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Datasheet for the decision of 9 February 2012

Case Number: T 0302/09 - 3.3.02

Application Number: 99941537.5

Publication Number: 1105105

IPC: A61K 9/28, A61K 31/44, A61K 9/20

Language of the proceedings: EN

Title of invention:
Oral administration form for pyridin-2-ylmethylsulfinyl-1H-benzimidazoles

Patent Proprietor:
Nycomed GmbH

Opponent:
EISAI Co., Ltd.

Headword:
Oral administration forms/NYCOMED GmbH

Relevant legal provisions:
EPC Art. 54, 84, 123(2), 111

Keyword:
"Main request - novelty - (no)"
"Auxiliary request I - clarity - (no): Claim 1 contradictory in itself"
"Auxiliary request II - allowability of amendments, clarity (yes)"
"Remittal - (yes): undecided issues"

Decisions cited:
G 0002/10

Catchword:
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Case Number: T 0302/09 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 9 February 2012

Appellant: (Patent Proprietor)	Nycomed GmbH Byk-Gulden-Strasse 2 D-78467 Konstanz (DE)
Representative:	UEXKÜLL & STOLBERG Patentanwälte Beselerstrasse 4 D-22607 Hamburg (DE)
Respondent: (Opponent)	EISAI Co., Ltd. Koishikawa 4-6-10, Bunkyo-ku Tokyo 112 (JP)
Representative:	Harris, Jennifer Lucy Kilburn & Strode LLP 20 Red Lion Street London WC1R 4PJ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 5 December 2008 revoking European patent No. 1105105 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 105 105, based on application No. 99 941 537.5, was granted on the basis of 23 claims.

The independent claims read as follows:

"1. An oral fixed combination administration form for an active compound, which is a pyridin-2-ylmethylsulfinyl-1H-benzimidazole or a pharmaceutically acceptable salt thereof, wherein said active compound is in a capsule in two different administration forms, which have a different release of the active compound, wherein one administration form comprises the active compound together with a tablet disintegrant and bears a coating film for sustained-release and wherein the other administration form comprises the active compound and which bears an enteric coating film.

23. Use of an oral fixed combination administration form according to any one or claims 1 to 22 in the manufacture of a medicament used for treating disorders of the stomach."

II. Notice of opposition was filed against the patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC for amendments that contained subject-matter extending beyond the content of the parent application as filed.

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

(6) WO 99/32093

(6a) priority document of WO 99/32093

(17) The United States Pharmacopeia USP 23 NF 18 (1995), pages 1790-1796 and 1949-1951

(18) K.H. Bauer et al., "Überzogene Arzneiformen", Wissenschaftliche Verlagsgesellschaft mbH Stuttgart (1988), pages 71-77 and 127-139

(19) R. Voigt, "Lehrbuch der pharmazeutischen Technologie", Verlag Chemie Weinheim - New York (1979), pages 225-228

(20) Hagers Handbuch der Pharmazeutischen Praxis, Springer Verlag Berlin - Heidelberg - New York (1971), pages 679-680, 687-688, 734-735, 776-778 and 839-850

(21) Evonik Industries, "Eudragit® Application Guidelines, 10th Edition, 06/2008

(22) Concise Medical Dictionary, seventh edition, Oxford University Press (2007), page 240-241

IV. The appeal lies from a decision of the opposition division pronounced on 6 November 2008 revoking the European patent.

V. In said decision the opposition division decided that the subject-matter of independent claims 1 and 23 as granted met the requirements of Articles 123(2) and 83 EPC, but was not novel over example 7 and claims 8 and 16 of document (6). In this context the opposition division emphasised that the wording of the claims as granted did not exclude administration forms comprising an enteric coating in addition to a sustained release coating. Furthermore, the opposition division came to the conclusion that the subject-matter of claim 1 of

the auxiliary request was not clear, as the feature "a coating film for sustained release which will release the active compound only after gastric passage, an enteric coating being absent" was contradictory in itself.

VI. The patentee (appellant) lodged an appeal against that decision.

VII. With a letter dated 23 February 2010, the appellant submitted auxiliary requests II and III (set B and set C).

VIII. In the annex to the summons to oral proceedings pursuant to Article 15(1) RPBA, the board gave its preliminary opinion on some of the points to be discussed at the oral proceedings, according to which claims 1 and 23 of the main request did not appear to be novel and claim 1 of auxiliary request I appeared to lack clarity. In connection with auxiliary request II, the board indicated a possible basis in the original application for the amendments made in claim 1. Finally, the board was of the preliminary opinion that the disclaimer introduced into claim 1 of auxiliary request III was not allowable.

IX. In a letter dated 5 January 2012, the respondent (opponent) informed the board that it would not attend the oral proceedings scheduled for 9 February 2012.

X. Oral proceedings were held before the board on 9 February 2012.

XI. The independent claims of auxiliary requests I and II read as follows:

(i) Auxiliary request I:

"1. An oral fixed combination administration form for an active compound, which is pyridin-2-ylmethylsulfinyl-1H- benzimidazole or a pharmaceutically acceptable salt thereof, wherein said active compound is in a capsule in two different administration forms, which have a different release of the active compound, wherein one administration form comprises the active compound together with a tablet disintegrant and bears a coating film for sustained release which will release the active compound only after gastric passage, an enteric coating being absent, and wherein the other administration form comprises the active compound and which bears an enteric coating film.

22. Use of an oral fixed combination administration form according to any one or claims 1 to 21 in the manufacture of a medicament used for treating disorders of the stomach."

(ii) Auxiliary request II:

"1. An oral fixed combination administration form for an active compound, which is pyridin—2—ylmethylsulfinyl-lH- benzimidazole or a pharmaceutically acceptable salt thereof, wherein said active compound is in a capsule in two different administration forms, which have a different release of the active compound, wherein one administration form

comprises the active compound together with a tablet disintegrant and bears a coating film for sustained release which will release the active compound only after gastric passage, an enteric coating comprising free acidic groups in a polymer being absent, and wherein the other administration form comprises the active compound and which bears an enteric coating film.

22. Use of an oral fixed combination administration form according to any one or claims 1 to 21 in the manufacture of a medicament used for treating disorders of the stomach."

XII. The appellants' arguments can be summarised as follows:

The passages in paragraphs [0011] and [0038] of the contested patent made it clear that the present invention did not foresee compositions wherein one and the same administration comprised both a sustained release coating and an enteric coating. As a consequence, the subject-matter of claim 1 was novel over example 7 of document (6).

Regarding clarity of claim 1 of auxiliary request I, the appellants argued that the terms "enteric coating" and "sustained release coating" did not have identical meanings. Enteric coatings were characterised by pH-dependent release. They were inert in the acidic environment of the stomach, which they left utterly unchanged, and released the active agent in the weakly alkaline milieu of the small intestine. In contrast thereto, sustained release coatings had a time-dependent release which was independent of the pH.

Sustained release coatings swelled in the stomach. Alternatively, an enteric coating could be regarded as a subset of the more general term sustained release coating. In both cases, there was no contradiction in the claim, so that the requirements of Article 84 EPC were met.

The passage on page 2, line 3-5, in combination with page 2, lines 10-12, provided a basis for the amendments effected in claim 1 of auxiliary request II. Moreover, the enteric coating as defined in claim 1 of auxiliary request II was more specific than the sustained release coating. As a consequence, the requirements of Articles 123(2) and 84 EPC were met.

XIII. The respondents' arguments can be summarised as follows:

Regarding novelty of the main request, reference was made to the decision under appeal. In connection with clarity of the subject-matter according to claim 1 of auxiliary request I, it was argued that "enteric" meant "relating to or affecting the intestine". As a consequence, the limitation introduced into claim 1 of auxiliary request I did not make sense and therefore lacked clarity.

No comments were made in connection with auxiliary request II.

XIV. The appellant requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or on the basis of one of the following auxiliary requests:

- set of claims 1 to 22 filed on 2 August 2007 entitled "Set A" (first auxiliary request);
- sets of claims 1 to 22 filed on 23 February 2010 entitled "Set B" and "Set C" (second and third auxiliary request respectively);
- set of claims 1 to 22 received during oral proceedings entitled "Set D" (fourth auxiliary request);
- set of claims 1 to 17 filed on 5 January 2012 entitled "Set E" (fifth auxiliary request). The appellant further requested to remit the case to the department of first instance for consideration of outstanding issues in case either the main request was found to meet the requirements of Articles 84, 123 and 54, or one of the auxiliary requests was found to meet the requirements of Articles 84 and 123 EPC.

The respondent requested in writing that the appeal be dismissed. It further requested to remit the case to the department of first instance for consideration of novelty and inventive step in case one of the auxiliary requests was found to meet the requirements of Articles 84, 123 and 54 EPC.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request - novelty*

Document (6) published on 1 July 1999 claims the priority date of 22 December 1997. It has been supplied

to the European Patent Office in one of its official languages and the filing fee has been paid. Its content as filed is therefore considered to be comprised in the state of the art relevant to the question of novelty, pursuant to Article 54(3) EPC. Example 7 of document (6) discloses capsules containing both pellets and a tablet. The pellets comprise sugar sphere cores onto which a layer comprising Mg omeprazole is added. Then a separating layer, an enteric coating based on methacrylic acid copolymer and an overcoating are added.

The tablet comprises a core containing Mg omeprazole and tablet disintegrants such as microcristalline cellulose or PVP-XL, onto which a "lag time regulating layer" based on ethyl cellulose (= sustained release coating) and an enteric coating layer based on hydroxypropyl methylcellulose phthalate are added.

It follows therefrom that the capsules according to example 7 of document (6) contain pellets comprising an enteric coating and tablets comprising both a sustained release coating and an enteric coating. As a consequence, the subject-matter of claim 1 of the main request is not novel. In this context, it is emphasised that the wording of the claim does not exclude tablets comprising both a sustained release coating and a further coating retarding the release of Mg omeprazole. Furthermore, the wording of the claim is clear, so that the skilled person has no reason to consult the description for a proper reading thereof, as was alleged by the appellant.

It is further noted that example 7 of document (6) is identical to example 7 of document (6a), so that its priority is validly claimed. As a consequence, the subject-matter of claim 1 of the main request does not meet the requirements of Article 54(3) EPC.

3. *Auxiliary request I - clarity*

As compared to claim 1 of the main request, claim 1 of auxiliary request I contains the additional feature that the coating will release the active compound only after gastric passage, an enteric coating being absent. In the decision under appeal, the opposition division regarded an enteric coating as a coating that prevents the release of the active compound until the small intestine is reached and concluded that an enteric coating was identical to a coating which releases the active compound only after gastric passage. The appellant submitted documents (17) to (21) to demonstrate that enteric coatings are characterised by a pH-dependent release and are therefore different from time-dependent sustained release coatings. The board, however, notes that the available prior art does not unambiguously disclose this specific meaning. Thus, document (17) states that "such [enteric] coatings are intended to delay the release of the medication until the tablet has passed through the stomach" (see the paragraph "Enteric-Coated Tablets" in the left-hand column on page 1951). This is exactly how claim 1 of auxiliary request I defines sustained release coating. This shows that it is not possible to make a clear distinction between enteric coating and sustained release coating.

The appellant also cited document (22), which indicates that enteric-coated tablets are "tablets that are coated with a substance that enables them to pass through the stomach and into the intestine unchanged" (see right- hand column on page 240). According to the appellant, only pH-dependent enteric coatings leave the stomach unchanged, while the time-dependent but pH independent sustained release coatings swell in the stomach. Apart from the fact that this document is post-published, the board is of the opinion that in this context the word "unchanged" does not exclude swelling but simply indicates that no active compound is released. The tablet is unchanged in the sense that it still carries the whole amount of the active compound when it leaves the stomach.

It is true that there also exists prior art regarding enteric coating and sustained release coating as two different concepts (see documents (18), (19) and (20)), but in the light of the overall situation, which is characterised by numerous and varying definitions, the board came to the conclusion that it is not possible to distinguish enteric coatings from sustained release coatings. As a consequence, the feature "a coating film for sustained release which will release the active compound only after gastric passage, an enteric coating being absent" is contradictory in itself, so that the requirements of Article 84 EPC are not met.

4. Auxiliary request II

4.1 Allowability of the amendments

4.1.1 Regarding the feature "coating film for sustained release", the board concurs with the finding of the opposition division that "a film coating which is customary per se for sustained release compositions" (claim 1 and third paragraph on page 2 of the original application) provides a basis therefor, as both expressions refer to any coating which is suitable for sustained release (see point 2.1 of the decision under appeal).

4.1.2 The basis for the feature "which will release the active compound only after gastric passage, an enteric coating comprising free acidic groups in a polymer being absent" can be found on page 2, lines 3-5 and lines 10-12, of the original application. The board is aware of the fact that the passage on page 2, lines 3-5, which relates to enteric coatings whose resistance to gastric juice is based on the fact that free acidic groups are present in a polymer, relates to the description of the prior art. However, when seen in the whole context of the disclosure, it is clear that the passage "Surprisingly, it has now been found that an enteric coating for pyridin-2-ylmethylsulfinyl-1H-benzimidazoles is unnecessary..." on page 2, lines 10-12, can only mean that the above-mentioned enteric coatings of the prior art are excluded from the present invention.

It is additionally emphasised that in view of the fact that the **absence** of enteric coatings is disclosed in

the application as originally filed, the feature in question does not constitute a so-called "disclosed disclaimer" according to decision G 2/10 of 30 August 2011.

4.1.3 As a consequence, the subject-matter of claim 1 meets the requirements of Article 123(2) EPC.

4.2 Clarity

By indicating that the enteric coating comprises free acidic groups in a polymer, the unclarity observed in claim 1 of auxiliary request I has been overcome, as now the excluded coatings form a subgroup of the more general sustained release coatings, with all sustained release coatings not comprising free acidic groups in a polymer remaining in claim 1. Therefore, the subject-matter of claim 1 of auxiliary request II meets the requirements of Article 84 EPC.

5. Remittal to the department of first instance

Although Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party should where appropriate be given the opportunity to have two readings of the important elements of the case. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In view of the fact that the opposition division did not decide on inventive step and in view of the parties' requests (see point XV above), the board has reached the conclusion that, in the prevailing circumstances, the case should be remitted to the examining division for further prosecution.

6. In view of these findings, evaluation of the further auxiliary requests is unnecessary.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

N. Maslin U. Oswald