examples 1 and 2 of the patent in suit. The reproduced data and corresponding graph demonstrate a considerably lower dissolution rate of nitrendipine when the conventional form is used as compared to the micronized form as used in the examples of the patent in suit. The second set of data compares the dissolution rate of micronized nitrendipine in association with enalapril in the form of sodium salt compared to that when in association with enalapril maleate in an otherwise identical galenic formulation as in examples 1 and 2 of the patent in suit. The reproduced data and corresponding graph demonstrate a considerably lower dissolution rate of the micronized nitrendipine when the maleate form of enalapril is used as compared to when the sodium salt of enalapril is used as in the examples of the patent in suit. *Prima facie* therefore, the board is satisfied that the "comparative examples" seem to support the presence of a synergistic effect on the dissolution rate of nitrendipine of a particular association falling within the ambit of claim 1.

19. The board considers however that, in line with the case law as developed by the boards of appeal in relation to the problem-and-solution approach for examining inventive step, in order for a synergistic effect to be supportive of a "combination invention" in the sense of the case law, such effect must be present for all subject-matter claimed, i.e. across the entire breadth of the claim. Otherwise, it cannot be taken into consideration.
  
20. Accordingly, in the present case it needs to be established whether or not the data in the "comparative examples" can satisfy the board that the claimed subject-matter solves the technical problems as defined by the respondent (see point 14, above). The following considerations appear relevant to the board in order to answer this question:
  - 20.1 The "comparative examples" do not contain any further technical detail beyond a mere reference to the compositions of examples 1 and 2 of the patent in suit, both for the definition of the reference compositions and for the definition of the "identical galenic formulations" which either comprise the "conventional" nitrendipine (see the first example) or enalapril in the maleate form (see the second example).
  
  - 20.2 The "comparative examples" are devoid of an indication of the particle size of the micronized nitrendipine used in the experiments. There is furthermore no indication that the particle size of the micronized nitrendipine was identical for all experimental measurements. The same is true for the exact

experimental pH for which the measurements are obtained. As can be taken from the disclosure in document (D8) in e.g. Figure 12, however, the specific particle size of hydrophobic micronized compounds has a substantial influence on their dissolution rate. It is concluded in the relevant part of document (D8), on page 133, lines 19 to 22, that "*[i]n summary, it is the effective surface area of a drug particle that determines its dissolution rate. The effective surface area may be increased by physically reducing the particle size, by adding hydrophilic diluents to the dosage form, or by adding surface-active agents to the dissolution medium or to the dosage form.*"

- 20.3 Considering that apart from the use of conventional nitrendipine or enalapril maleate the formulations were identical to the galenic formulations in the compositions in examples 1 and 2 of the patent in suit, it must be assumed that all experimental data were obtained with compositions comprising, besides the relevant agents enalapril and nirtendipine, also dissolution agents including polyvinylpyrrolidone and sodium lauryl-sulphate. As can be taken however from document (D8) the presence of surface active agents has a positive influence on the dissolution of hydrophobic micronized compounds, especially in the smaller particle size range (see page 132, lines 7 to 17). Claim 1 however, does not make any reference to the presence of surface active agents. The "comparative examples" therefore merely relate to specific compositions within the ambit of the claim which have further compounds present having an influence on the measured characteristic, i.e. dissolution, and which are however not defined in the claim.

- 20.4 The second "comparative example" measured the effect of the presence of enalapril, in the sodium salt form as compared to the maleate form, on the dissolution rate of nitrendipine. However, the "comparative example" does not indicate how these compositions are prepared. It is in particular not explicitly indicated whether the maleate form is obtained by the omission, as compared to the reference compositions of example 1 and 2 of the patent, of sodium bicarbonate or by other means. The board notes therefore that it is not clear whether the compared compositions differ merely by one parameter or by more than one and what exactly their influence is on the dissolution rate of nitrendipine.
- 20.5 In view of the above considerations the board is not in a position to accept that the "comparative examples" submitted with the letter dated 16 July 2002 are unambiguously supportive of a synergistic effect of the specific use of enalapril in the form of its sodium salt on the dissolution rate of micronized nitrendipine.
21. As a consequence of that finding, the board considers that it has not been established that either of the two ambitious problems as formulated by the respondent (see point 15, above) has been solved by the claimed subject-matter across the whole breath of claim 1.
22. It therefore needs to be examined whether the claimed subject-matter was rendered obvious to the skilled person by the prior art at the relevant date when embarking on finding a solution to the objective technical problem as defined by the board in point 12, above.

*Obviousness*

23. Faced with the problem of providing a fixed-dose association formulation containing enalapril and nitrendipine with good stability properties for enalapril and good dissolution properties for nitrendipine and starting from the association as disclosed on document (D1) the prior art would lead the skilled person to find a solution for each of the two aspects of the objective technical problem. The aggregation or juxtaposition of these solutions would then provide an obvious solution to this problem.
24. It has been argued by the opposition division and the appellant that the provision of stable enalapril in the form of a sodium salt was known in the prior art as represented by both documents (D2) and (D3). The board agrees with this finding which has in fact not been contested by the respondent. Indeed, the process as disclosed in the paragraphs bridging columns 2 and 3 of document (D3) appears in essence to be identical to the formulation processes as used in examples 1 and 2 of the patent in suit. The board concludes therefore that the use of the sodium form of enalapril in order to provide for a stable form of enalapril was rendered obvious to a skilled person.
25. The board has referred to document (D8) in point 20.2, above. From the summary on page 133, lines 19 to 22, it can be taken that at the relevant date it could be considered common general knowledge of the skilled person that physically reducing the particle size of a crystalline drug, i.e. so-called "micronization", was

an obvious measure for the skilled person to increase the dissolution rate of the drug. Furthermore, from document (D4) it can be taken that micronization was also a known measure for providing acceptable solubility or dissolution of nitrendipine (see e.g. Figure 1).

26. It has been argued by both the opposition division and the respondent that, in view of the fact that document (D4) discloses an alternative formulation to micronization for nitrendipine, i.e. spraying, the teaching would point the skilled person away from using the micronized form of nitrendipine when formulating a solution to the problem relevant for the present case. The board notes however that the objective technical problem here under consideration is not to provide the formulation of the nitrendipine in a form with the *highest* dissolution rate but rather with a mere *good* dissolution rate. Accordingly, the board is satisfied that micronization would be an obvious alternative to the skilled person for such a formulation.
27. In view of the above considerations, the claimed association of enalapril and nitrendipine, whereby enalapril is formulated as its sodium salt and nitrendipine is in a micronized form, has been rendered obvious to the skilled person by the prior art. Accordingly, also, the aggregation of the two solutions was obvious to the skilled person. The board concludes therefore that the subject matter of claim 1 lacks an inventive step (Article 56 EPC).
28. As a consequence of the finding that the subject-matter of claim 1 of the patent as granted lacks an inventive

step pursuant to Article 56 EPC, and in the absence of any further requests on file, the patent is revoked.

**Order**

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

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar

The Chairman

P. Cremona

C. Rennie-Smith