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Datasheet for the decision of 26 September 2014

Case Number: T 1032/09 - 3.3.02

Application Number: 03011903.6

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Language of the proceedings: EN

Title of invention:
ORAL PHARMACEUTICAL DOSAGE FORMS COMPRISING A PROTON PUMP INHIBITOR AND A NSAID

Applicant:
AstraZeneca AB

Headword:
Dosage form comprising a proton pump inhibitor and a NSAID/ ASTRAZENECA

Relevant legal provisions:
RPBA Art. 12, 15(1), 15(3)
EPC Art. 76(1)

Keyword:
Oral proceedings - held in absence of appellant
Divisional application - added subject-matter (yes)

Decisions cited:
G 0004/92, G 0010/93

Catchword:

Europäisches Patentamt
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Case Number: T 1032/09 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 26 September 2014

Appellant: (Applicant)	AstraZeneca AB 151 85 Södertälje (SE)
Representative:	AstraZeneca AB Global Intellectual Property 151 85 Södertälje (SE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 12 December 2008 refusing European patent application No. 03011903.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	U. Oswald
Members:	M. C. Ortega Plaza
	S. Fernández de Córdoba

Summary of Facts and Submissions

I. The present appeal lies from a decision of the examining division refusing European patent application No. 03011903.6 under Article 97(2) EPC. The application was filed as a divisional application of European patent application No. 96944724.2, filed as an international application published as WO 97/25064 (parent application).

II. The examining division's decision is based on the set of claims which was filed with letter of 11 June 2007, representing the main and sole request before the examining division.

The set of claims according to the main request comprised 16 claims, of which the independent claims 1, 14 and 15 read as follows:

"1. An oral pharmaceutical dosage form comprising an acid susceptible proton pump inhibitor together with one or more Non Steroidal Antiinflammatory Drug (NSAID) and optionally pharmaceutical acceptable excipients, characterized in that the dosage form is in the form of a capsule formulation comprising an acid susceptible proton pump inhibitor and one or more NSAID, and wherein the acid susceptible proton pump inhibitor is in the form of individually enteric coating layered units and the one or more NSAID is in the form of granules or in the form of modified release units and wherein the one or more NSAID is acetyl salicylic acid, diclofenac, piroxicam, ibuprofen, ketoprofen or naproxen or a pharmaceutical[ly] acceptable salt thereof."

"14. A process for the manufacture of a fixed dosage form comprising a proton pump inhibitor and one or more NSAID(s) in a capsule, characterized in that the proton pump inhibitor is prepared in the form of enteric coating layered pellets and that the NSAID(s) is/are acetyl salicylic acid, diclofenac, piroxicam, ibuprofen or naproxen or a pharmaceutically acceptable salt thereof, and that the pellets are filled into a capsule together with prepared NSAID(s) granules or enteric coating layered NSAID(s) pellets, or NSAID(s) pellets coating layered with an extended release film, optionally the mixture of pellets or granules are mixed with pharmaceutically acceptable excipients, and filled in a capsule."

"15. Use of a dosage form according to any one of claims 1 to 13 for the manufacture of a medicament for treatment or prevention of gastro intestinal side-effects associated with NSAID(s) treatment."

III. The examining division considered that the main request met the requirements of Articles 123(2), 54, 83 and 84 EPC, but it did not mention whether in its opinion the requirements of Article 76(1) EPC were fulfilled.

Furthermore, the examining division considered that the main request did not meet the requirements of inventive step in the light of the cited prior art (Article 56 EPC).

IV. The applicant (appellant) lodged an appeal against said decision and filed grounds of appeal. With its grounds of appeal it filed a main request (identical to the set of claims serving as basis for the examining division's decision) and a first auxiliary request.

The independent claims of the auxiliary request read as follows:

"1. An oral pharmaceutical dosage form comprising an acid susceptible proton pump inhibitor together with one Non Steroidal Antiinflammatory Drug (NSAID) and optionally pharmaceutical[ly] acceptable excipients, characterized in that the dosage form is in the form of a capsule formulation comprising an acid susceptible proton pump inhibitor and one NSAID, and wherein the acid susceptible proton pump inhibitor is in the form of individually enteric coating layered units and the NSAID is in the form of granules or in the form of modified release units and wherein the NSAID is acetyl salicylic acid."

"13. A process for the manufacture of a fixed dosage form comprising a proton pump inhibitor and one NSAID in a capsule, characterized in that the proton pump inhibitor is prepared in the form of enteric coating layered pellets and that the NSAID is acetyl salicylic acid, and that the pellets are filled into a capsule together with prepared NSAID granules or enteric coating layered NSAID pellets, or NSAID pellets coating layered with an extended release film, optionally the mixture of pellets or granules are mixed with pharmaceutically acceptable excipients, and filled in a capsule."

"14. Use of a dosage form according to any one of claims 1 to 12 for the manufacture of a medicament for treatment or prevention of gastro intestinal side-effects associated with NSAID treatment."

V. As an annex to the summons to oral proceedings, the board issued a communication pursuant to Article 15(1) RPBA.
In said communication the board established that the present application was a divisional application and that following the principles set out in Enlarged Board of Appeal decision G 10/93, OJ EPO, 1995, 172, the board had the power to examine whether the application or the invention to which it related met the requirements of the EPC, including requirements which the examining division had not taken into consideration.
The board in its communication expressed a detailed negative opinion in relation to added subject-matter under Article 76(1) EPC for the main request and first auxiliary request.

VI. The appellant did not file any reply to the board's communication.

VII. Oral proceedings took place on 26 September 2014 in the absence of the appellant.

VIII. The appellant requested with its grounds of appeal that the decision under appeal be set aside and that a patent be granted on the basis of the main request or alternatively on the basis of the auxiliary request, both filed with the grounds of appeal.

Reasons for the Decision

1. The appeal is admissible.

2. The oral proceedings before the board took place in the absence of the appellant, who had been duly summoned but had decided not to attend.
The present decision is based on facts and evidence presented in the written procedure and on which the appellant had had an opportunity to comment.
The appellant chose not to reply to the board's communication, which expressed a negative opinion, and thus did not provide any arguments in response to the objections raised by the board in view of added subject-matter under Article 76(1) EPC. The conditions set forth in Enlarged Board of Appeal decision G 4/92, OJ EPO 1993, 149, are therefore met.

Moreover, as stipulated by Article 15(3) RPBA, the board shall not be obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

3. Added subject-matter, Article 76(1) EPC

3.1 The present application is a **divisional application** and therefore the provisions of Article 76(1) EPC in relation to added subject-matter have to be examined.

The fact that the examining division's decision is silent on the requirements of Article 76(1) EPC does not hinder the board from assessing them, since according to the principles set out in Enlarged Board of Appeal decision G 10/93, OJ EPO, 1995, 172): "*In an appeal from a decision of an examining division in which a European patent application was refused the board of appeal has the power to examine whether the application or the invention to which it relates meets*

the requirements of the EPC. The same is true for requirements which the examining division did not take into consideration in the examination proceedings or which it regarded as having been met. If there is reason to believe that such a requirement has not been met, the board shall include this ground in the proceedings".

3.2 In this context it is noted that the description of the present application differs from the description of the parent application. Moreover, the set of claims of the present application as originally filed differs substantially from the set of claims of the parent application as filed.

3.3 Main request

3.3.1 Claim 1 of the main request is a product claim, which relates to an oral pharmaceutical dosage form ... characterized in that the dosage form is in the form of a **capsule formulation** comprising an acid susceptible proton pump inhibitor and one or more Non Steroidal Antiinflammatory Drug (NSAID).
The acid susceptible proton pump inhibitor, according to claim 1, is in the form of individually enteric coating layered units and
the one or more NSAID is in the form of granules or in the form of modified release units.
Furthermore, the one or more NSAID is acetyl salicylic acid, diclofenac, piroxicam, ibuprofen, ketoprofen or naproxen or a pharmaceutical[ly] acceptable salt thereof.

3.3.2 The focus of the parent application as filed is on an oral pharmaceutical dosage form in the form of a **tablet.** The option that the oral pharmaceutical dosage form is in the form of a **capsule** is mentioned in very

few parts of the application, namely page 4, line 14 (as an option for "oral, fixed unit dosage forms"); page 6, line 29-30, and page 7, lines 1-3 (as a separate alternative, where the "active substances are dry mixed and filled into a capsule"); page 23, line 14 (as further specific alternative, in which "the acid susceptible proton pump inhibitor in the form of enteric coating layered pellets may be filled in a capsule together with the NSAID(s) in the form of granules or enteric coating layered pellets"), claim 3 ("the dosage form is a capsule formulation") and claim 29 (relating to a process for the manufacture of a "fixed dosage form" using the wording of the process claim 14 of the main request).

None of the above-cited passages discloses all the technical features of the oral pharmaceutical dosage form according to claim 1 of the main request; in particular there is no disclosure of the feature "wherein the one or more NSAID is acetyl salicylic acid, diclofenac, piroxicam, ibuprofen, ketoprofen or naproxen or a pharmaceutical[ly] acceptable salt thereof" in connection with the form of a capsule and the specific physical form of the components.

3.3.3 Moreover, the only examples of the parent application relating to capsules and the "capsule formulations" are examples 8 and 9 on page 40. Example 8 discloses a specific "capsule formulation" comprising enteric coating layered magnesium **omeprazole** pellets and enteric coating layered **piroxicam** pellets filled into hard gelatin capsules. Example 9 discloses "a capsule formulation" comprising enteric coating layered **S-omeprazole magnesium salt** pellets and **naproxen** granules filled into hard gelatin capsules.

These specific examples cannot serve as an allowable basis for the subject-matter of claim 1 of the main request, which relates generally to "an acid susceptible proton pump inhibitor" together with "one or more NSAID" which "is acetyl salicylic acid, diclofenac, piroxicam, ibuprofen, ketoprofen or naproxen or a pharmaceutical[ly] acceptable salt thereof", as the examples are restricted to specific substances, i.e. magnesium omeprazole or S-omeprazole magnesium salt and piroxicam or naproxen.

3.3.4 Additionally, the technical features appearing in claim 1 that "*the acid susceptible proton pump inhibitor is in the form of individually enteric coating layered units*" and that "*the NSAID(s) is/are in the form of granules*" or "*in the form of modified release units*" are disclosed on page 6, line 30, to page 7, line 3, of the parent application as filed as a separate alternative of capsules only when filled with the different actives substances **dry mixed**.

The subject-matter of claim 1 of the main request is however not restricted to this separate alternative of capsules filled with the different actives substances dry mixed but on the contrary relates to capsule formulations in general.

Moreover, claim 1 of the parent application as filed is clearly broader than claim 1 of the main request, since claim 1 of the parent application as filed relates generally to an oral pharmaceutical dosage form comprising an acid susceptible proton pump inhibitor together with at least one NSAID, without further specifications in relation to the components.

Therefore, even the combination of claim 1 of the parent application as filed and the disclosure which can be found on page 6, line 30, to page 7, line 3, does not provide a direct and unambiguous basis for the subject-matter of claim 1 of the main request, since the fact that the components are dry mixed is not mentioned.

3.3.5 Furthermore, claim 1 of the main request requires that the dosage form (or dosage form formulation) comprises an acid susceptible proton pump inhibitor **together with one** or more NSAID being "**acetyl salicylic acid**, diclofenac, piroxicam, ibuprofen, ketoprofen or naproxen or a pharmaceutical[ly] acceptable salt thereof" (emphasis added).

Although these NSAID substances appear among the substances mentioned as suitable NSAIDs on page 13, first full paragraph, of the parent application as filed, claim 1 of the main request relates **to an individualised singularisation of a specific dosage form** in which an acid susceptible proton pump inhibitor in the form of individually enteric coating layered units is present together with acetyl salicylic acid in the form of granules or in the form of modified release units.

The general disclosure of the parent application mentions that preferably those "NSAIDs for the new fixed dosage form are diclofenac, ibuprofen, naproxen and piroxicam" (page 13, second full paragraph, of the parent application as filed). However, **acetyl salicylic acid** is not mentioned as a preferred NSAID.

Moreover, none of the examples illustrates either formulations containing acetyl salicylic acid in the

form of granules or in the form of modified release units, or the combination of acetyl salicylic acid and a specific acid susceptible proton pump inhibitor.

3.3.6 Summarising, the parent application as originally filed does not disclose the individualised oral pharmaceutical dosage form, being a capsule formulation or filled in a capsule, comprising acetyl salicylic acid and an acid susceptible proton pump inhibitor, e.g. omeprazole or S-omeprazole magnesium salt.

3.3.7 For the reasons given above the main request fails since the subject-matter of claim 1 extends beyond the content of the parent application as filed (Article 76(1) EPC).

3.4 Auxiliary request

3.4.1 The set of claims of the auxiliary request essentially differs from the main request in that the formulation of claim 1 contains only one NSAID, namely acetyl salicylic acid, and that, as a consequence of this restriction, claim 5 of the main request has been deleted. The remaining claims have been renumbered.

3.4.2 Therefore, claim 1 of the auxiliary request relates **to an individualised singularisation of a specific dosage form** in which an acid susceptible proton pump inhibitor in the form of individually enteric coating layered units is present together with acetyl salicylic acid in the form of granules or in the form of modified release units.

3.4.3 The reasons given in point 3.3.5 above apply mutatis mutandis to the auxiliary request, since the parent application as filed does not provide a direct and

unambiguous disclosure of such an individualised singularisation of a specific dosage form.

3.4.4 The auxiliary request therefore fails to meet the provisions of Article 76(1) EPC in relation to added subject-matter.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated