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**Datasheet for the decision  
of 25 October 2011**

**Case Number:** T 0181/08 - 3.3.02

**Application Number:** 95926055.5

**Publication Number:** 723437

**IPC:** A61K 9/26

**Language of the proceedings:** EN

**Title of invention:**

Multiple unit pharmaceutical preparation containing proton pump inhibitor

**Applicant:**

AstraZeneca AB

**Opponents:**

Hexal AG  
Krka, Tovarna Zdravil, d.d.  
Teva Pharmaceutical Industries Ltd.

**Headword:**

Multiple unit preparation/ASTRAZENECA

**Relevant legal provisions:**

EPC Art. 123(2)

**Keyword:**

"Amendments - added subject-matter (yes): claimed combination of features not directly and unambiguously disclosed"

**Decisions cited:**

T 1050/09, T 0330/05

**Catchword:**

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Case Number: T 0181/08 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 25 October 2011

**Appellant I:** AstraZeneca AB  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
3 December 2007 concerning maintenance of the  
European patent No. 723437 in amended form.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** H. Kellner  
J.-P. Seitz

## Summary of Facts and Submissions

- I. European patent No. 0 723 437, based on international application PCT/SE1995/000678, published as WO 1996/001624 and having application No. 95 926 055.5 in the EPO, was granted with 17 claims.

Independent claims 1 and 11 as granted read as follows:

"1. An oral pharmaceutical multiple unit tableted dosage form comprising tablet excipients and individually enteric coating layered units of a core material containing active substance in the form of an acid labile  $H^+K^+$ -ATPase inhibitor or one of its single enantiomers or an alkaline salt thereof, optionally the active substance is mixed with alkaline compounds and pharmaceutically acceptable excipients, the core material is covered with one or more layer(s) of which at least one is an enteric coating layer, characterised in that the enteric coating layer has a thickness of at least 10  $\mu m$  and said layer comprises a plasticizer an amount of 15 - 50 % by weight of the enteric coating layer polymer and the enteric coating layer has mechanical properties such that the compression of the individual units mixed with the tablet excipients into the multiple unit tableted dosage form does not significantly affect the acid resistance of the individually enteric coating layered units.

11. A process for the manufacture of a pharmaceutical multiple unit tableted dosage form comprising tablet excipients and individually enteric coating layered units of a core material containing an active substance

as defined in claim 1 optionally mixed with alkaline compounds and pharmaceutically acceptable excipients, characterised in that the process comprises the following steps:

- a) forming a multiple of the core material comprising the active substance optionally mixed with the alkaline compound(s) and excipients,
- b) optionally covering the core material from step (a) with one or more separating layer(s),
- c) covering the core material from step (a) or step (b) with one or more enteric coating layer(s) comprising a plasticizer in an amount of 15 - 50 % by weight of the enteric coating layer polymer,
- d) optionally covering the individually enteric coating layered units with an over-coating layer,
- e) mixing the multiple of enteric coating layered units of step (c) or step (d) with tablet excipients, and
- f) compressing the mixture of step (e) into a tableted dosage form, and whereby the enteric coating layer has mechanical properties such that the compression of the individual units mixed with the tablet excipients into the multiple unit tableted dosage form does not significantly affect the acid resistance of the individually enteric coating layered units."

II. The documents cited during the proceedings before the opposition division and the Board of appeal included the following

(8) EP-A-0 723 777.

III. Opposition was filed against the granted patent under Article 100(a) EPC, novelty and inventive step and Article 100(b) EPC, sufficiency of disclosure.

Additionally, objections concerning Article 100(c) EPC were raised, on the grounds that the granted patent contained subject-matter which had not originally been disclosed.

The opposition division held that the contested patent as amended according to the first auxiliary request met the requirements of the Convention.

Independent claim 11 as granted was part of the main request and lacked novelty with respect to document (8), state of the art under Article 54(3) EPC, while the subject-matter of its claim 1, based on the amendment that the thickness of the enteric coating layer was 20  $\mu\text{m}$  instead of 10  $\mu\text{m}$ , was new.

- IV. The patent proprietor and opponents 01 and 03 filed appeals against the decision of the opposition division.
- V. With its statement of grounds of appeal, the appellant (patent proprietor) submitted four sets of claims as main request and first, second and third auxiliary request.
- VI. On 20 July 2011, a communication of the Board was despatched, expressing in particular the Board's concern with respect to entitlement to priority and to the sets of claims of the present requests containing amendments extending the subject-matter of these claims beyond the content of the application as filed.

Additional considerations with respect to Articles 84, 54 and 56 EPC were indicated.

VII. The appellant (patentee), in reply to the communication of the Board and in order to clarify its requests, with letter of 26 September 2011 once again filed its four sets of claims without further amendment.

With respect to the claims as granted, the single amendment in the set of claims of the main request is the replacement of "at least 10  $\mu\text{m}$ " as the value characterising the thickness of the enteric coating layer by "more than 20  $\mu\text{m}$ " in its claim 1.

Claim 1 of the first auxiliary request has the same wording as claim 1 of the main request; there is only an amendment in claim 11.

In claim 1 of the second auxiliary request the following text is added at the end of claim 1 of the main request:

**"and in that the amount of the enteric coating layered pellets constitutes less than 60% by weight of the total tablet weight."**

The wording of claim 1 of the third auxiliary request reads (additions or amendments with respect to claim 1 as granted in bold):

"An oral pharmaceutical multiple unit tableted dosage form comprising tablet excipients and individually enteric coating layered units of a core material containing active substance in the form of an acid labile  $\text{H}^+\text{K}^+$ -ATPase inhibitor or one of its single enantiomers or an alkaline salt thereof, optionally the active substance is mixed with alkaline compounds and

pharmaceutically acceptable excipients, the core material is covered with one or more layer(s), of which at least one is an enteric coating layer, characterised in that the enteric coating layer has a thickness of **more than 20 µm** and said layer comprises a plasticizer an amount of 15-50 % by weight of the enteric coating layer polymer and the enteric coating layer has mechanical properties such that the compression of the individual units mixed with the tablet excipients into the multiple unit tableted dosage form does not significantly affect the acid resistance of the individually enteric coating layered units, **the individually enteric coating layered units are further covered with an overcoating layer comprising pharmaceutically acceptable excipients and in that the amount of the enteric coating layered pellets constitutes less than 60% by weight of the total tablet weight.**"

VIII. Opponent 04 withdrew its opposition on 25 November 2010 and is not party in this appeal procedure.

Opponent 02, party as of right, filed a letter dated 22 July 2011 indicating that it would not join the oral proceedings.

IX. Oral proceedings took place on 25 October 2011.

X. Appellant (opponent 01) and appellant (opponent 03) raised objections concerning unallowed amendments with respect to Article 123(2) EPC.



In particular, the decisions cited by the appellant (patent proprietor) in writing, T 1050/09 - 3.2.08 of 7 April 2011 and T 0330/05 - 3.3.09 of 30 August 2005 (neither published in the OJ) either were not relevant or even expressed reasons and conclusions which were disadvantageous with respect to the case of the appellant (patent proprietor).

The appellant (patent proprietor)'s arguments may be summarised as follows:

The combination of features with respect to the thickness of the enteric coating and the amount of plasticizer as a percentage by weight of the enteric coating layer polymer as contained in claims 1 of the requests could be derived directly and unambiguously from the application as originally filed, since only preferred values were introduced.

There was also no selection from lists leading to totally different embodiments for each item as selected, as would be the consequence of choosing different substances to produce different reaction products. The current case simply related to the narrowing down of parameters to achieve a lower decrease in the acid resistance during the compression of pellets into tablets.

In addition, all of the examples were covered by the amended claims, meaning that the amount of plasticizer lay in the range as set out in the claim and that in example 15 the value of 20  $\mu\text{m}$  was mentioned.

With respect to claim 1 of the second auxiliary request, the tablet to be produced from the most preferred pellets was further characterised by the feature that the amount of the enteric coating layered pellets constituted less than 60% by weight of the total tablet weight, another preferred value from the description as originally filed.

This feature also was represented in all examples.

In the third auxiliary request, simply the feature of claim 8 as originally filed was introduced into claim 1.

XI. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims filed as main request or on the basis of one of the sets of claims of the first to third auxiliary requests, all filed with letter of 26 September 2011.

XII. The appellants (opponents 01 and 03) requested that the decision under appeal be set aside and that the European patent No. 723 437 be revoked.

## **Reasons for the Decision**

1. The appeals are admissible.

2. *Requirements of Article 123(2) EPC; all requests (main request and first to third auxiliary request)*

2.1 Claims 1 of all these requests contain differing or additional features with respect to claim 1 as granted and with respect to claim 1 as originally filed.

2.2 Claims 1 of all requests concern an oral pharmaceutical multiple unit tableted dosage form comprising

- an enteric coating layer having a thickness of more than 20  $\mu\text{m}$  and said layer
- comprising a plasticizer in an amount of 15-50 % by weight of the enteric coating layer polymer.

Both features are not contained in claim 1 as originally filed. They are derived from the description as originally filed, namely page 15, lines 18 to 23 and lines 10 to 12:

"... the enteric coating layer(s) constitutes a thickness of

- approximately at least 10  $\mu\text{m}$ ,
- preferably more than 20  $\mu\text{m}$ .

The maximum thickness of the applied enteric coating layer(s) is normally only limited by processing conditions."

"The amount of plasticizer is

- usually above 10 % by weight of the enteric coating layer polymer(s),
- preferably 15 - 50 % and

- more preferably 20 - 50 %."

Claim 1 of the second auxiliary request contains a further feature which is also taken from the description as originally filed, i.e. page 16, lines 29 to 30:

"The amount of enteric coating layered pellets constitutes less than 75% by weight of the total tablet weight and preferably less than 60 %."

As can be seen with regard to this further feature as an example, there are even more parameters in the description than thickness of the enteric coating layer or amount of plasticizer referring to multiple values and characterised by being "usual", "preferred" or "more preferred"

Under these circumstances, the person skilled in the art reading this description firstly finds no guidance with which of the preferred features to start and secondly which of the other features to combine.

2.3 Therefore, the combination of the two features "thickness of enteric coating layer of more than 20  $\mu\text{m}$ " and "an amount of 15-50 % by weight of the enteric coating layer" is not directly and unambiguously disclosed in the application as originally filed and claims 1 of all requests containing this combination are in breach of Article 123(2) EPC.

3. In addition to the arguments and conclusions set out under point 2 above which lead to the consequence under point 2.3, for the sake of taking account of all

arguments presented by the appellant (patent proprietor), the following remarks are added:

- 3.1 As a supporting argument, it was mentioned that all the examples covered the "20  $\mu\text{m}$ " and "15-50 % by weight" combination of features.

This remark could put the case close to that of cited decision T 0330/05 in asserting that "coverage" by all the examples at least put particular weight on an embodiment carrying one of these features and that this weight would enable the skilled person to directly and unambiguously derive the combination of these features by starting at the particularly weighted embodiment and adding the further feature directly by selecting it from a single list.

However, there is neither particular reference to the amount of plasticizer being in the range of "15-50 % by weight" in each of the examples (the values even have to be figured out by the reader himself and are not indicated as such and, in addition, at least also lie above 10%, one of the other alternatives on page 15 of the description) nor is there any mention of the thickness of the enteric coating layer in any of the examples, except example 15, and there, the thickness is not defined as representing "more than 20  $\mu\text{m}$ " but only corresponding to "approx. 20  $\mu\text{m}$ " which usually also includes a thickness slightly less than 20  $\mu\text{m}$ .

Thus, the appellant (patent proprietor)'s argument that - following the language in T 0330/05 - a "most preferred embodiment" based on

- either the enteric coating layer having a thickness of more than 20  $\mu\text{m}$  or
- said layer comprising a plasticizer in an amount of 15-50 % by weight of the enteric coating layer polymer

could be derived from the examples to start with and then simply the second feature had to be added, cannot be followed.

- 3.2 The argument that there was no selection from lists leading to totally different embodiments for each item as selected also cannot hold.

Narrowing down parameters or percentages of ingredients of compositions as used in current claims 1 does not in fact result in different products in terms of chemical structure. In any case, however, it results in products carrying different characteristics that, in case of doubt, create a difference with respect to products of the state of the art - which is usually precisely why such "narrowing down" of parameters and percentages is introduced into claims.

4. Thus, amended claims 1 of the main request and of the first to third auxiliary requests represent subject-matter extending beyond the content of the application as originally filed (Article 123(2) EPC).

**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:

N. Maslin

U. Oswald