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D E C I S I O N
of 9 June 2005

Case Number: T 0082/04 - 3.3.2

Application Number: 95302628.3

Publication Number: 0679400

IPC: A61K 31/71

Language of the proceedings: EN

Title of invention:
Oral dosage forms of azithromycin avoiding drugfood interaction

Patentee:
PFIZER INC.

Opponents:
Hexal Aktiengesellschaft
RATIOPHARM GMBH
Laboratorios Vita, S.A.

Headword:
Dosage form of azithromycin/PFIZER INC.

Relevant legal provisions:
EPC Art. 123(2), 84, 111
EPC R. 57a

Keyword:
"Admissibility - yes: reply to a newly raised objection"
"Rule 57a - yes: bona fide attempt to overcome an objection"
"Article 123(2) - no: sub-range is a restriction of a broader range not a selection within it"
"Article 84 - yes: a feature is clear when it is possible to determine whether the conditions it requires are fulfilled"
"Article 111 - remittal - yes: unexamined grounds of opposition"

Decisions cited:
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Catchword:
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Case Number: T 0082/04 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 9 June 2005

Appellant: (Proprietor of the patent)
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Respondent: (Opponent 03)
Laboratorios Vita, S.A.

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 15 December 2003 revoking European patent No. 0679400 pursuant to Article 102(1) EPC.

Composition of the Board:

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

Summary of Facts and Submissions

I. European patent No. 0 679 400 based on application No. 95 302 628.3 was granted on the basis of 8 claims.

Independent claims 1 and 2 as granted read as follows:

"1. Use of azithromycin in the manufacture of an oral dosage form which does not exhibit an adverse food effect in the treatment of a microbial infection in a mammal; wherein said dosage form effects at least 90% dissolution of azithromycin within 30 minutes when an amount of the dosage form equivalent to 200 mg of azithromycin is tested as set forth in USP test ⟨711⟩in a USP-2 dissolution apparatus under conditions at least as stringent as the following: 900ml phosphate buffer, pH 6.0, 37°C with paddles turning at 100 rpm, provided that said dosage form is not a capsule and that it contains less than a taste-masking amount of an alkaline earth metal oxide or hydroxide.

2. Use of azithromycin in the manufacture of an oral dosage form which does not exhibit an adverse food effect in the treatment of a microbial infection in a mammal; wherein said dosage form exhibits a value of $(AUC_{fed})/(AUC_{fst})$ of at least 0.80 with a lower 90% confidence limit of at least 0.75, provided that said dosage form is not a capsule and that it contains less than a taste-masking amount of an alkaline earth metal oxide or hydroxide."

II. Notices of opposition were filed against the granted patent by opponent O1, opponent O2 and opponent O3. The patent was opposed under Article 100(b) EPC for

insufficiency of disclosure and under Article 100(a) EPC for lack of novelty and inventive step.

III. The decision of the Opposition Division pronounced on 12 November 2003 revoked the patent under Article 102(1) EPC.

The Opposition Division was of the opinion that independent claims 1 and 2 of the sole set of claims under consideration filed during the oral proceedings did not fulfil the requirements of Article 84 EPC.

Independent claims 1 and 2 of this set of claims read as follows:

"1. Use of azithromycin in the manufacture of an oral dosage form which does not exhibit an adverse food effect for the treatment of a microbial infection in a mammal **which has eaten or will eat in the period commencing 1 hour prior to dosing and terminating 2 hours after dosing**; wherein said dosage form effects at least 90% dissolution of azithromycin within 30 minutes when an amount of the dosage form equivalent to 200 mg of azithromycin is tested as set forth in USP test ⟨711⟩ in a USP-2 dissolution apparatus under conditions at least as stringent as the following: 900ml phosphate buffer, pH 6.0, 37°C with paddles turning at 100 rpm, provided that said dosage form is not a capsule and that it contains less than a taste-masking amount of an alkaline earth metal oxide or hydroxide.

2. Use of azithromycin in the manufacture of an oral dosage form which does not exhibit an adverse food effect for the treatment of a microbial infection in a

mammal **which has eaten or will eat in the period commencing 1 hour prior to dosing and terminating 2 hours after dosing**; wherein said dosage form exhibits a value of $(AUC_{fed})/(AUC_{fst})$ of at least 0.80 with a lower 90% confidence limit of at least 0.75, provided that said dosage form is not a capsule and that it contains less than a taste-masking amount of an alkaline earth metal oxide or hydroxide." (Emphasis added).

It considered that the feature "a mammal who has eaten or will eat in the period commencing one hour prior to dosing and terminating two hours after dosing" used in claims 1 and 2 contravened Article 84 EPC because it did not properly defined a group a patients and because the quantity of food to be eaten was moreover not indicated in these claims.

In addition, it was of the opinion that there was a discrepancy between these claims and the subject-matter of dependent claim 7, which recited that the dosage form could be taken with or without food.

IV. The appellant (patentee) lodged an appeal against the said decision.

V. Oral proceedings were held before the Board on 9 June 2005.
A new main request was filed during the oral proceedings.

Independent Claims 1 and 2 of the set of claims of the main request read as follows:

"1. Use of azithromycin in the manufacture of an oral dosage form which does not exhibit an adverse food effect in the treatment of microbial infection in a mammal **that has eaten any quantity or nature of food within a period of 1 hour prior to dosing**; wherein said dosage form effects at least 90% dissolution of azithromycin within 30 minutes when an amount of the dosage form equivalent to 200 mg of azithromycin is tested as set forth in USP test ⟨711⟩in a USP-2 dissolution apparatus under conditions at least as stringent as the following: 900ml phosphate buffer, pH 6.0, 37°C with paddles turning at 100 rpm, provided that said dosage form is not a capsule and that it contains less than a taste-masking amount of an alkaline earth metal oxide or hydroxide.

2. Use of azithromycin in the manufacture of an oral dosage form which does not exhibit an adverse food effect in the treatment of microbial infection in a mammal **that has eaten any quantity or nature of food within a period of 1 hour prior to dosing**; wherein said dosage form exhibits a value of $(AUC_{fed})/(AUC_{fst})$ of at least 0.80 with a lower **90%** confidence limit of at least 0.75, provided that said dosage form is not a capsule and that it contains less than a taste-masking amount of an alkaline earth metal oxide or hydroxide." (Emphasis added).

The set of claims of the first auxiliary request corresponds to the set of claims of the request on which the opposition division's decision was based wherein the contested feature has been amended to read **"that has eaten any quantity or nature of food within a period of 1 hour prior to dosing"** instead of **"which has**

eaten or will eat in the period commencing 1 hour prior to dosing and terminating 2 hours after dosing" in both independent claims 1 and 2.

VI. The appellant first contested the status of Procter & Gamble Pharmaceutical SARL as legal successor and new opponent O3 because the documents on file did not establish that Procter & Gamble Pharmaceutical SARL was the legal successor of Laboratorios Vita, S.A.

It then submitted that the main request filed during the oral proceedings complied with both Articles 123 and 84 EPC.

VII. The representative of Procter & Gamble Pharmaceutical SARL did not contest the appellant's findings regarding the status of Procter & Gamble Pharmaceutical SARL as legal successor and new opponent O3.

It however submitted that the appellant's objection should not be taken into account as it was raised at a very late stage.

Respondents R1 and R2 argued that the set of claims filed during the oral proceedings should not be admitted into the proceedings as late filed and under Rule 57a as it did not overcome the grounds of opposition and in particular because it did not restore novelty over the state of the art.

They were also of the opinion that the amended claims 1 and 2 were not disclosed in the application as originally filed contrary to the requirements of Article 123(2).

Moreover, they held that the feature "**that has eaten any quantity or nature of food within a period of 1 hour prior to dosing**" introduced in claims 1 and 2 was unclear because the time interval thus defined had no start and no end and because it was not suitable for defining a group of patients.

VIII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the main request filed during the oral proceedings.

The respondents (opponents O1 and O2) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible

2. Transfer of opponent's status

At the beginning of the oral proceedings, the appellant submitted that the documentary evidence (Annex A) filed by the representative of Procter & Gamble Pharmaceuticals SARL with its letter dated 28 February 2005 did not establish that Procter & Gamble Pharmaceutical SARL was the legal successor of Laboratorios Vita, S.A., so that the representative should not be allowed to present its case.

In that respect, the Board observes that the representative of Procter & Gamble Pharmaceutical SARL did not contest these findings.

Moreover, the representative refused the Board's proposal to have the oral proceedings postponed in order to have a further chance to provide the Board with the necessary documentary evidence in connection with the transfer of opponent status from the former opponent Laboratorios Vita, S.A., to Procter & Gamble Pharmaceutical SARL.

Under these circumstances, the Board decided that Procter & Gamble is not party to the proceeding and to continue the oral proceedings with the remaining parties and that the representative of Procter & Gamble Pharmaceutical SARL was not allowed to present its case at the hearing as the transfer of opponent status was not established.

As to the representative's argument not to take the appellant's objection into account on the grounds that it was submitted late, the Board notes that the appellant has in fact clearly announced its intention to deal with this particular point at the hearing (appellant's letter dated 2 March 2005, under item 35: "The patent proprietor takes the view that the question of the transfer of the opposition can be resolved at the hearing of the appeal.").

Accordingly, the Board had no reason to refuse to deal with the objection.

3. *Admissibility of the set of claims filed during the oral proceedings*

This set of claims differs from the set of claims corresponding to the set of claims of auxiliary request 1 filed with the grounds of appeal on 30 March 2004 only in that the value **90%** was added in claim 2.

As this amendment was made in response to the objection made by respondent R2 for the first time during the oral proceedings that this value was missing in said claim, with the consequence that it therefore infringed Article 123(3), the Board considers that the request is not late filed as the appellant had in fact no opportunity to react beforehand since the objection was not previously known to him.

Accordingly, the set of claims presented during the oral proceedings may be introduced into the proceedings.

4. *Rule 57a EPC*

As to the feature "**that has eaten any quantity or nature of food within a period of 1 hour prior to dosing"** introduced in both independent claims 1 and 2 instead of **"which has eaten or will eat in the period commencing 1 hour prior to dosing and terminating 2 hours after dosing"**, which was deemed to be unclear according to the opposition's decision, the Board considers that the change in the wording and in the interval scope of this feature constitutes *a priori* a *bona fide* attempt to overcome an objection which led to

the revocation of the patent by the department of first instance.

Accordingly, the set of claims is admitted into the proceedings.

The Board does not agree with the respondents' view that an amendment should lead to a patentable subject-matter in order to comply with the requirements of Rule 57a EPC since said Article is silent about the merit of the amendments.

The question whether this feature provides for novelty or not is therefore irrelevant to that end.

5. *Article 123 (2) and (3) EPC*

5.1 Compared with claim 1 as granted, independent claims 1 and 2 of the main request are now restricted to a group of patients, "**that has eaten any quantity or nature of food within a period of 1 hour prior to dosing".**

The Board observes that a different time range was in fact explicitly disclosed in the application as originally filed, namely a **"period commencing 1 hour prior to dosing and terminating 2 hours after dosing"** (page 3, lines 30 to 33, claim 1, claim 8).

According to the reasoning in point 3 of the grounds in T 2/81 (OJ 1982, 394), the simple sub-combination of the part ranges would not merit novelty as "selection", so that this mere restriction would not represent new subject-matter. This is precisely the situation in the present case where a mere restriction in a disclosed

time interval has been made by choosing, on the one hand, the disclosed starting point of the disclosed time interval (ie one hour prior to dosing) and, on the other hand, a specifically disclosed point within the disclosed time interval (the dosing time) in order to creature a time sub-range within the disclosed one.

As to the definition **"any quantity or nature of food"** given in these claims, the Board notes that this wording is disclosed *expressis verbis* on page 14, lines 10 to 13, of the application as originally filed.

Accordingly, the Board concludes that the amendment contravenes neither Article 123(2) EPC nor Article 123(3) EPC since, as a rule, the addition of a supplementary feature in a claim restricts its scope of protection.

5.2 As is apparent from the above, the Board does not share the respondent's view that the new time range amounts to an unallowable selection.

The Board agrees with the respondents that this restriction was not disclosed *expressis verbis* in the form of a second medical use claim.

It is however directly and unambiguously derivable for the skilled person reading the subject-matter of claims 8 and 12 as originally filed that the claimed dosage forms were intended for a medical use:

"8. An oral dosage form of azithromycin administrable to a mammal that has eaten or will eat **in the period commencing 1 hour prior to dosing** and terminating 2

hours after dosing, which comprises azithromycin and which exhibits substantially no adverse food effect, said dosage form effecting at least 90% dissolution of azithromycin within 30 minutes when an amount of the dosage form equivalent to 200 mg of azithromycin is tested as set forth in USP test <711> in a USP-2 dissolution apparatus under conditions at least as stringent as the following: 900 ml phosphate buffer, pH 6.0, 37°C with paddles turning at 100 rpm, provided that said dosage form is not a capsule and that it contains less than a taste-masking amount of an alkaline earth metal oxide or hydroxide.

12. An oral dosage form of azithromycin administrable to a mammal that has eaten or will eat **in the period commencing 1 hour prior to dosing** and terminating 2 hours after dosing, which comprises azithromycin and which exhibits substantially no adverse food effect, said dosage form exhibiting a value of $(AUC_{fed})/(AUC_{fst})$ of at least 0.80 with a lower 90% confidence limit of at least 0.75, provided that said dosage form is not a capsule and that it contains less than a taste-masking amount of an alkaline earth metal oxide or hydroxide." (Emphasis added).

Therefore, the Board considers that there was an unambiguously disclosed relation between the described dosage form, its medical use, the group of patients and the time period, so that no added matter can be seen in the reformulation of the product claims into use claims.

6. *Article 84 EPC*

6.1 Claims 1 and 8 concern the use of azithromycin in the manufacture of an oral dosage form which does not exhibit an adverse food effect in the treatment of microbial infection.

Claims 1 and 8 moreover require that the patient to be treated "**has eaten any quantity or nature of food within a period of 1 hour prior to dosing**".

The Board notes that both the time period (**one hour prior to dosing**) and the food (**any quantity or nature of food**) are clearly indicated in these claims.

The Board therefore sees no difficulty in determining whether a patient would fulfil this condition or not, so that the matter for which protection is sought appears to be clearly defined in the claims as required by Article 84 EPC.

6.2 The Board does not agree with the respondent's submissions that neither the starting time of the time interval nor the end time are clearly defined in the claims.

In fact, since as recited in the claims the oral dosage form is intended to avoid adverse food effects, it appears that the time period of one hour can only be the time period starting 60 minutes prior to dosing and not any time period of one hour at any time preceding the dosing(eg 5 hours before dosing, one day before dosing, and so on), contrary to the respondent's submissions.

As to the question of, whether the patient should or should not eat at dosing time, the Board observes that there is no feature in the claims which deals with that point, so that this consideration is irrelevant as far as the clarity of the features present in the claims is concerned.

In order not to fall within the scope of the claims, a patient merely needs not to take **any quantity or nature of food within the period of one hour prior to dosing;** what the patient does before 60 minutes to dosing, or at dosing time, or after dosing time is not part of the claims and, as such, these considerations are irrelevant for the assessment of the clarity of the features present in the claims.

The second point raised by the respondents that a patient eating one minute before dosing cannot be **physiologically** distinguished from a patient eating just one second after dosing is also irrelevant for the assessment of the clarity of the claims.

In fact, the only point at issue when it comes to the assessment of clarity of a claim is whether it is possible in any case to know when an embodiment patient fulfils the requirements indicated by the features of the claims. The fact that these features have a technical meaning leading to patentable matter or not is irrelevant to that end.

7. *Remittal to the department of first instance*

7.1 Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of the case. The essential function of an appeal is to consider whether the decision which has been issued by the first-instance department is correct. 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 particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party solely upon one particular issue which is decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111(1) EPC).

7.2 The observations made above apply fully to the present case. The Opposition Division decided that claim 1 was not patentable on the grounds of lack of clarity, but disregarded the essential issues of sufficiency of disclosure (Article 83), novelty (Articles 52(1), 54 EPC) and inventive step (Articles 52(1), 56 EPC). These issues, however, formed, *inter alia*, the basis for the requests that the patent be revoked in its entirety and

must therefore be considered as essential substantive issues in the present case.

7.3 Thus, in view of the above considerations, the board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit the case to the Opposition Division for further prosecution on the basis of the set of claims of the request filed by the appellant during the oral proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

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

The Registrar: The Chairman:

A. Townend U. Oswald