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DECISIONS OF THE BOARDS OF APPEAL

Decision of Technical Board of Appeal 3.3.2 dated 16 June 1999

T 80/96 - 3.3.2

(Translation)

Composition of the board:

Chairman: P.A.M. Lançon
Members: U. Oswald
R.E. Teschemacher

Patent proprietor/Respondent: LONZA AG

Opponent/Appellant: SIGMA-TAU INDUSTRIE FARMACEUTICHE REUNITE S.P.A.

Headword: L-carnitine/LONZA

Article: 52, 56, 57, 54, 84 EPC

Keyword: "Main and auxiliary requests - formally allowable - industrial applicability of the use of a substance to make a physical form under Article 57 EPC (yes)" - "Main request - novelty (no) - in the case of a non-defined [auxiliary] substance of unspecified effect, lack of functionality leads to lack of delimitation" - "Auxiliary request - inventive step (no) - obvious alternative physical form of the known substance"

Headnote

I. In the case of an active agent which is known as such to be water-soluble, it is clear to a person skilled in the art that describing and claiming the active agent as a solution does not add to or change the definition of that active agent.

II. Analogously, in a claim directed to a preparation of a known structurally defined active agent with at least one auxiliary substance, in which the feature "with an auxiliary substance or auxiliary substances" means that something is added to the active agent, the admixture of an unspecified auxiliary substance cannot, in view of the unlimited number of substances which may enter into consideration, be deemed a substantive and distinctive addition to the active agent, unless this feature, which is necessary if novelty is to be recognised, is specified in such a way that a person skilled in the art can recognise what it is that should be added to the active agent (see reason No. 4).

Summary of facts and submissions

I. European patent No. 0 434 088 was granted in respect of European patent application No. 90 125 138.9 with the following three claims:

"1. Use of L-carnitine-L-tartrate for making forms of oral administration containing L-carnitine.

2. Use of L-carnitine-L-tartrate for making tablets, capsules, powders or granules containing L-carnitine.

3. Preparation containing L-carnitine, particularly for enteral application in the form of tablets, capsules, powders or granules, characterised in that it contains L-carnitine-L-tartrate."

II. The appellant filed an opposition against the granted patent on the basis of Article

100(a) EPC, alleging the lack of novelty and lack of inventive step of the subject-matter of the patent in suit. Of the large number of publications cited in support of the opposition, only the following were of relevance to the further proceedings:

(1) Z. Physiol. Chem., vol. 353, April 1972, 618-622, and
(6) EP-A-0 150 688.

III. In its interlocutory decision under Article 106(3) EPC, posted on 19 December 1995, the opposition division held that, taking account of the changes made by the respondent (patent proprietor) in the opposition proceedings according to the auxiliary request submitted at the oral proceedings on 30 November 1995, the patent and the invention on which it was based met the requirements of the Convention. The amended claims according to that auxiliary request read as follows (amendments shown in bold):

"1. Use of L-carnitine-L-tartrate **with an auxiliary substance or auxiliary substances and, possibly, one or more further active agents** to make **solid** forms of oral administration containing L-carnitine-**L-tartrate**.

2. Use of L-carnitine-L-tartrate **with an auxiliary substance or auxiliary substances and, possibly, one or more further active agents** to make tablets, capsules, powders or granules containing L-carnitine-**L-tartrate**.

3. Preparation containing L-carnitine in the form of tablets, capsules, powders or granules, in particular for enteral application, characterised in that it contains L-carnitine-L-tartrate **with an auxiliary substance or auxiliary substances and, possibly, one or more further active agents**."

The opposition division based its decision substantially on the grounds that the use claims according to the main and auxiliary requests were allowable on a purely formal basis as the normal use of L-carnitine-L-tartrate to make a form of oral administration and were not to be interpreted as so-called second medical use

claims within the meaning of decision G 1/83.

Furthermore, there were no objections with respect to Article 84 EPC, as the active agents and auxiliary substances named in the claims were defined in the description of the patent in suit and were part of the common general knowledge.

As to the requirements for patentability, the subject-matter of use claim 1 of the main request, which did not specify the state of aggregation in which L-carnitine was to be used, lacked in any event novelty under Article 54(1) EPC over citation (1), as the latter described an aqueous solution of the tartrate compound used in claim 1.

The auxiliary request, which was clearly directed to **solid** L-carnitine-L-tartrate, was, however, novel over citation (1).

In view of the disclosure of citation (6), according to which predictions as to the hygroscopicity of the salts of L-carnitine were difficult and unreliable, such that this citation, in conjunction with the remaining prior art, actually led away from the invention, the subject-matter of the patent in suit could also be said to have the necessary inventive step.

IV. The appellant lodged an appeal against that decision. On 16 June 1999 oral proceedings took place, during which the respondent submitted, by way of an auxiliary request, the following new set of claims (amendments shown in bold):

"1. Use of L-carnitine-L-tartrate with an auxiliary substance or auxiliary substances and, possibly, one or more further active agents to make tablets, **hard gelatine** capsules, **effervescent** powders or granules containing L-carnitine-L-tartrate **for oral administration**.

2. Preparation containing L-carnitine in the form of tablets, **hard gelatine** capsules, **effervescent** powders or granules, for enteral application, characterised in that it contains L-carnitine-L-tartrate with an auxiliary substance or auxiliary substances

and, possibly, one or more further active agents."

V. The appellant made the following written and oral submissions:

According to the decisions of the Enlarged Board of Appeal on second medical use (including G 5/83, OJ EPO 1985, 64), use claims directed to a production process were only allowable in conjunction with a use within the meaning of Article 52(4) EPC. On the basis of these decisions and subsequent EPO practice, the present claims should be seen as being directed towards therapeutical uses. However, as the claims were not restricted to a therapeutical use, they were not allowable.

Irrespective of this, the subject-matter of the patent in suit was no longer novel compared with citation (1), which had already characterised the L(-)carnitine-L(+)-tartrate compound and given the melting point and the optical rotatory power. The appellant pointed out in particular that citation (1) was a publication in the field of physiological chemistry and referred to the long-standing therapeutical use of L(-)carnitine in a variety of illnesses.

VI. The respondent opposed this, submitting, amongst other things, that the present formulation of the use claims was allowable, as it plainly described the use of a substance to make a special form of administration, which obviously also covered non-therapeutical areas of use. The claims were thus neither so-called "Swiss-type" claims, nor directed to the activities of a doctor. Consequently, they clearly related to an industrially applicable invention within the meaning of Article 52(1) EPC.

As far as the novelty of the subject-matter of the patent in suit was concerned, citation (1), which was unambiguously directed to the pure form of L-carnitine, did indeed disclose the melting point and the specific optical rotation of the intermediate products described therein, for example the said characteristics of the conversion product from L-tartaric acid to the corresponding carnitine salt. However, the citation did not contain any teaching to use L-carnitine-L-tartrate as a component in forms of oral administration, nor could it be deduced therefrom that, contrary to the expected

hygroscopic behaviour of the compound, no difficulties would occur. Furthermore, citation (1) was clearly directed to the use of camphorates and dibenzoyltartrates as intermediate products for the racemate cleavage of DL-carnitine, the tartrates as such having only a secondary role. The said intermediate products were, however, not disclosed in conjunction with the therapeutical and non-therapeutical uses indicated for the pure L-carnitine in citation (1). With regard to the disclosure of the property of hygroscopicity or non-hygroscopicity of the L-carnitine-L-tartrate intermediate product disclosed in citation (1), the respondent referred in particular to decision G 1/92 (OJ EPO 1993, 277), reason No. 3, according to which characteristics which are only revealed by specifically chosen external conditions should be regarded as not having been disclosed. This also applied to the present case, in which the hygroscopicity was recognisable only through the purposive selection of a particular level of humidity in the surrounding atmosphere. Some of the respondent's own observations had shown that, for example, even after several hours of being stored open on a desk, L-carnitine and L-carnitine-L-tartrate had the same consistency, and that the hygroscopicity of these substances was at any rate not a trivial feature and consequently could not be derived from citation (1).

Irrespective of this, the respondent claimed that the novelty of the subject-matter according to the main and auxiliary requests was already given by the claimed obligatory auxiliary substances, which were defined in the patent in suit for the individual applications, oral application being expressly mentioned in the claim. The latter application included the conventional galenical formulation for this. Because of the rapid developments in the field of pharmacology, there was no point in listing individually in the claim all the conceivably suitable auxiliary substances which a skilled person in the field of galenical medicine could where necessary modify without changing the effect of the L-carnitine-L-tartrate.

The closest prior art for assessing the inventive step was undoubtedly citation (6), in relation to which the problem was to prepare a further stable, non-hygroscopic salt of L-carnitine with all the characteristics listed in lines 29-33 on page 2 of the patent

specification, to make forms of oral administration.

With regard to the desired characteristics of a form of oral administration, citation (6) clearly gave the person skilled in the art the idea of producing acid salts of L-carnitine and therefore led away from the subject-matter of the invention. Even a synopsis of citations (1) and (6) did not lead to the predictability of the non-hygroscopic characteristics of L-carnitine-L-tartrate, as (1) did not provide any information on corresponding galenically relevant characteristics. Furthermore, both tartaric acid and L-carnitine showed in themselves hygroscopic properties, and their tartrate salts were not expected to have stable properties.

The fact that citation (1) was known more than ten years before the priority date of citation (6) and that recourse was not made in citation (6) to the intermediate product salts in (1) indicated that it was not obvious to a person skilled in the art to combine the teachings of (1) and (6) and that there was an inventive step. Moreover, the undoubted marked economic success of the invention also had to be taken into account.

In the auxiliary request, the auxiliary substances were further defined by delimiting them to hard gelatine capsules, which were suitable only for solid L-carnitine-L-tartrate, and by the specification of effervescent powder.

VII. The appellant requested that the contested decision be set aside and European patent No. 0 434 088 be revoked.

The respondent requested that the patent be maintained in amended form in the version on which the contested decision was based (main request). Auxiliarily, it requested that the patent be maintained on the basis of the claims submitted at the oral proceedings.

Reasons for the decision

1. The appeal is admissible.

2. The subject-matter of claims 1 and 2 according to the main request as well as of claim 1 according to the auxiliary request relates to the production of certain physical forms of L-carnitine-L-tartrate specified as tablets, capsules, powders or granules. Even though these claims start with the words "Use of L-carnitine-L-tartrate ...", they relate to a process susceptible of industrial application under Articles 57 and 52(1) EPC for making corresponding products in the said forms using L-carnitine-L-tartrate. According to decision G 5/83 (loc. cit., reason No. 16), patent claims directed to the use of a substance or composition for the preparation of a pharmaceutical product are clearly inventions susceptible of industrial application within the meaning of Article 57 EPC. Accordingly, the use of a substance to make a new pharmaceutical product without delimitation to an indication does not contravene the requirements of Article 57 EPC in conjunction with Article 52(1) EPC. In the board's opinion, the requirement for clarity of the claims (Article 84 EPC) likewise does not mean that a claim for a process for preparing a particular product cannot be drafted in the form of a use claim. No other meaning can be given to the individual process steps (see, for example, T 279/93 of 12 December 1996, not published in the OJ EPO, reason No. 4).

The appellant's objection relating to decision G 5/83, namely that claims 1 and 2 of the main request and claim 1 of the auxiliary request are not allowable on a purely formal basis, as there is no reference to a particular therapeutical use (indication) of the L-carnitine-L-tartrate in the wording of the supposed use claims, cannot therefore be endorsed.

3. The individual features of the claims in the present main and auxiliary requests can be derived from the original application documents as well as the patent specification and, in combination, represent a desired protection which is restricted in relation to the claims as granted. The main and auxiliary requests thus meet the

requirements of Article 123(2) and (3) EPC. In the end this was no longer contested by the appellant.

4. One of the alternatives referred to in claim 3 of the main request, previously claim 3 of the auxiliary request deemed allowable by the opposition division (see section III above), relates with regard to the obligatory features to a preparation containing L-carnitine-L-tartrate in powder form with a non-defined auxiliary substance.

The subject-matter of claim 3 relates to a product as such. It is generally accepted as a principle underlying the EPC that a patent which claims a physical entity per se confers absolute protection upon such physical entity, that is wherever it exists and whatever its context (and therefore for all uses of such physical entity, whether known or unknown) (see, for example, G 2/88, OJ EPO 1990, 93, in particular reason No. 5). In the present case this means that claim 3 includes every conceivable therapeutical and non-therapeutical use of the said preparation in powder form. The fact that the preparation is intended for enteral application is only specified as part of a preferred embodiment. Under these circumstances no substantive function is defined for the auxiliary substance. Thus the auxiliary substance cannot be defined by way of its function either. Consequently, the "auxiliary substance or auxiliary substances" feature means nothing more than that something is added to the L-carnitine-L-tartrate.

It is clear to the person skilled in the art that describing or claiming an aqueous solution of a product which is known in itself to be water-soluble does not add to or change the definition of that product. Without further specification, the mere characterisation of a solvent or diluent as liquid or solid in a claim does not change the assessment of the novelty of the subject-matter of the claim.

In the present case the phrase "with an auxiliary substance" may therefore be seen as a purely mental addition to claim 3, which does not give the person skilled in the art any specific guidance as to how the claimed product should be formed. It is thus not able to characterise the claimed product specifically. Accordingly, an unlimited

number of theoretically possible auxiliary substances with no details as to their structure and effect cannot be deemed in a claim to be a substantive addition to a structurally defined product. It does not therefore either change or add to the subject-matter defined in the claim, in other words the claimed product.

As a direct consequence, the mere statement that a non-defined auxiliary substance of unspecified effect should be mixed with the L-carnitine-L-tartrate powder, albeit itself defined as such, cannot be used under Article 54 EPC as a delimiting feature in the said product claim.

The subject-matter of present claim 3 of the main request thus also relates to a preparation of L-carnitine-L-tartrate in powder form.

4.1 In the table at the bottom of page 621, citation (1) describes the substance di-L(-)-carnitine-L(+)-tartrate with a melting point of "176/8" °C.

4.2 At the oral proceedings the parties did not question the fact that this information had to be interpreted as meaning that the melting point was determined using pure substance in powder form. In this connection, in a letter dated 27 August 1996 the respondent wrote (page 5, first paragraph, last sentence): "In the field of synthetic organic chemistry it is customary to determine the melting point and other data of isolated intermediate products as well, in order either to provide proof of the compounds produced or to compare the measured data with the data in the literature". Thus no further consideration need be given to whether, according to the respondent's argument, di-L(-)-carnitine-L(+)-tartrate can be deemed to be disclosed in citation (1) only as an intermediate product present in solution with no recognisable characteristics. Furthermore, in view of decision G 1/92, the question as to the extent to which a skilled person could derive from (1) any hygroscopic properties of the di-L(-)-carnitine-L(+)-tartrate as described no longer needs to be answered for the product claim concerned per se, as the claimed product is by definition not prepared for a specific purpose (see 4 above).

4.3 The above arguments can be applied analogously at least to claim 2 of the main request since, as far as the obligatory features suitable for the purposes of delimitation in relation to the prior art are concerned, this claim is directed to the use of L-carnitine-L-tartrate to make powders of this substance, ie the production of L-carnitine-L-tartrate powders based on L-carnitine-L-tartrate.

4.4 The respondent's main request therefore cannot be allowed, as claims 2 and 3 are not new within the meaning of Article 54(1) EPC.

5. Claim 2 of the auxiliary request relates in one of the alternative preparation forms to L-carnitine-L-tartrate tablets for enteral application with an auxiliary substance.

5.1 A person skilled in the art familiar with citation (1) knows that in pharmacology both L-carnitine on the one hand and tartaric acid or tartrate derivatives on the other are suitable for enteral application, and this fact was not contested by the parties. Moreover, it was expressly acknowledged at the oral proceedings that the di-L(-)-carnitine-L(+)-tartrate described in citation (1) is suitable as such for enteral application.

The parties disagreed about the hygroscopic properties of the L-carnitine-L-tartrate powder and how they manifest themselves. Thus in the present context it may be assumed in favour of the patent proprietor that the non-specified auxiliary substance in claim 2 of the auxiliary request merely permits the powder to be compressed into tablet form.

The subject-matter of claim 2 of the auxiliary request can therefore be deemed to be new in relation to citation (1) within the meaning of Article 54(1) EPC.

6. With regard to the question of inventive step under Article 56 EPC, in the light of the prior art in citation (1) as outlined above in 4.1, 4.2 and 5.1, the problem of the patent in suit according to the auxiliary request may be seen as to provide an alternative form of enteral application of L-carnitine-L-tartrate.

6.1 According to claim 2, this problem is solved by L-carnitine-L-tartrate in tablet form.

6.2 With regard to embodiments 2 to 4 of the patent in suit, which show that L-carnitine-L-tartrate, if not on its own, then at least with conventional auxiliary substances, may be compressed into tablet form, the problem may be deemed actually to have been solved.

6.3 Neither the documents pertaining to the patent in suit nor the respondent's submissions reveal anything which would indicate any special features in connection with the presence of L-carnitine-L-tartrate in a variety of tablet forms as claimed. From this the board can only conclude that compressing a substance known in powder form and in itself suitable for enteral application into tablets of whatever type must within the meaning of Article 56 EPC be deemed to be an obvious measure for providing an alternative form of enteral application.

6.4 In these circumstances, it is not necessary to deal with the use claim 1 also contained in the auxiliary request, as decisions can only be made on requests as a whole.

6.5 Thus the respondent's auxiliary request cannot be allowed either.

Order

For these reasons it is decided that:

1. The contested decision is set aside.

2. The patent is revoked.