BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS | BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE | CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen

D E C I S I O N
of 1 April 1998

Case Number: T 0516/94 - 3.3.2

Application Number: 88309665.3

Publication Number: 0320097

IPC: A61K 31/55

Language of the proceedings: EN

Title of invention:
Controlled absorption diltiazem formulations

Applicant:
Elan Corporation P.L.C.

Opponent:
-

Headword:
Diltiazem formulations/ELAN

Relevant legal provisions:
EPC Art. 123(2), 111(1)
EPC R. 66(1), 86(3)

Keyword:
"Late filed claims: admissibility - yes - degree of success which might be achieved in a further examination procedure"
"Remittal after request by the appellant"

Decisions cited:
T 0047/90, T 0667/94

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0516/94 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 1 April 1998

Appellant: Elan Corporation P.L.C.
Monksland Industrial Estate
Athlone
County Westmeath (IE)

Representative: Goldin, Douglas Michael
J.A. Kemp & Co.
14 South Square
Gray's Inn
London WC1R 5LX (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 3 February 1994 refusing European patent application No. 88 309 665.3 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: U. Oswald
M. B. Günzel

Summary of Facts and Submissions

I. European patent application No. 88 309 665.3 (publication No. 0 320 097), which is concerned with diltiazem pellet formulations allowing controlled absorption over a twenty-four hour period following oral administration, was refused under Article 97(1) EPC by a decision of the Examining Division.

The Examining Division considered that the subject-matter of claim 1 of the main request and that of the auxiliary request was novel because of the fact that the closest prior art known from document

(1) EP-A-0 149 920

did not describe diltiazem formulations being effective to achieve a Tmax (peak plasma level) of 10 to 19 hours. The claimed subject-matter, however, did not involve an inventive step in the light of the disclosure of document (1).

More particularly, it was pointed out that in relation to the conventional diltiazem therapy the problem underlying document (1) was to reduce the frequency of administration which was of three to four times daily administration. Since this problem was solved by a formulation allowing a twice-daily administration, the provision of a diltiazem formulation suitable for once-daily administration according to the patent in suit was an obvious consequence of the prior-art teaching.

The formulations claimed in the application contained the same materials as those used to prepare the prior-art formulations. Furthermore, there was a clear correlation between the in-vitro dissolution pattern and in-vivo plasma levels. Accordingly, it would have

been a matter of routine experimentation to modify the membrane composition and the number of coatings so as to find the Tmax value suitable for once-daily administration. The same reasoning would also apply to the auxiliary request comprising a further limitation of the in-vitro dissolution pattern.

II. The Appellant lodged an appeal against the said decision.

Oral proceedings took place on 1 April 1998 during which the Respondent sought to file several sets of claims. Claim 1 of the final set of filed claims 1 to 7 forming the basis for the then single request reads as follows:

"1. A controlled absorption diltiazem pellet formulation for oral administration, said pellet comprising

(i) a core of

(a) a powder mixture containing diltiazem or a pharmaceutically acceptable salt thereof, and an organic acid selected from adipic acid, ascorbic acid, citric acid, fumaric acid, malic acid, succinic acid and tartaric acid or a mixture thereof, the diltiazem component and the organic acid being present in a ratio of from 50:1 to 1:1, and

(b) polyvinylpyrrolidone, said core comprising layers of said powder mixture and said polyvinylpyrrolidone superimposed one upon the other and said polyvinylpyrrolidone being present in an amount effective to ensure that all of said powder mixture is coated into said core; and

(ii) a multi-layer membrane surrounding said core and consisting of EUDRAGIT RS and EUDRAGIT RL in a weight ratio of 4.1 : 1 or 4.0 : 1 and talc; the number of layers in said membrane and the ratio of said water soluble to water insoluble polymer being effective to achieve a Tmax of 10 to 19 hours and to permit release of said diltiazem from said pellet at a rate allowing controlled absorption thereof over a twenty-four hour period following oral administration, said rate being measured *in vitro* as a dissolution rate of said pellet, which when measured in a type 2 dissolution apparatus (paddle) according to U.S. Pharmacopoeia XXI in 0.05 M KCl at pH 7.0 substantially corresponds to the following dissolution pattern:

(a) from 0 to 35% of the total diltiazem is released after 2 hours of measurement in said apparatus;

(b) from 0 to 45% of the total diltiazem is released after 4 hours of measurement in said apparatus

(c) from 10 to 75% of the total diltiazem is released after 8 hours of measurement in said apparatus;

(d) from 25 to 95% of the total diltiazem is released after 13 hours of measurement in said apparatus;

(e) not less than 85% of the total diltiazem is released after 24 hours of measurement in said apparatus.

The Appellant argued that in comparison with the claims forming the basis for the refusal of the application the new set of claims included further limitations to polyvinylpyrrolidone as the polymeric material of the

pellet core and EUDRAGIT RS and EUDRAGIT RL as the membrane-forming materials surrounding said core. These limitations made the core of the invention more understandable and showed the invention in its true light in relation to the prior art. The Appellant put emphasis on the fact that the said limitations to the pellet formulation came very close to the product now on the market.

III. The Appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance with the set of claims submitted during the oral proceedings for further prosecution.

Reasons for the Decision

1. The appeal is admissible.

2. The late filing of the new set of claims 1 to 7 raises the procedural problem of their admissibility.

The Board notes that it is the normal purpose of oral proceedings to **bring the case to a conclusion**, Article 11(3) RPBA. The summons to oral proceedings are normally not sent before the basis for discussion is clearly apparent from the writs of the parties and/or, where appropriate, is defined in a communication from the Board. This implies that the requests have to be filed in advance. Thus, if an Appellant intends to file amendments it should do so in advance and not wait until the oral proceedings, which might jeopardize the usefulness of the oral proceedings.

Whether the Board of Appeal will consent to the subsequent filing of any amendments lies within its discretionary powers in accordance with Rules 66(1) and 86(3) EPC.

This means that for the decision as to whether the late-filed claims are admitted into the proceedings the Board of Appeal has to weigh the relevant criteria applicable to the case under consideration. Generally speaking the interest of the general public that proceedings before the EPO should be speedily concluded and unjustified procedural delays should be avoided, has to be balanced with the interest of the applicant, in particular in ex parte proceedings, where the application has been refused by the Examining Division, to defend his application as long as possible on as broad a basis as possible. In order to achieve this balance of interests the Boards of Appeal make the admission of late-filed requests dependent on factors such as the extent of lateness and the reasons given for the late filing, on the nature of the amendments made and on their allowableness, see the comprehensive report on case law on this issue in "Case law of the Boards of Appeal of the European Patent Office", 2nd edition, 1996, p.347 et seq.

2.1 Thus, according to established case law amended or entirely new requests are not permissible at this stage of the proceedings where there is considerable doubt as to whether the requirements under Article 123(2) EPC are met. This was the case with the sets of claims which the Appellant sought to introduce at the start of the oral proceedings.

On the contrary, it is to be noted that the last set of claims filed as the sole request as a consequence of the discussion during the oral proceedings a priori did not give rise to any problems regarding their support

by the application documents originally filed. Claim 1 is based on claims 1, 2, 6, 7, originally filed and finds support on page 5, line 20 up to page 6 line 5 and page 8, lines 4 to 12 in combination with Example 1 on pages 21/22 and Example 3 on pages 23/24. Claim 2 is based on claim 3 originally filed. Claims 3 to 7 are based on claims 11 to 15 originally filed. The requirements of Article 123(2) EPC are accordingly satisfied.

2.2 Where the amendment, as is the case here, results from a combination of previous claims and/or only constitutes a restriction of the subject-matter to preferred embodiments of the invention it has to be regarded as being admissible (see i.a. T 252/92 point 3; T 626/90, point 2).

2.3 As regards the contents, i.e. the substance, of the sole main request filed in the oral proceedings the Board is of the opinion that the amendments constitute a bona fide attempt of the applicant to overcome the objections raised by the Examining Division in its decision to refuse the application for lack of inventive step (see e.g. T 38/89 and T 626/90: bona fide attempt accepted in inter partes proceedings).

Therefore, also considering the degree of success which **might** be achieved in a further examination procedure by the restriction of the claimed pellet formulation to a very special combination of polymer materials in the core and the membrane surrounding said core, the Board exercises its discretion under Rules 66(1) and 86(3) EPC in favour of the Appellant. Thus, it is decided to admit the new set of claims 1 to 7 into the proceedings.

3. The Board notes that the limitations in new claim 1 relating to polyvinylpyrrolidone as the polymeric material of the pellet core and EUDRAGIT RS and EUDRAGIT RL as the membrane- forming materials surrounding said core have not been really discussed during the proceedings before the Examining Division. The decision of the Examining Division is indeed focused on a discussion of peak plasma levels and the in-vitro pattern achievable when applying the teaching of document (1).

The Appellant has argued that having regard to the disclosure in document (1) the said limitations would show the claimed subject-matter in a more favourable light. However, it does not seem appropriate at the present stage of the proceedings for the Board to carry out an investigation in the state of the art on file on the basis of the new requests not having formed the basis for the decision of the Examining Division since the Appellant would be deprived of an instance of jurisdiction. Moreover, the essential function of appeal proceedings is seen to be to determine whether the decision of the first instance was correct (T 47/90, OJ EPO 1991, 486). Accordingly, in following the Appellant's request, the Board has decided to invoke its powers under Article 111(1) EPC and to remit the case to the Examining Division with the order to resume the examination on the newly-filed claims.

4. In the present case a complete examination, before dealing with the question of novelty and inventive step, should also make sure that the definition of the multi-layer membrane by the product names EUDRAGIT RS and EUDRAGIT RL under point "(ii)" of claim 1 is sufficient to define unambiguously the matter for which protection is sought and that a person skilled in the

art confronted with the said product names **and reading the application documents as a whole** has no difficulty in carrying out the invention (see decision T 667/94 of 16 October 1997 of Board of Appeal 3.3.2, particularly point 4.4 of the reasons for the decision).

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:

P. Martorana

The Chairman:

P. A. M. Lançon