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**Datasheet for the decision
of 13 December 2018**

Case Number: T 0767/12 - 3.3.01

Application Number: 04723764.9

Publication Number: 1605930

IPC: A61K31/202, A23L1/29, A61P43/00

Language of the proceedings: EN

Title of invention:
USE OF ARACHIDONIC ACID FOR NORMALIZATION OF INFRADIAN RHYTHM

Applicant:
Suntory Holdings Limited

Headword:
Treatment of biorhythm disorders/SUNTORY

Relevant legal provisions:
EPC Art. 84, 56

Keyword:
Clarity - main request (no)
Inventive step - auxiliary request (yes)

Decisions cited:
G 0001/03, G 0001/16, T 0469/94, T 0584/88, T 0144/83



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Case Number: T 0767/12 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 13 December 2018

Appellant: Suntory Holdings Limited
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 14 November
2011 refusing European patent application No.
04723764.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman A. Lindner
Members: J. Molina de Alba
L. Bühler

Summary of Facts and Submissions

- I. The appellant (applicant) filed an appeal against the decision of the examining division refusing European patent application No. 04 723 764.9.
- II. The following documents are referred to in the present decision:
- (1) WO 03/013497
 - (1a) EP 1 419 768
 - (2) EP 0 920 323
 - (3) EP 1 283 038
 - (4) WO 96/21037
 - (5) US 6,184,251
 - (6) WO 2004/028529

Document (1a) is a member of the patent family of WO 03/013497 and was considered to be a faithful translation into English of document (1) during the examination proceedings.

- III. The decision under appeal was based on a main request and an auxiliary request, both filed at the oral proceedings held before the examining division.

The division found that the disclaimer "non-therapeutic" in claim 2 of the main request added subject-matter because it was not disclosed in the

application as filed and it was not possible to distinguish and separate the claimed non-therapeutic indications from therapeutic indications. In addition, the use in claim 1 of the auxiliary request lacked inventive step over the combination of documents (2) and (1).

- IV. With its statement of grounds of appeal, the appellant filed five claim sets as the main request and auxiliary requests 1 to 4.
- V. In a communication dated 28 June 2018, the board gave its preliminary opinion that, among other things, the disclaimer "non-therapeutic" in claim 2 of the then pending main request and auxiliary requests 1 and 2 was not allowable because its scope was unclear and did not fulfil the requirement for undisclosed disclaimers established in G 1/03, Headnote, point 2.4.
- VI. With a letter of 4 December 2018, the appellant filed a new main request and auxiliary requests 1 to 4 to replace the previous ones.

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

"1. Use of triglyceride comprising arachidonic acid as a part of or all of the constituting fatty acids, or of methyl arachidonate or ethyl arachidonate, as active ingredient in the manufacture of a composition having a normalising action for infradian rhythm and/or a synchronisation promoting action for circadian rhythm, the composition being for therapeutic prevention or alleviation of biorhythm disorder caused by abnormality of infradian rhythm, or by retardation of synchronisation of circadian rhythm.

2. Use of a composition comprising as active ingredient triglyceride comprising arachidonic acid as a part of or all of the constituting fatty acids, or of methyl arachidonate or ethyl arachidonate, for non-therapeutic normalising of infradian rhythm and/or promoting synchronisation of circadian rhythm."

VII. In the course of the oral proceedings held before the board on 13 December 2018, the appellant filed a new auxiliary request 1 and withdrew all previous auxiliary requests. Auxiliary request 1 differs from the main request filed on 4 December 2018 essentially by the fact that independent claim 2 has been deleted.

VIII. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

On the issue of clarity of the disclaimer in claim 2 of the main request, the appellant maintained that in the present case it was possible to distinguish between therapeutic and non-therapeutic methods and therefore it should be allowed to claim both types of methods separately. It referred to the conditions associated with jet lag and argued that these could vary from a mild disruption of the sleeping pattern to severe symptoms, and that the skilled person was able to make a distinction between transitory physiological conditions removable by a simple rest (non-therapeutic) and pathological conditions requiring a therapeutic treatment. In the particular case where the methods were carried out preventively, the skilled person could still distinguish between two groups of persons based on their previous experience under jet lag situations: those who merely experienced a transient nuisance and did not require a therapeutic treatment, and those who

had suffered or could be expected to suffer pathological symptoms and hence required therapy. In this respect, the appellant made an analogy with the case underlying decision T 469/94, where the board had concluded that a reduction of the fatigue induced by the performance of physical exercises was not therapeutic and that it could be distinguished from the therapeutic treatment of pathological fatigue. The appellant referred also to case T 144/83, where a method for losing weight for individuals who were slightly overweight and who only wanted to improve their bodily appearance was considered to be non-therapeutic, as opposed to the same method carried out on obese patients, which was therapeutic. Similarly, in T 584/88, the board distinguished between the treatment of unhealthy (therapeutic) and irritating (non-therapeutic) snoring.

In its analysis of inventive step, the appellant noted that document (2) focused on DHA rather than on arachidonic acid and that the problems addressed in document (2) and in the application were different: while document (2) was directed to the promotion of melatonin secretion, the application concerned the normalisation of infradian rhythm or the synchronisation of circadian rhythm. Therefore, starting from document (2), it was not obvious that arachidonic acid containing triglycerides or esters would solve the problem posed in the application.

IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the main request filed with the letter dated 4 December 2018, or, alternatively, of auxiliary request 1 filed during the oral proceedings of 13 December 2018.

- X. At the end of the oral proceedings, the board's decision was announced.

Reasons for the Decision

1. The appeal is admissible.
2. Main request

The disclaimer "non-therapeutic" in claim 2 of the main request was not disclosed in the application as originally filed. Accordingly, its allowability has to be examined in the light of decision G 1/03 (see also G 1/16, Reasons, point 43).

On this issue, the examining division held that it was not possible to distinguish between the therapeutic and non-therapeutic methods of the invention and hence the condition set out in G 1/03, Headnote, item 2.4, that the disclaimer must meet the requirements of clarity and conciseness (Article 84 EPC), was not fulfilled.

In the board's view, the disclaimer in claim 2 of the main request at hand also introduces a lack of clarity, since the methods of the invention are necessarily therapeutic and their exclusion renders the scope of claim 2 void. This conclusion derives from the fact that desynchronisation of circadian or infradian rhythm causes symptoms which are generally recognised as being pathology-related and which produce at best discomfort.

On this issue, the appellant argued that when the symptoms caused by biorhythm desynchronisation merely represent a transient nuisance, such as a slight sleep disorder removable by having some rest, they do not reflect a pathological state and their treatment cannot be considered to be therapeutic.

The board disagrees. Whether or not a symptom is of pathological nature cannot be established subjectively on the basis of the symptom intensity perceived by the patient. As the symptoms caused by biorhythm desynchronisation, such as sleep disorder, dizziness or headache, are generally recognised as being pathology-related, their treatment or prevention is necessarily therapeutic. The argument that the patient may be relieved from symptoms merely by resting cannot be accepted as a criterion for classifying a method as being non-therapeutic, since this is also a way of curing a cold, for instance, which is a clear pathological condition.

In addition, the appellant compared the methods in claim 2 with the treatment of fatigue discussed in the decision T 469/94. In that case, the board acknowledged that reducing the perception of fatigue in a person being about to participate in a major exercise or having completed a major exercise was non-therapeutic for two reasons: i) it was a transitory physiological condition caused by natural circumstances and removable by simple rest, in contraposition to situations where the person is relieved from pain or discomfort (see Reasons, point 4.2); and ii) non-therapeutic and therapeutic treatments could be separated because they involved different groups of persons (see Reasons, point 4.4).

In the board's view, the present case differs from the situation underlying T 469/94 in both of those essential aspects. Firstly, the symptoms treated with the alleged non-therapeutic method are not caused by natural circumstances but rather by an artificial shifting of natural rhythm which puts the person in a situation of at least discomfort and which provokes symptoms that are identified with pathologies, e.g. sleep disorder, dizziness, headache. Secondly, in view of the finding that the symptoms caused by biorhythm desynchronisation are necessarily therapeutic (see point 2, fourth paragraph above), the question of whether or not a therapeutic application can be separated from a non-therapeutic use does not arise.

Similarly to the case of T 469/94, the situations underlying decisions T 144/83 and T 584/88 are not applicable to the present case because in T 144/83 and T 584/88 the board could effectively distinguish between two groups of subjects: those suffering from being slightly overweight and those suffering from obesity (T 144/83), and those suffering from unhealthy snoring and those suffering from disturbing snoring (T 584/88).

In consequence, the disclaimer in claim 2 does not meet the requirements of Article 84 EPC and is therefore unallowable under G 1/03 (see Headnote, point 2.4) and G 1/16 (see Reasons, point 43).

3. Auxiliary request 1

The board has no Article 123(2) EPC objection in relation to this request.

Furthermore, having regard to the fact that the indications defined in claim 1 (sole independent claim) are therapeutic, the Swiss-type wording of the claim is adequate (Article 84 EPC) and renders the claimed subject-matter novel over the cited prior art (Article 54 EPC).

With regard to the requirement of sufficiency of disclosure, the application examples, in particular example 5, show that a triglyceride containing arachidonic acid is suitable for promoting circadian rhythm synchronisation in rats. The board sees no reason to question that this effect is also achieved by the other arachidonic acid esters cited in claim 1 and, considering the close relationship between circadian and infradian rhythms, that the application examples also make credible a normalising effect on infradian rhythm. Hence, the claimed invention is sufficiently disclosed (Article 83 EPC).

3.1 Inventive step

The application is directed to the use of triglycerides containing arachidonic acid, methyl arachidonate or ethyl arachidonate as active ingredients for preventing or alleviating biorhythm disorders caused by abnormality of infradian rhythm or by retardation of synchronisation of circadian rhythm.

- 3.1.1 Document (2) was considered as the closest prior art by both the examining division and the appellant. The board has no reason to take a different stance.

Document (2) teaches (see paragraphs [0010], [0011] and [0019]) the use of phospholipids of animal origin rich in arachidonic acid and DHA (docosahexaenoic acid) for

regulating melatonin secretion and hence improving nocturnal sleep quality, diurnal alertness and psychomotor and learning performances in poor sleepers.

- 3.1.2 In the appealed decision (see page 9, paragraph 6), the examining division concurred with the appellant that the use in claim 1 of auxiliary request 1 before it differed from the use in the closest prior art by the chemical form in which arachidonic acid was administered (triglyceride, methyl or ethyl ester vs. phospholipid). However, it disputed that the therapeutic effect mentioned in claim 1 constituted an additional difference because the regulation of melatonin secretion in document (2) could be equated with a synchronisation of circadian rhythm in poor sleepers.

In claim 1 at hand, the active ingredients remain the same as in claim 1 of auxiliary request 1 underlying the appealed decision. Hence, the active ingredients constitute a difference over the closest prior art. With respect to the therapeutic effect, the board considers that the regulation of melatonin secretion dealt with in document (2) is related to but not the same as the alleviation of retardation in the synchronisation of circadian rhythm mentioned in claim 1. The effect in document (2) consists of an improvement in the quality of nocturnal sleep in patients having an insufficient nocturnal secretion of melatonin, such as elderly people or poor sleepers (see document (2), paragraphs [0047] and [0048]). That improvement is achieved by a promotion of nocturnal melatonin secretion. By contrast, the effect in claim 1 of auxiliary request 1 does not concern any increase in melatonin secretion but a faster synchronisation of melatonin secretion in subjects that have been

submitted to a time shift, such as travellers and rotating night workers. Thus, the aim of document (2) was increasing the amount of nocturnal melatonin secretion, while in the application the aim is promoting a shift in the time at which melatonin is secreted to make it coincide with the normal sleeping hours.

In consequence, the subject-matter of claim 1 differs from the closest prior art in both the active compound and the therapeutic indication.

- 3.1.3 The technical problem to be solved by the use in claim 1 may be formulated as the provision of an active ingredient which prevents or alleviates biorhythm disorders caused by abnormality of infradian rhythm or by retardation of synchronisation of circadian rhythm.
- 3.1.4 As mentioned in point 3 above in relation to Article 83 EPC, the board is satisfied that the application examples, especially example 5, make credible that the arachidonic acid compounds cited in claim 1 are a suitable solution to the problem posed. This was not disputed in the appealed decision.
- 3.1.5 On the question of whether the solution proposed in claim 1 was obvious on the filing date, the answer is no.

Document (2) teaches that omega-3 fatty acids, in particular DHA (docosahexaenoic acid), increase nocturnal melatonin secretion, while arachidonic acid triglycerides in the absence of DHA fail to do it. This derives from the experimental part of document (2), where four groups of Wistar rats were studied (see paragraph [0028]):

- a reference group fed with a mixture of peanuts and rapeseed during two generations ("groupe témoin" or "graines de colza"),

- a group fed with peanut oil during two generations ("groupe déficient en n-3" or "arachide"), and

- two additional groups consisting of offspring from the previous groups, which had received a food supplement of animal phospholipids rich in both omega-3 fatty acid and arachidonic acid ("group témoin + phospholipides animaux" and "group déficient en n-3 + phospholipides animaux").

The study revealed that the different feed regimes resulted in important differences in the epiphyseal content of omega-3 fatty acids, especially DHA, and in the rats' nocturnal release of melatonin (see paragraphs [0030] and [0031]). The group fed exclusively with peanut oil ("group déficient en n-3" or "group arachide"), which is a source of arachidonic acid triglycerides but contains negligible amounts of omega-3 fatty acids, exhibited 32% lower nocturnal melatonin secretion than the control group ("group témoin"), which had been fed with a mixture of peanuts and colza, i.e. a diet poorer in arachidonic acid than peanut oil and equally deficient in omega-3 fatty acids. By contrast, the groups supplemented with phospholipids rich in both DHA and arachidonic acid experienced a considerable increase in nocturnal melatonin secretion - 31% more than the control group and 75.8% more than the group fed with peanut oil (see paragraph [0031]). It was then apparent from these results that a feed rich in arachidonic acid

triglycerides without DHA supplementation does not increase nocturnal melatonin secretion (see also paragraphs [0047] and [0048]).

The board then concludes that, apart from the fact that document (2) fails to establish a link between arachidonic acid derivatives and synchronisation of melatonin secretion, document (2) teaches away from the use of arachidonic acid derivatives in the absence of DHA. Hence, it cannot render the claimed use obvious.

- 3.1.6 For the sake of completeness, the board notes that documents (1a), (4), (5) and (6) disclose the use of triglycerides or esters of arachidonic acid for purposes other than the prevention or alleviation of biorhythm disorders: document (1a) deals with the treatment of diseases or symptoms caused by decreased brain function accompanying ageing (see paragraphs [0021] and [0022]); document (4) discloses the treatment of neurological disorders such as tardive dyskinesia, schizophrenia or peroxisomal disorder (see claim 30); document (5) is directed to the treatment of dyspraxia (see abstract); and document (6) addresses the improvement of cognitive abilities in a healthy person.

The only cited document directed to the normalisation of circadian rhythm is document (3). However, the active ingredient suggested in it is astaxanthin or one of its esters, rather than an arachidonic acid derivative.

- 3.1.7 In conclusion, none of the cited documents or their combinations suggests the use of an arachidonic acid triglyceride, methyl arachidonate or ethyl arachidonate for the normalisation of biorhythm disorders. Hence,

the subject-matter claimed in the only independent claim of auxiliary request 1 is inventive.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division with the order to grant a patent with the following claims and a description to be adapted thereto:

claims 1 to 15 of auxiliary request 1 filed during the oral proceedings of 13 December 2018.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated