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**Datasheet for the decision
of 19 June 2008**

Case Number: T 1283/05 - 3.3.02

Application Number: 93109159.9

Publication Number: 0578965

IPC: A61K 31/415

Language of the proceedings: EN

Title of invention:

Compositions and methods for treating gastrointestinal disorders

Applicant:

THE PROCTER & GAMBLE COMPANY

Opponent:

-

Headword:

Composition for gastrointestinal disorders/THE PROCTER & GAMBLE COMPANY

Relevant legal provisions:

EPC Art. 111(1)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Remittal - yes - fresh case"

Decision cited:

G 0002/08

Catchword:

-



Case Number: T 1283/05 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 19 June 2008

Appellant:

THE PROCTER & GAMBLE COMPANY
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Representative:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 10 May 2005
refusing European application No. 93109159.9
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
P. Mühlens

Summary of Facts and Submissions

- I. European patent application No. 93 109 159.9 entitled "Compositions and methods for treating gastrointestinal disorders", which is a divisional application of European patent application No. 88 200 396.5, was refused by a decision of the Examining Division given to EPO postal service on 04.05.05 on the grounds of lack of inventive step.

Claim 1 as filed reads as follow:

"1. The use of a campylobacter-inhibiting antimicrobial agent for the manufacture of a medicament for the treatment or prevention of gastrointestinal disorders selected from non-ulcerative gastrointestinal disorders such as chronic or atrophic gastritis, non-ulcer dyspepsia, esophageal reflux disease, gastric motility disorders, and peptic ulcer disease, selected from gastric, duodenal and jejunal ulcers, in humans or lower animals, said treatment or prevention comprising administering to said human or lower animal a composition comprising, by weight, from 0.1% to 99.8% of the campylobacter-inhibiting antimicrobial agent and concurrently administering to said human or lower animal a safe and effective amount of an H2 receptor blocking anti-secretory agent."

- II. The text of the Examining Division's decision reads as follow:

"REASON FOR DECISION

1). The present application does not meet the requirements of Article 56 EPC. The present claims relate to the use of one agent to manufacture medicament to be used with another agent for the treatment of gastrointestinal disorders. The parent patent related to the use to both agents together to manufacture a medicament and a composition of both agents for the treatment of the same disorders. The Examining division do not believe that the differences in the two applications are substantially sufficient for them to consider the present case in a different manner to the parent.

2). The parent application was revoked by an Opposition division under Article 56 EPC, a decision which was upheld by the Board of Appeal under T1048/99. The Examining division see no reason why this decision (especially paragraphs, 3.1- 3.6) cannot be fully applied under Article 56 EPC to the present claims.

3). The Applicant did not wish to take to opportunity given to him to comment on this decision and how it applies (or should not be applied) to the present application."

Claim 1 before the Examining Division as received on 19.09.1997 reads:

"1. The use of a campylobacter-inhibiting antimicrobial agent for the manufacture of a medicament for the treatment or

prevention of gastrointestinal disorders selected from non- ulcerative gastrointestinal disorders such as chronic or atrophic gastritis, non-ulcer dyspepsia, esophageal reflux disease, gastric motility disorders, and peptic ulcer disease, selected from gastric, duodenal and jejunal ulcers, in humans or lower animals, said treatment or prevention comprising administering to said human or lower animal a composition comprising, by weight, from 0.1% to 99.8% of the campylobacter-inhibiting antimicrobial agent and **concurrently** administering to said human or lower animal a safe and effective amount of an H₂ receptor blocking anti-secretory agent, **wherein use of the anti-secretory agent in the manufacture of the same medicament is excluded**" (emphasis added).

III. The appellant (applicant) lodged an appeal against the said decision and filed a main request and three auxiliary requests with its grounds of appeal.

Claim 1 of the main request reads:

"1. The use of a campylobacter-inhibiting antimicrobial agent selected from antibiotics for the manufacture of a medicament for the treatment or prevention of gastrointestinal disorders selected from non-ulcerative gastrointestinal disorders such as chronic or atrophic gastritis, non-ulcer dyspepsia, esophageal reflux disease, gastric motility disorders, and peptic ulcer disease, selected from gastric, duodenal and jejunal ulcers, in humans or lower animals, said treatment or prevention comprising administering to said human or lower animal a composition comprising, by weight, from 0.1% to 99.8% of the campylobacter-

inhibiting antimicrobial agent and a safe and effective amount of an H₂ receptor blocking anti-secretory agent, **wherein the campylobacter-inhibiting antimicrobial agent and the H₂ receptor blocking anti-secretory agent are administered within 1 hour of each other**" (emphasis added).

- IV. In a communication dated 11 April 2008, the appellant informed the Board that it would not attend or be represented at the oral proceedings.
- V. Oral proceedings were held before the Board on 19 June 2008.
- VI. The appellant's submissions in the written procedure essentially concerned the benefits of the dosage regimen according to the claimed subject-matter vis-à-vis the prior art.
- VII. The appellant requested that the decision under appeal be set aside and that the patent be granted on the basis of the main request or of one of the auxiliary requests 1 to 3 filed with the grounds of appeal.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. *Main request*
 - 2.1 The Examining Division found that the present divisional application did not meet the requirements of Article 56 EPC because it did not consider the

differences vis-à-vis the parent application to be substantially sufficient for it to consider the present case in a different manner to the parent, which was revoked on the grounds of lack of inventive step.

The newly filed main request is now characterized by a specific dosage regimen. Thus, the finding of the Opposition Division in the present case that claim 1 of the application was not inventive because there was no significant difference vis-à-vis the parent application, which concerned a composition of both agents, does not hold good.

2.2 Remittal to the department of first instance

2.2.1 Although Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case considered by two instances, that may well be appropriate as regards essential issues. Hence, cases are often referred back if essential questions regarding the patentability of the claimed subject-matter have not been examined and decided by the department of first instance.

As it appears from the wording of the newly filed main request, the new feature lies now in the indication of a specific dosage regimen.

The relevance of this feature has therefore never been assessed.

Accordingly, this feature now falls to be considered as an essential substantive issue in the present case.

2.2.2 In view of the above, the Board has reached the conclusion that, in the circumstances of the present case, it is appropriate to remit the case to the Examining Division.

In that respect, as this case will clearly be affected by the Enlarged Board of Appeal decision in G 2/08 on the question of dosage regimen patenting, the Examining Division should postpone its decision until the Enlarged Board of appeal gives its decision.

3. *General matters*

3.1 Articles 123(2) and 84 EPC

The Board observes that it is questionable whether the disclaimer introduced in claim 1 of the request before the Examining Division fulfilled the requirements of the case law relating to disclaimers having regard to Article 123(2) EPC.

It is moreover in contradiction with the statement in the description of the application as originally filed, i.e. "the term "concurrently"... includes co-administration of the agents by administering a composition of the present invention" (page 19, lines 14-16) (Article 84 EPC).

These issues should have been dealt with in any case and before the inventive-step assessment since, as the rule, any amendments to the claims as filed have to be checked in these respects.

3.2 Completeness of the first instance decision

The function of appeal proceedings is to give a judicial decision upon the correctness of a separate earlier decision taken by a first-instance department. A reasoned decision issued by the first-instance department meeting the requirements of Rule 111(2) EPC is accordingly mandatory.

In the present case the Examining Division refused the application merely by reference to the revocation of the patent of the parent application based on lack of inventive step and to the related Opposition Division's and Board of Appeal's decisions (see point III).

In the case of a divisional application - which is an independent application like any other - the Examining Division however remains obliged by Rule 111(2) EPC to issue a decision presenting all the legal and factual reasons for refusing it.

In that respect, the Board observes that the Examining Division decision is not complete as it should contain a full examination of the case with related prior art documents and evidence, which are not available in the file at issue.

The duty to provide substantiated reasons in administrative decisions is a fundamental principle in all contracting states, Rule 111(2) EPC simply being an expression of that principle. Further, from the point of view of the practical functioning of the system envisaged in the EPC, in the absence of the documents and an adequately related reasoned decision within the meaning of Rule 111(2) EPC the Board cannot examine the

appeal as to its merits in an **adequate** manner
(Article 110 EPC).

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