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Datasheet for the decision of 16 March 2011

Case Number: T 0273/08 - 3.3.02

Application Number: 00903030.5

Publication Number: 1143974

IPC: A61K 31/505

Language of the proceedings: EN

Title of invention:
Pharmaceutical compositions for alleviating discomfort

Patentee:
N.V. Nutricia

Opponents:
Fresenius Kabi Deutschland GmbH
Friesland Brands B.V.
Kruidvat Retail B.V.

Headword:
Use of combination of folic acid and vitamin B6 and B12/NUTRICIA

Relevant legal provisions:
EPC Art. 100(c), 123(2)(3), 84
RPBA Art. 12, 15

Keyword:
"Main request: not allowable"
"Auxiliary requests (not admissible)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0273/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 16 March 2011

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 22 November 2007 revoking European patent No. 1143974 pursuant to Article 102(1) EPC 1973.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 143 974, which was filed as application number 00903030.5, based on international application WO 00/43013, was granted on the basis of fourteen claims.

Claim 1 as granted reads as follows:

> 1. Use of a combination of folic acid, vitamin B6 and B12 and at least one component selected from riboflavin, thiamine and niacin for the manufacture of a pharmaceutical composition for the treatment or prevention of serotonin- or melatonin-mediated disorders, such as for improving senses of well-being, control of feeling of pain and improvement of mood and sleeping behaviour.

Independent claim 14 as granted reads as follows:

> 14. A pharmaceutical composition suitable for the treatment or prevention of serotonin- or melatonin-mediated disorders, such as improving senses of well-being, control of feeling of pain and improvement of mood and sleeping behaviour, the composition comprising carbohydrates, fats and proteins and containing more than 44 µg of folic acid, more than 0.8 µg of vitamin B12 and more than 50 µg of vitamin B6 per 100 kcal of carbohydrates, fats and proteins, and further containing at least one of riboflavin, thiamine, and niacin.

II. Oppositions were filed and revocation of the patent in its entirety was requested pursuant to Articles 100(c) (the subject-matter of the patent extends beyond the content of the application as filed), 100(b) (lack of sufficiency of disclosure) and 100(a) EPC (lack of novelty and lack of inventive step).

III. The present appeal lies from a decision of the opposition division revoking the patent (Article 102(1) EPC 1973).

IV. The opposition division considered that the claims as granted contained added matter pursuant to the grounds in Article 100(c) EPC and that the auxiliary requests 1 to 8 did not meet the requirements of Article 123(2) EPC. Furthermore, the opposition division did not admit

the late-filed auxiliary requests 9 to 14 into the proceedings (Rule 71a(1) EPC 1973).

V. The patent proprietor filed an appeal to said decision. It filed with the grounds of appeal twenty four auxiliary requests.

VI. The respondents (opponents O1, O2 and O3) filed counterarguments to the patentee's appeal.

VII. A board's communication pursuant to Article 15(1) RPBA was sent to the parties as an annex to the summons to oral proceedings. In said communication the board expressed the preliminary opinion that the requests on file were not admissible and gave reasons thereto. Moreover, the board also expressed its preliminary opinion about the requirements of Article 123 EPC.

In particular, the board expressed the opinion that the admissibility of the appellant's main request pending at that point of the proceedings was at stake. The reasons were that the appellant had maintained with its grounds of appeal the set of claims as granted (main request before the opposition division), but had not given any reasons for challenging the correctness of the opposition division's decision in respect of Article 100(c) EPC.

Moreover, the board had also pointed out to numerous and manifest deficiencies (*inter alia* within the meaning of Rule 80 EPC) in the twenty four auxiliary requests, which put into question their admissibility.

VIII. Opponent O3 announced with a letter dated 2 February 2011 that it will not attend the oral proceedings before the board of appeal.

IX. The appellant filed a reply to the board's communication with a letter dated 16 February 2011. The appellant withdrew the main request and the auxiliary requests previously on file, and filed a new main request and one auxiliary request.

Claim 1 of the main request read as follows:

> 1. Use of a combination of folic acid, vitamin B6 and B12 and riboflavin, thiamine and niacin for the manufacture of a pharmaceutical composition for use in decreasing undesirable symptoms related to neurodegenerative disorders associated with serotonin and melatonin levels in the brain.

Claim 1 of the auxiliary request read as follows:

> 1. Use of a combination of folic acid, vitamin B6 and B12 and riboflavin, thiamine and niacin for the manufacture of a pharmaceutical composition for the treatment or prevention of serotonin- or melatonin-mediated disorders selected from decreasing undesirable symptoms related to neurodegenerative disorders selected from Alzheimer, Parkinson and schizophrenia.

X. Respondent opponent O1 filed a reply dated 4 March 2011 in which it raised objections within the meaning of Articles 123 and 84 EPC against the main request and auxiliary request filed by the appellant with its letter of 16 February 2011.

XI. Oral proceedings took place on 16 March 2011.

During the oral proceedings the appellant-patentee withdrew the auxiliary request filed with the letter of

16 February 2011 and filed two further sets of claims as auxiliary requests I and II.

Claim 1 of auxiliary request I differed from claim 1 of the main request in that the expression "a disorder in" was introduced between the expression "associated with" and the term "serotonin", and in that at the end of the claim the following had been added: ", the presence of pterines and folate in the brain and the functioning of the methylating system in the body".

Claim 1 of auxiliary request II was identical to claim 1 of the auxiliary request filed with the letter of 16 February 2011.

XII. The appellant arguments as far as relevant for the present decision may be summarised as follows:

The main request and auxiliary request filed with the letter of 16 February 2011 should be admitted into the proceedings since they represented a direct response to the board's communication sent as an annex to the summons to oral proceedings. The reasons why they were not filed before were that no guidance could be found during the opposition proceedings about concrete objections within the meaning of Articles 123 and 84 EPC.

As regards the admissibility of the auxiliary requests I and II filed at the oral proceedings before the board, the appellant submitted that they were filed as a direct reply to the discussions during the oral proceedings. The requests filed with the letter dated 16 February 2011 concerned an attempt to deal with all

the objections in the board's communication. The auxiliary requests filed during the oral proceedings addressed issues heard for the first time at the oral proceedings. The opponents should have been able to raised those objections before.

As regards the main request, the appellant submitted the following. There was support in the application as filed for amended claim 1. The claim found its basis in paragraphs [0006] and [0022] of the application as filed. Moreover, all the ingredients were mentioned in paragraph [0022]. Pyridoxal phosphate was the active form of vitamin B6. Thus, the skilled person would read pyridoxal phosphate as being vitamin B6. Additionally, there was only one list of components in claim 1 and the claim did not relate to choices from two separate lists. The suppression of the "functional derivatives" mentioned in paragraph [0022] of the application as filed had been undertaken during the examination proceedings in order to overcome a lack of clarity objection. Further basis for amended claim 1 was to be found in paragraphs [0021], [0008] and [0006] of the application as filed. Thus, the disorders that were treated in the use claim were serotonin- and melatonin-mediated disorders. The claimed addressed the treatment of the symptoms resulting from such disorders.

Claim 1 of the main request did not contravene Article 123(3) EPC either since its scope was more restrictive than that of claim 1 as granted.

Asked by the board, the appellant acknowledged that some symptoms were similar to symptoms not originated by serotonin- and melatonin-mediated disorders, but

these were clearly not under the scope claimed. The claim did not relate to the treatment of some symptoms *per se*, but it expressed that the symptoms to be treated related to neurodegenerative disorders associated with serotonin and melatonin levels in the brain.

The "invention" related to the cases in which there were problems with the tryptophan metabolism and the serotonin and melatonin levels in the brain. The basis was given in paragraph [0008] of the application as filed.

The basis for claim 2 was paragraph [0017] of the application as filed. Moreover, the dependent claims could be deleted, if necessary.

Claim 1 was clear for the skilled person willing to understand what was taught in the description about the claimed "invention".

XIII. The respondents' arguments, as far as relevant for the present decision, may be summarised as follows.

The respondents did not raise any objections against the admissibility of the requests filed with the letter of 16 February 2011.

Respondents O1 and O2 submitted that the auxiliary requests I and II filed at the oral proceedings before the board should not be admitted into the proceedings. Both requests were too late-filed and they could have been filed earlier. The patent had been revoked for grounds pursuant to Articles 100(c) and 123(2) EPC.

Thus, the appellant should have been earlier in a position to provide for a set of claims which met said requirements. Respondent opponent O2 also contested the appellant's argument that the opponents should have raised all the formal objections against the amended sets of claims earlier since, under the circumstances of the case, the appellant should have been in a position to expect further objections within the meaning of Article 123 EPC.

As regards the main request the respondents O1 and O2 argued as follows:

(a) The respondent opponent O1 raised objections within the meaning of Article 123 (2) and (3) EPC. Claim 1 related now to the medical use of a combination of several substances. Paragraph [0022] of the application as filed specifically mentioned pyridoxal phosphate, which was the active form of vitamin B6, but which was not a synonym for vitamin B6. Vitamin B6 was a generic term which included several forms, such as pyridoxine or pyridoxamine, which were commonly used in dietary supplements and pharmaceutical compositions. In this context the respondent opponent O1 cited paragraph [0049]. Moreover, paragraph [0022] of the application as filed disclosed two lists of components. The amended claim concerned unallowable selections from two lists. Moreover, claim 1 of the main request had been re-drafted as regards the definition of the medical condition to be treated. The new definitions did not correspond to what had been claimed in claim 1 as granted. Moreover, the appellant had cited paragraph [0006] as a basis for the amendments. However, said paragraph stressed with the words "in addition" that

the treatment of "undesirable symptoms" related to neurodegenerative disorders like Alzheimer, Parkinson and schizophrenia was never addressed separately from the prevention and/or treatment of the disorders previously mentioned in that paragraph. Additionally, the also cited paragraph [0008] made it clear that the serotonin- and melatonin-mediated disorders were associated not only with a disorder in the serotonin and melatonin levels in the brain but also with the presence of pterines and folate and with the functioning of the methylating system in the body. Thus, claim 1 of the main request related to an unallowable generalisation. Moreover, paragraph [0026] of the application as filed showed that the administration of riboflavin and thiamine addressed the deficiencies in riboflavin and thiamine (which frequently occurred among the groups of patients to be treated by the combination of folic acid, vitamin B6 and B12). However, these deficiencies were not mentioned in the claim.

Claim 1 of the main request contravened the requirements of Article 123(3) EPC since the use was no longer directed to the treatment or prevention of serotonin- or melatonin-mediated disorders but encompassed the treatment of symptoms related to neurodegenerative disorders associated with serotonin and melatonin levels in the brain which may have different causative origins. The respondent opponent O1 gave as an example tremor as a symptom associated with Parkinson but also present as a result from other causes (e.g. essential tremor, psychogenic tremor, flapping tremor by certain liver diseases). Tremor as a symptom may be the result of frost cold and have no medical condition to be treated at its origins.

Paragraph [0006] made it clear that the treatment and prevention of serotonin- and melatonin-mediated disorders was not equivalent to the treatment of the symptoms related to neurodegenerative disorders.

Contrary to the appellant's allegation, the content in paragraph [0017] could not serve as a basis for claim 2 as dependent on claim 1 of the main request. Said paragraph addressed nutritional deficits in infants and elderly people and thus, had nothing to do with the treatment of neurodegenerative disorders in diseased and elderly persons.

The respondent opponent O1 also submitted that claim 1 of the main request did not meet the requirements of Article 84 EPC for reasons intertwined with the arguments already provided in relation to Article 123 EPC. It was unclear from the claim's wording whether the symptoms to be treated were the result of serotonin- and melatonin-mediated disorders. The relative and subjective term "undesirable" which was used in connexion with the term "symptoms" lead to a lack of clarity of the subject-matter claimed. The simultaneous use in claim 1 of the expressions "related to" and "associated with" lead to a lack of clarity in the definition of the medical indication for which the use was claimed. None of these expressions were defined in the description.

(b) Respondent opponent O2 endorsed respondent opponent's O1 objections against the main request. Moreover, respondent opponent O2 added the following.

There was a further contravention of Article 123(2) EPC in view of the dependencies of claims 2 to 4 to the new drafted claim 1.

Paragraph [0006] of the application as filed referred only to three components and not to all the components in claim 1 of the main request. The content of paragraph [0008] of the application as filed could not be split into separate teachings. The expression "not only" stressed that point. Paragraph [0017] of the application as filed gave no valid support for the medical use now claimed in the main request.

The expression "undesirable" in connexion with the term "symptoms" caused an insurmountable problem of lack of clarity in the context of a claim directed to a medical treatment which encompassed *inter alia* the neurological decline in the elderly.

XIV. The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the main request filed with the letter of 16 February 2011.

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

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 *Admissibility of the requests*

The reasons for the admissibility of the main request filed with the letter of 16 February 2011 are that it relates to a fair attempt to respond to the board's communication sent as an annex to the summons to oral proceedings (Article 12(1)(c) RPBA). None of the respondents objected to its admissibility.

However, as regards the late-filing of the two further auxiliary requests during the oral proceedings before the board, the following has been considered.

The oral proceedings were scheduled with the intention to arrive at a final decision in observance of the principles of law governing the procedure (expressed *inter alia* in Articles 113 and 116 EPC). Moreover, the board sent a communication within the meaning of Article 15 RPBA containing detailed observations in relation to the admissibility of the requests pending at that time. Additionally, the board draw the parties' attention to the matters of special significance in the present appeal case which were the problems linked to the claim's construction and the requirements of Article 123(2) and (3) EPC. Moreover, it was also clearly stated that said communication did not contain "an exhaustive list of all items to be treated at the oral proceedings".

The appellant filed two amended sets of claims with its letter of 16 February amounting to that time of the proceedings to a total of twenty six attempts meant to overcome the grounds of opposition pursuant to Article 100(c) EPC against the granted set of claims.

Respondent opponent O1 with its letter of 4 March 2011 raised objections within the meaning of Articles 123 and 84 EPC against the newly filed sets of claims.

Auxiliary requests I and II were filed only after the discussion about Articles 123 and 84 EPC had taken place at the oral proceedings before the board for the main request.

This late-filing is not justified in the present case since major formal deficiencies had been pointed out by the opponents in their replies to the grounds of appeal for the former requests. Additionally, the board had sent a detailed communication in relation to the unsuccessful attempts to redraft the claims in compliance with Article 123 EPC. Thus, it was manifestly clear that the main issue in the present appeal was the examination of the grounds pursuant to Article 100(c) EPC and that it was inevitable to assess at the oral proceedings before the board the allowability under Articles 123 and 84 EPC of the amendments which were introduced in the sets of claims filed one month before the oral proceedings.

Therefore, it was the appellant's duty to provide earlier for a complete defence of its own case in the

form of adequate fallback positions dealing with expectable formal objections.

Moreover, a patent proprietor may submit amended claims during the proceedings. However, in *inter partes* appeal proceedings the principles of fairness and equity in relation to all parties must apply.

After an evaluation of the particular circumstances of the present case the board is convinced that to admit the two sets of claims filed during the oral proceedings would have put into question the basic principles governing a fair *inter partes* proceedings. The reasons are as follows: *inter partes* appeal proceedings are not a re-examination of the application, and the patent proprietor has not an absolute procedural right for a sequential filing of auxiliary requests during the course of the discussions in oral proceedings before the board of appeal.

As a matter of fact, there was not a surprise that during the oral proceedings in the present appeal case discussions within the sense of Article 123 EPC will take place and that they will definitively address each of the new drafted claims and the new dependencies between claims arising from the amendments introduced for the first time in the sets of claims filed about one month before the oral proceedings before the board.

Thus, the board is convinced that the appellant should have been prepared to address objections within the meaning of Article 123 (2) EPC filing earlier adequate sets of claims.

Additionally, the amendments introduced in claim 1 of auxiliary request I opened new issues for discussion in relation to Article 84 EPC at such a late stage of the proceedings. Moreover, the filing of auxiliary request II only concerned the deletion of dependent claims which may have served to pre-empt the attack against the dependent claims, but which did not address any of the issues raised by the respondent opponent O1 with its letter dated 4 March 2011 against claim 1.

Consequently, auxiliary requests I and II are not admitted into the proceedings.

2. *Main request*

2.1 Claim 1 relates to a medical use claim in Swiss-type form. Claim 1 of the main request concerns the medical use of a combination of the products: folic acid, vitamin B6, vitamin B12, riboflavin, thiamine and niacin. The medical indication is defined in claim 1 as follows: "for use in decreasing undesirable symptoms related to neurodegenerative disorders associated with serotonin and melatonin levels in the brain".

The application as filed discloses infant formulae for complete nutrition that decreases the number of crying episodes and promotes sleeping behaviour for the child, or that compensate for the relative capacity of the developing metabolic systems of the child shortly after birth (paragraphs [0003] and [0004]).

The application as filed also discloses that "in a further aspect, the invention is related to the use of **folic acid, vitamins B12 and B6** or their functional

analogues in the manufacture of compositions for the prevention and/or treatment of specific neurological disorders...Products according to the invention will be effective in improving sleep behaviour, insomnia, mood, decrease feelings of fear and depression and increase feelings of wellbeing. **In addition**, undesirable symptoms related to neurodegenerative disorders like Alzheimer, Parkinson and schizophrenia are decreased. Also, the products can be helpful in the prevention and/or treatment of symptoms associated with restless legs syndrome, myoclonus, Gilles de la Tourette, phenylketonuria, multiple sclerosis, analgesia, epilepsy, mania, aggressive behaviour, bulimia and other disorders associated with saturation feelings after eating, ADHD, and psychiatric disorders associated with ageing". (paragraph [0006]) (emphasis added).

Thus, the disclosure in paragraph [0006] of the application as filed does not teach the specific use of a combination of all the products in claim 1 for decreasing undesirable symptoms related to neurodegenerative disorders associated with serotonin and melatonin levels in the brain.

Moreover, paragraph [0008] of the application as filed makes it clear that all the disorders mentioned in the two previous paragraphs ([0006] and [0007]) "are associated **not only with** a disorder in serotonin levels, **but also with** the melatonin levels in the brain, **the presence of pterines and folate in the brain and the functioning of the methylating system in the body"** (emphasis added).

Therefore, paragraph [0008] cannot serve either as an allowable basis for the definition of the medical condition in claim 1 of the main request which is incomplete in the claim.

Additionally, paragraph [0019] of the application as filed teaches about "the restoration of the patient's capacity to metabolise tryptophan to serotonin and especially melatonin" and paragraph [0020] discloses that this restoration "can be achieved by administering extra amounts of certain cofactors, at least folic acid, vitamin B12 and vitamin B6". However, these paragraphs do not disclose whether (and in how far) said restoration is to be linked to the decrease of the symptoms of certain neurodegenerative disorders attained by using the combination of all the products in claim 1 of the main request.

Paragraph [0021] of the application as filed, which discloses that "In cases **where a patient has a limited capacity for serotonin biosynthesis**, e.g. by damage to tissue that is rich in serotoninergic neurons or due to an inherited disorder, administration of cofactors appeared to increase serotonin and melatonin levels in the brain, if a certain basal level of tryptophan was available" (emphasis added), is too specific in relation to the definition of the particular patients to be treated for providing a valid basis for the wording in claim 1 of the main request.

As regards paragraph [0022] of the application as filed, it reads as follows: "It was found that the cofactors of interest are at least folic acid, pyridoxal phosphate and vitamin B12 or their functional

equivalents. In addition it may be required to administer riboflavin, thiamine and niacin, or their functional equivalents".

It has to be recalled that pyridoxal phosphate is the biologically active form of, but not a synonym for, vitamin B6. The expression vitamin B6 is a generic term including several forms, such as pyridoxine or pyridoxamine, which may also be administered as vitamin B6 (see also paragraph [0049] of the application as filed).

Therefore, in order to arrive at the use of the combination of all the products listed in claim 1 of the main request for the particular use now specified in the claim, the skilled person has to perform several selections concerning both the choice of the products to be combined and the ailments to be treated (in this case the "undesirable symptoms" related to certain neurodegenerative disorders).

Moreover, the application as filed discloses the use of folic acid, vitamin B6 and vitamin B12 or their functional analogues for the treatment or prevention of serotonin- or melatonin-mediated disorders (claim 1 of the application as filed) but does not single out, as a particular embodiment, the symptomatic treatment of neurodegenerative disorders associated with serotonin and melatonin levels in the brain by using the combination of all products appearing in the claim.

Therefore, claim 1 of the main request contravenes the requirements of Article 123(2) EPC. Consequently, the main request fails.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald