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Datasheet for the decision of 10 June 2024

Case Number: T 1898/22 - 3.3.07

Application Number: 11003486.5

Publication Number: 2359815

IPC: A61K9/20, A61K31/138, A61K31/4422

Language of the proceedings: EN

Title of invention:
Compositions comprising amlodipine and bisoprolol

Patent Proprietor:
Egis Gyógyszergyár Zrt.

Opponent:
KRKA, d.d., Novo mesto

Headword:
Amlodipine-bisoprolol formulation/EGIS

Relevant legal provisions:
EPC Art. 100(c), 76(1)
RPBA 2020 Art. 12(4), 12(6)

Keyword:

Main request - no reason to deviate from the decision
Auxiliary request 1 - added subject-matter (yes)
Auxiliary requests 2 to 4 - should have been submitted in the opposition proceedings (yes)

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Case Number: T 1898/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 10 June 2024

Appellant: (Patent Proprietor)	Egis Gyógyszergyár Zrt. Keresztúri út 30-38 1106 Budapest (HU)
Representative:	Stolmár & Partner Patentanwälte PartG mbB Blumenstraße 17 80331 München (DE)
Respondent: (Opponent)	KRKA, d.d., Novo mesto Smarjeska cesta 6 8501 Novo Mesto (SI)
Representative:	Hoefer & Partner Patentanwälte mbB Pilgersheimer Straße 20 81543 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 7 June 2022 revoking European patent No. 2359815 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Molina de Alba
	A. Jimenez

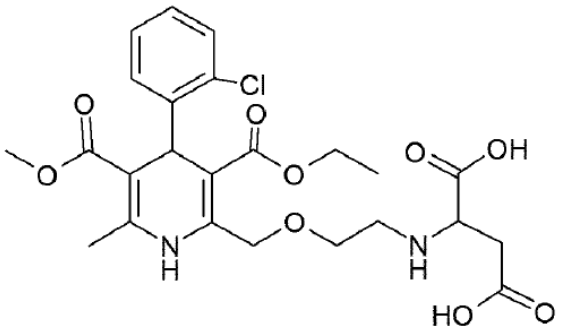
Summary of Facts and Submissions

I. The decision under appeal is the opposition division's decision revoking European patent No. 2 359 815.

II. The patent had been granted with ten claims. Claims 1, 8 and 9 as granted read as follows:

"*1. Packaged dosage form comprising*

i) a homogeneous stable solid pharmaceutical composition containing amlodipine besylate, bisoprolol fumarate, organic or inorganic fillers, disintegrants, lubricants, anti-adhesives and optionally a binding agent, further comprising less than 0.5% of the compound of the formula



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based on the weight of the active ingredients,
ii) wherein the homogeneous composition is in the form of a tablet or a capsule,
iii) the tablet or capsule is packaged in a damp-proof package,
iv) wherein the damp-proof package is selected from the group comprising a cold-formed blister formed from a composite foil covered with an aluminum lidding foil, a blister prepared from a thermoformable, damp-proof

composite foil covered with an aluminum lidding foil, and a glass or polypropylene vessel having an airtight cap of polyethylene or polypropylene."

"*8. Process for the preparation of a stable solid packaged dosage form containing a homogeneous composition comprising amlodipine base or a pharmaceutically acceptable salt thereof and bisoprolol fumarate, characterized in that the amlodipine base or a pharmaceutically acceptable salt thereof and the bisoprolol fumarate, a disintegrant, a lubricant and if necessary further excipients used in the pharmaceutical industry are homogenised, then an antiadhesive is added, the homogenisation is continued, then*

a.) the homogenizate is pressed into tablets using a direct compressing process or,
b.) filled into hard gelatine capsules in a known manner,

then, the obtained tablets or capsules are packaged into damp-proof protecting packages in a known manner."

"*9. Process for the preparation of a stable solid packaged dosage form in the form of tablets according to Claim 8, characterised in that for the homogeneous composition 2%-20%, preferably 2%-10%, more preferably 1-6% of amlodipine base or a pharmaceutically accepted acid addition salt thereof, preferably amlodipine besylate, 2%-20%, preferably 2%-10%, more preferably 1%-6% of bisoprolol fumarate, further 60%-90%, preferably 70%-90%, more preferably 80%-90% of filler, 1%-10%, preferably 4%-6% of disintegrant, 0.5%-3%, preferably 1%-2% of lubricant, 0.3%-2%, preferably 1%-10%, preferably 0.5%-1% of binding agent are used based on the weight of the tablets.*"

III. The decision is based on the patent as granted and the claims of ten auxiliary requests. In the decision, the opposition division concluded, among other things, that the main request and auxiliary requests 1 to 8 added subject-matter. Auxiliary requests 9 and 10, filed at the oral proceedings before the opposition division, were not admitted.

IV. The patent proprietor (appellant) filed an appeal against the decision. With the statement of grounds of appeal, the appellant requested that the decision under appeal be set aside and that the patent be maintained as granted. In addition, the appellant filed four sets of claims as auxiliary requests 1 to 4.

Claim 1 of auxiliary request 1 is identical to claim 1 as granted. Claim 4 reads as follows:

"*4. Packaged dosage form according to anyone of claims 1 to 3, characterized in that it is a tablet packaged in a damp-proof package, the homogeneous composition comprising 2%-20%, preferably 2%-10%, more preferably, 1-6% of amlodipine besylate, 2%-20%, preferably 2%-10%, more preferably 1%-6% of bisoprolol fumarate, further comprising 60%-90%, preferably 70%-90%, more preferably 80%-90% of filler, 1%-10%, preferably 4%-6% of disintegrant, 0.5%-3%, preferably 1%-2% of lubricant, 0.3%-2%, preferably 0.1%-5% of binding agent based on the weight of the tablet.*"

Claim 1 of auxiliary request 2 differs from claim 1 as granted in that the following text has been added at the end of the claim:

"*characterized in that the packaged dosage form is a tablet packaged into a cold-formed blister (so-called cold blister /CFF/) of OPA/AL/PVC composite foil covered with an aluminium lidding foil, or into a blister of thermoformable, damp-proof composite foil and covered with an aluminium lidding foil, or into a glass or polypropylene vessel equipped with an airtight container cap of polyethylene or polypropylene, the homogeneous composition comprising 1%-6% of amlodipine besylate, 1%-6% of bisoprolol fumarate, 80%-90% of microcrystalline cellulose, 4%-6% of sodium starch glycolate, 1%-2% of magnesium stearate, 0.5%-1% of colloid silica based on the weight of the tablet,*
or
a capsule packaged into a cold-formed blister (so-called cold blister /CFF/) of OPA/AL/PVC composite foil covered with an aluminium lidding foil, or into a blister of thermoformable damp-proof composite foil and covered with an aluminium lidding foil, or into a glass or polypropylene vessel equipped with an airtight container cap of polyethylene or polypropylene, the homogeneous composition comprising 10%-15% of amlodipine besylate, 10%-15% of bisoprolol fumarate, further 55%-65% of microcrystalline cellulose, 4%-6% of sodium starch glycolate, 1%-2% of magnesium stearate, 0.5%-1% of colloid silica based on the weight of the filling substance of the capsule."

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 in that it specifies that the capsule is a hard-gelatine capsule.

Claim 1 of auxiliary requests 4 differs from claim 1 of auxiliary request 2 in that the part of the additional text relating to a capsule has been deleted.

V. In its reply to the statement of grounds of appeal, the respondent (opponent) requested that auxiliary requests 1 to 4 not be admitted into the appeal proceedings.

VI. The board scheduled oral proceedings, in line with the parties' requests, and gave its preliminary opinion on the case.

VII. The appellant replied to the board's preliminary opinion with a letter dated 25 April 2024.

VIII. Oral proceedings were held before the board. At the end of the oral proceedings, the board announced its decision.

IX. The appellant's arguments relevant to the present decision can be summarised as follows.

Auxiliary requests 2 to 4 should be admitted into the appeal proceedings because they were filed at the first possible occasion in reaction to an added subject-matter objection raised for the first time in the decision under appeal.

Throughout the opposition proceedings, the objection that claim 1 as granted added subject-matter was directed against the combination of the "homogeneous" feature with the mention of the excipients in point i) in the plural form. This was clear from point III.2 of the notice of opposition and the minutes of the oral proceedings before the opposition division (page 2, lines 4 to 6). However, in the decision under appeal, the opposition division argued for the first time that the mention of the excipients in the plural form alone added subject-matter.

The amendments in auxiliary requests 2 to 4 overcame the added subject-matter objection and were not overly complex or unexpected.

X. The respondent's arguments relevant to the present decision can be summarised as follows.

The appellant had not challenged the reasoning of the decision under appeal that claims 8 and 9 as granted added subject-matter. Therefore, the patent could not be maintained as granted.

Auxiliary request 1 added subject-matter because claim 4 contained the "0.3%-2% of binding agent" feature, which had been found to add subject-matter in claim 9 as granted.

Auxiliary requests 2 to 4 should not be admitted into the appeal proceedings because they were filed to deal with an added subject-matter objection that had been raised in the notice of opposition and was discussed throughout the opposition proceedings. Contrary to the appellant's contention, point III.2 of the notice of opposition stated that the mere mention of the excipients in point i) of claim 1 in the plural form added subject-matter by itself. The fact that the heading of point III.2 read "homogeneous composition" did not change this. Furthermore, the objection was explicitly addressed by the opposition division in point 12.3.2 of its communication in preparation for oral proceedings.

In addition, the amendments in auxiliary requests 2 to 4 raised issues of claim interpretation and failed to overcome the objection.

XI. The parties' final requests were as follows.

- The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1 to 4 filed with the statement of grounds of appeal.

- The respondent requested that the appeal be dismissed. It also requested that auxiliary requests 1 to 4 and the appellant's submissions in the letter of 25 April 2024 not be admitted into the appeal proceedings.

Reasons for the Decision

1. The patent as granted – amendments (Article 100(c) EPC)

In its communication under Article 15(1) RPBA, the board agreed with the respondent that the appellant had not contested the finding in the decision under appeal that claims 8 and 9 as granted added subject-matter (decision, points 4.4 and 4.5).

This issue was not addressed by the appellant in its reply to the board's communication. When asked about it at the oral proceedings before the board, the appellant did not comment. Therefore, the board had no reason to deviate from the opposition division's conclusion that the ground for opposition of Article 100(c) EPC prejudices the maintenance of the patent as granted.

2. Auxiliary request 1 - amendments (Article 76(1) EPC)

In its communication under Article 15(1) RPBA, the board also noted the respondent's observation that claim 4 of auxiliary request 1 contained the "0.3-2% of binding agent" feature, which had been found to add subject-matter in claim 9 as granted in the decision under appeal (point 4.5.2).

This issue was not addressed by the appellant in its reply to the board's communication, either. When asked about it at the oral proceedings before the board, the appellant did not comment. Given that the conclusion in the decision under appeal that the "0.3-2% of binding agent" feature added subject-matter was not contested, the board concluded that auxiliary request 1 did not meet the requirements of Article 76(1) EPC.

3. Auxiliary request 2 - admittance (Article 12(4) and (6) RPBA)

3.1 Auxiliary request 2 was filed by the appellant for the first time with the statement of grounds of appeal. It constitutes a change to the appellant's case in the opposition proceedings, and its admittance is to be assessed under Article 12(4) and (6) RPBA.

3.2 Article 12(4) RPBA establishes that the board must exercise its discretion in view of, *inter alia*, the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal and the need for procedural economy.

Claim 1 results from the incorporation of claims 5 and 7 as granted into claim 1 as granted. The appellant

argued in the statement of grounds of appeal (page 8, penultimate paragraph) that these amendments overcame the added subject-matter objection because they limited the excipients in claim 1 to those explicitly cited in the claim, excluding other excipients.

As noted by the respondent (reply to the statement of grounds of appeal, page 17), this interpretation of claim 1 is incorrect, at least because the composition in claim 1 is defined in open language (comprising) and defines concentration ranges that allow the presence of additional excipients. Furthermore, the appellant's interpretation of claim 1 is inconsistent because, according to point i) of the claim, the composition contains a plurality of excipients in each category, while the text incorporated from claims 5 and 7 as granted allegedly limits the excipients to only one excipient in each category.

Considering that the amendments in auxiliary request 2 raise issues of claim interpretation and do not clearly overcome the added subject-matter objection based on the mention of the excipients in claim 1 in the plural form, the request is not admissible under Article 12(4) RPBA.

3.3 Article 12(6) RPBA establishes that the board must not admit requests, facts, objections or evidence which should have been submitted, or which were no longer maintained, in the proceedings leading to the decision under appeal unless the circumstances of the appeal case justify their admittance.

3.3.1 According to the appellant, auxiliary request 2 was filed to overcome the objection in the decision under appeal (point 4.3.2, last sentence and points 4.3.3 and

4.3.4) that the mention of the excipients in point i) of claim 1 as granted in the plural form added subject-matter. The appellant argued that this objection was different from the one discussed in the opposition proceedings, which was directed to the combination of the "homogeneous" feature with the mention of the excipients in the plural form. Therefore, auxiliary request 2 was a reaction to the decision under appeal and could not be filed during the opposition proceedings.

3.3.2 This argument is not convincing. The appellant is right that in the opposition proceedings claim 1 as granted was considered to add subject-matter because the application as filed did not disclose the "homogeneous" feature in combination with the mention of the excipients in point i) in the plural form, i.e. "organic or inorganic fillers", "disintegrants", "lubricants" and "anti-adhesives".

However, in the context of this objection, the respondent also argued that the mere mention of the excipients in the plural form added subject-matter. The argument can be found in point III.2 of the notice of opposition. The first paragraph of this point stated that claims 1 to 8 as granted constituted an unallowable generalisation of the process disclosed in the last paragraph of page 23 of the application as filed. The second paragraph referred to several aspects why the claimed subject-matter went beyond the disclosure of the application as filed. The first aspect mentioned was that:

"*the composition in claim 1 contains a plurality of filler**s**, disintegrant**s**, lubricant**s**, anti-adhesive**s**,*

whereas the process on page 23/24 uses only the singular forms" (emphasis in the original)

Therefore, it was clear from this sentence that the use of the plural form of the excipients alone added subject-matter since, in the application as filed, they were disclosed in the singular form.

Furthermore, the opposition division explicitly referred to this objection in point 12.3.2 of its communication in preparation for the oral proceedings, even if it disagreed with the opponent's view. The opposition division stated that:

"*O contested the use of the plural associated with the terms organic and inorganic fillers, disintegrants, lubricants, anti-adhesives as being not supported. The OD is of the preliminary opinion that an explicit basis for the use of the plural in combination with the excipients can be found in the paragraph bridging pages 12 and 13.*"

Therefore, the opposition division identified that an objection was directed exclusively against the use of the plural form of the excipients and gave its preliminary opinion on this issue.

Considering that the objection that the plural form of the excipients in claim 1 as granted adds subject-matter was raised and discussed during the opposition proceedings, auxiliary request 2 could and should have been filed in those proceedings.

3.4 Therefore, the board decided not to admit auxiliary request 2 under Article 12(4) and (6) RPBA.

4. Auxiliary requests 3 and 4 - admittance (Article 12(4) and (6) RPBA)

Claim 1 of auxiliary request 3 derives from claim 1 of auxiliary request 2 by limiting the capsule to a gelatine capsule. Claim 1 of auxiliary request 4 results from limiting claim 1 of auxiliary request 2 to the embodiment relating to the tablet. Therefore, the above reasons for not admitting auxiliary request 2 apply equally to auxiliary requests 3 and 4, which were not admitted into the appeal proceedings, either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated