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Datasheet for the decision of 28 June 2021

Case Number:	T 0914/18 - 3.3.01
Application Number:	09792438.5
Publication Number:	2344148
IPC:	A61K31/195, A61P35/00, A61P37/04
Language of the proceedings:	EN

Title of invention:
NUTRITIONAL SUPPORT TO PREVENT OR MODERATE BONE MARROW PARALYSIS OR NEUTROPENIA DURING ANTI-CANCER TREATMENT

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
N.V. NUTRICIA

Headword:
Immunonutritional composition/NESTLE

Relevant legal provisions:
EPC Art. 100(c), 123(2), 111(1), 83
RPBA 2020 Art. 13(2)

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Keyword:
Main request and auxiliary requests 1-3, 4,4',5,5',6,6': amendments - added subject-matter (yes)
Auxiliary request 7 - taken into account (yes)
Auxiliary request 7 - added subject-matter (no)
Auxiliary request 7 - insufficiency of disclosure (no)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:
G 0001/10, T 0995/18, T 1151/18

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Case Number: T 0914/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 28 June 2021

Appellant: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Respondent: (Opponent)	N.V. NUTRICIA Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	V.O. P.O. Box 87930 2508 DH Den Haag (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 8 January 2018 revoking European patent No. 2344148 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	M. Pregetter
	P. Guntz

Summary of Facts and Submissions

I. European patent No. 2344148 is based on European patent application No. 09792438.5, filed as an international application published as WO2010/033425.

II. Claims 1 and 2 of the patent as granted read as follows.

"1. An immunonutritional composition comprising: at least one immuno-enhancing agent and a pharmaceutically acceptable carrier, said immune-enhancing agent comprising arginine, for use in transiently preventing or reducing anti-cancer treatment induced toxicity of the bone marrow, wherein said immunonutritional composition is used as part of neoadjuvant treatment and wherein said immunotritional [sic] composition is enterally administered.

2. The immunonutritional composition for use according to claim 1, additionally comprising n-3 fatty acids and RNA."

III. European patent No. 2344148 was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter was excluded from patentability, lacked novelty and an inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.

IV. In the course of the opposition proceedings, the patent proprietor requested the rejection of the opposition and submitted auxiliary requests 1 to 7, all filed on

6 October 2017, and auxiliary requests 2', 5', 6' and 7', all filed on 27 November 2017. During oral proceedings before the opposition division, the patent proprietor renumbered auxiliary requests 2', 5', 6' and 7' as 8 to 11, respectively, and filed auxiliary request 12.

V. The opposition division revoked the patent. The subject-matter of the main request (set of claims as granted) and auxiliary requests 1 to 11 was found to contravene Article 123(2) EPC. Auxiliary request 12 was found to not meet the requirements of Article 83 EPC.

VI. The patent proprietor appealed this decision. Together with its statement setting out the grounds of appeal, it submitted auxiliary requests 1 to 16. With a letter dated 21 June 2021, auxiliary requests 4' to 7' and 13' to 15' were submitted.

Claim 1 of auxiliary request 1 differs from claim 1 of the patent as granted in that the words "preventing or" have been deleted.

Claim 1 of auxiliary request 2 reads as follows.

"1. An immunonutritional composition comprising: at least one immuno-enhancing agent and a pharmaceutically acceptable carrier, said at least one immune-enhancing agent comprising arginine, n-3 fatty acids and RNA, for use in transiently reducing anti-cancer treatment induced toxicity of the bone marrow, wherein said immunonutritional composition is used as part of neoadjuvant treatment and wherein said immunonutritional composition is enterally administered."

Claim 1 of auxiliary request 3 reads as follows.

"1. An immunonutritional composition comprising: the immuno-enhancing agents arginine, n-3 fatty acids and RNA, and a pharmaceutically acceptable carrier, for use in transiently reducing anti-cancer treatment induced toxicity of the bone marrow, wherein said immunonutritional composition is used as part of neoadjuvant treatment and wherein said immunonutritional composition is enterally administered."

Claim 1 of auxiliary requests 4 and 5 is identical to claim 1 of auxiliary request 1.

Claim 1 of auxiliary request 6 reads as follows.

"1. An immunonutritional composition comprising: at least one immuno-enhancing agent and a pharmaceutically acceptable carrier, said immune-enhancing agent comprising arginine, for use in transiently reducing anti-cancer treatment induced toxicity of the bone marrow, wherein the bone marrow toxicity is bone marrow paralysis or neutropenia, wherein said immunonutritional composition is used as part of neoadjuvant treatment and wherein said immunonutritional composition is enterally administered."

The sets of claims of the "prime" series differ from the corresponding sets of claims not marked by the prime symbol in that dependent claims have been deleted.

VII. With its reply to the grounds of appeal, the opponent (respondent) submitted four documents to show that a

set of claims restricted to neutropenia could not fulfil the requirements of Article 123(3) EPC.

VIII. The following document, cited during the opposition and appeal proceedings, is referred to below:

(1) Heys et al., Int J Oncol, 1998, 12, 221-225

IX. Oral proceedings before the board took place on 28 June 2021 in the absence of the respondent, who had been duly summoned but who had chosen not to attend, as announced by letter of 16 June 2021.

During the oral proceedings, the appellant submitted an amended auxiliary request 7. Auxiliary request 7 consists of two claims. They read as follows.

"1. An immunonutritional composition comprising: at least one immuno-enhancing agent and a pharmaceutically acceptable carrier, said immune-enhancing agent comprising arginine, for use in transiently reducing anti-cancer treatment induced toxicity of the bone marrow, wherein the bone marrow toxicity is bone marrow paralysis, wherein said immunonutritional composition is used as part of neoadjuvant treatment and wherein said immunonutritional composition is enterally administered.

2. The immunonutritional composition for use according to claim 1, wherein said immunonutritional composition is a tube feed, a gel, or a complete nutrition."

X. The appellant (patent proprietor)'s arguments, insofar as they are relevant for the present decision, may be

summarised as follows.

Amendments

The subject-matter of claim 1 as granted was based on claim 14 as filed. Arginine was the most preferred active agent. This could be derived from the fact that arginine was used in almost all examples and that its effects, especially on red blood cells and tumour growth, were prominently discussed in example 2. Neoadjuvant treatment was defined in claim 26. Its implications, especially in view of red blood cells, were described in the first paragraph on page 59. The introduction of the term "transient" was consistent with the disclosure of the application as a whole (see pages 3 and 4, where myelosuppression is mentioned, and also pages 8 and 57, where a definition of bone marrow toxicity is given). Furthermore, claim 1 as filed defined transiently preventing or moderating bone marrow paralysis or neutropenia. Toxicity was merely a different term (see page 12, paragraph 3). As tube feeding (see claim 34 as filed) gave rise to exposing the bone marrow to the composition, the term "enterally administered" could replace the term "exposing said bone marrow". It was irrelevant whether each and every compound actually reached the bone marrow.

The subject-matter of claim 2 as granted was supported by several mentions of the compounds in the application as filed and the explicit disclosure of the claimed combination in the example bridging pages 54 and 55. It was clear that the terms "nucleotides" and "RNA" were used interchangeably throughout the application.

No additional arguments were provided in relation to auxiliary requests 1 to 5, including the "prime"

requests.

Claim 1 of auxiliary request 6 was based on claim 1 as filed in combination with page 54, first paragraph. As claim 1 of auxiliary request 6 was restricted to treating neutropenia in the context of anti-cancer-treatment-induced toxicity of the bone marrow and arginine was the preferred compound in this context, the skilled person would have understood that arginine was preferred overall. It was clear from page 54 that neutropenia was an important aspect in the context of neoadjuvant therapy and, when looking at page 59, first paragraph, the skilled person, on seeing the mention of hematocrit, platelets and immune cells, would have considered neutrophils, which were important immune cells, to be covered by this disclosure.

Nothing was added for auxiliary request 6'.

Sufficiency of disclosure

The person skilled in the art, capable of obtaining arginine, was in a position to carry out the medical use of claim 1 of auxiliary request 7. The application made it clear that arginine inherently possessed the functional requirements. No serious doubts had been substantiated.

XI. The respondent's arguments, insofar as they are relevant for the present decision, may be summarised as follows.

Amendments

The technical feature "the immune-enhancing agent comprising arginine", found in claim 1 as granted, was

a selection. Example 2 was the sole example that related to the use of arginine alone. However, this example did not concern neoadjuvant treatment, which was a further selection. Furthermore, the functional part of the definition of the immune-enhancing agent had been omitted, thus creating an unallowable generalisation. As it was not plausible that a composition administered enterally was inevitably exposed to the bone marrow, the omission of the feature "exposing said bone marrow of the subject to an immunonutritional composition" was a generalisation without basis. Furthermore, claim 14 as filed did not define a transient treatment. Neither claim 1 nor the further passages identified by the appellant provided a direct and unambiguous link between "transiently" and the other features of claim 1 as granted. In addition, the application as filed was not limited to bone marrow toxicity. The triple combination defined in claim 2 as granted was mentioned only in one specific setting not relating to effects on the bone marrow or to neoadjuvant therapy.

The change from "immunotritional" to "immunonutritional" was not allowable since the patent was not a document filed with the European Patent Office within the meaning of Rule 139 EPC, and the change was not occasioned by a ground for opposition as stipulated by Rule 80 EPC.

In addition, multiple selections were necessary to arrive at a claim defining "reducing" (selection from "preventing or moderating"), bone marrow paralysis (selection from "bone marrow paralysis or neutropenia"), enteral administration, and arginine (selection from a list of agents in claim 10 as filed). No direct and unambiguous disclosure for this multiple

combination of features existed. Furthermore, claims 34 to 36 as filed did not refer back to claims 1, 10 or 37 and thus constituted isolated embodiments which could not be freely combined with other technical features.

Sufficiency of disclosure

It was not plausible that arginine alone would be capable of achieving preservation of the innate and adaptive immune functions and the normal physiology of immune cells. Experimental data to support this activity, i.e. data showing fully normalised blood parameters, was lacking. Furthermore, the patent did not disclose how to determine whether an immuno-enhancing agent or immunonutritional composition was effective in reducing or preventing anti-cancer-treatment-induced toxicity of the bone marrow. This failure resulted in an undue burden.

If document (1) did not anticipate the subject-matter of claim 1 because it did not show a statistically significant finding, as argued by the appellant in opposition proceedings, then this document provided experimental evidence that the subject-matter of the claims was not enabled over the full scope.

XII. The parties' final requests were as follows.

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the case be remitted to the opposition division for consideration of novelty and inventive step with regard to the main request (to maintain the patent as granted) or, in the alternative, with regard to one of auxiliary requests 1 to 3, 4, 4', 5, 5', 6, 6', 7, 8, 8', 9 to 13, 14, 14', 15, 15', 16, 16' and 17 (auxiliary requests 1 to 6 and

8 to 17 submitted with the statement of grounds of appeal as auxiliary requests 1 to 16; auxiliary request 7 submitted during the oral proceedings; and auxiliary requests 4' to 6', 8' and 14' to 16' submitted with the letter dated 21 June 2021 as auxiliary requests 4' to 7' and 13' to 15').

The respondent requested that the appeal be dismissed and that the case not be remitted to the opposition division for discussion of sufficiency of disclosure.

Reasons for the Decision

1. The appeal is admissible.

2. The oral proceedings before the board took place in the absence of the respondent, who had been duly summoned but had chosen not to attend. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the board was not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned, who was treated as relying only on its written case. Hence, the board was in a position to announce a decision at the conclusion of the oral proceedings, as provided for by Article 15(6) RPBA.

3. *Amendments*

3.1 *Main request*

3.1.1 Claim 1 as granted defines an immunonutritional composition:

- comprising at least one immuno-enhancing agent and a

pharmaceutically acceptable carrier, said immune-enhancing agent comprising arginine,

- for use in transiently preventing or reducing anti-cancer-treatment-induced toxicity of the bone marrow,

- wherein said immunonutritional composition is used as part of neoadjuvant treatment

- and wherein said immunotritional [sic] composition is enterally administered.

3.1.2 Claim 14 as filed, on which the appellant relies as the basis, defines that the at least one immuno-enhancing agent is "capable of preserving the innate and adaptive immune functions and normal physiology of said immune cell". This functional definition is not present in claim 1 as granted. The same functional definition is given in claim 1 as filed ("wherein said at least one immuno-enhancing agent is capable of preserving the innate and adaptive immune functions and normal physiology of said immune cell"). Claim 6 as filed, referring to claim 1, defines that the at least one immuno-enhancing agent is selected from the group consisting of, *inter alia*, an amino acid. Claim 10 as filed, referring directly to claim 6, defines that the at least one amino acid may be arginine. The application as filed thus discloses directly and unambiguously that arginine is one of the agents that fulfils the functional requirements. Consequently, the omission of the functional definition does not lead to added matter. For the assessment of the allowability of the amendment, the disclosure of the application as filed as such is taken into account. Whether arginine in fact fulfils the functional requirements is irrelevant in the situation at hand for the assessment

of the allowability of the amendment.

3.1.3 Example 2 contains one study arm relying exclusively on arginine as the active agent. It discloses that solely the treatment with arginine as the sole active agent leads to a prevention of the marked fall of erythrocytes post-chemotherapy, which is described as reduced bone marrow toxicity (description as filed, page 39, last paragraph, Figure 3). Loss of CD3+ cells was partially modulated in this study arm (page 42, last paragraph). The arginine group showed delayed progression of an implanted tumour compared to the other study arms (page 43, last paragraph). In sum, arginine as the sole agent is disclosed in the context of alleviating erythrocyte depression, modulating certain types of lymphocytes and delaying tumour progression. Thus, the action of arginine is singled out with regard to certain effects, especially effects concerning red blood cells. Arginine is the preferred agent in this context.

3.1.4 Concerning the use of arginine for transiently preventing or reducing anti-cancer-treatment-induced toxicity of the bone marrow, no direct and unambiguous disclosure can be found in the application as filed. The term "bone marrow toxicity" or "toxicity of the bone marrow" is not clearly defined in the application. It seems that this term may include "bone marrow paralysis" and "neutropenia" (see claim 21 as filed). It is, however, not clear which other forms of deficiencies in the haematopoietic system are encompassed by this term. The passages cited by the appellant do not provide further information. Pages 8 and 12 do not mention the term "toxicity". Page 57, last paragraph, mentions in a general way that "toxicity" is related to a deficiency of blood cells.

No relationship to the terms "bone marrow paralysis" and "neutropenia" is established. In addition, the disclosure on page 57 relies on different terms to the explanation on page 12, paragraph 3, allowing no direct comparison. Furthermore, the application as filed does not link the term "bone marrow toxicity" to the term "transiently". "Transient", or "transiently", is used exclusively in combination with bone marrow paralysis and/or neutropenia, in combination with immunosuppression in general (see page 4, line 6) and in combination with the enhancement of immunogenicity, which, however, is irrelevant in the current context. In sum, there is no direct and unambiguous disclosure of the treatment of bone marrow toxicity and the term "transiently".

3.1.5 Neoadjuvant treatment is one of the cancer treatments disclosed in the application as filed. It is defined in claims 26 and 37 as filed. The description explains that neoadjuvant strategy is to use fewer doses of chemo- or radiotherapy in an effort to reduce the growth rate or size of the tumour prior to a major intervention. It goes on to state that oncologists will, however, delay these major interventions if the patient's blood cell counts are too low and proposes as a solution the intervention strategies described in the application as filed (page 59, first paragraph), thus generally linking neoadjuvant treatment to the methods claimed in the application as filed.

3.1.6 Claim 14 as filed discloses that the bone marrow of the treated subject is to be exposed to the immunonutritional composition. This technical feature has been omitted in claim 1 as granted. The appellant argued that the omission of "exposing said bone marrow" does not lead to an extension of the claimed subject-

matter since it replaced this term with the definition that the immunonutritional composition "is enterally administered". The board cannot accept this argument. The mode of administration of a composition comprising certain ingredients is not automatically linked to the location of potential action of the ingredients within the human body. Enteral administration, which includes oral administration (page 30, penultimate paragraph), means that the composition passes through the mouth and the gastrointestinal tract and is exposed to digestive enzymes and various pH zones. Degradation might occur, and not all ingredients of the immunonutritional composition under consideration will be absorbed intact so that they can be transported to the bone marrow. Exposure of the bone marrow to the composition is thus not equivalent to enteral administration of the composition. The omission of the location of action thus leads to added matter.

3.1.7 In sum, the subject-matter of claim 1 of the main request extends beyond the disclosure of the application as filed at least for the reasons given under points 3.1.4 and 3.1.6 above.

3.1.8 *Claim 2*

The triple combination of arginine, n-3 fatty acids and RNA is not generally disclosed in the application as filed. Whereas there are several passages that disclose a triple combination of arginine, n-3 fatty acids and nucleotides, which according to claim 11 as filed can be RNA or DNA, the triple combination specifically with RNA as the nucleotide can only be found in the example bridging pages 54 and 55. This example concerns a single patient with Hodgkin's disease. The treatment is clearly not neoadjuvant. Furthermore, as Hodgkin's

disease is a specific type of cancer, i.e. a lymphoma and thus a cancer which itself directly affects white blood cells, a generalisation to neoadjuvant treatment for all types of cancer is not possible. The terms "RNA" and "nucleotide" are not presented as synonyms in the application as filed (see claim 11).

The subject-matter of claim 2 extends beyond the application as filed.

3.1.9 The ground for opposition of Article 100(c) EPC prejudices the maintenance of the patent as granted.

3.2 *Auxiliary requests 1 to 5 (including the "prime" requests)*

3.2.1 *Auxiliary requests 1, 4, 4', 5, 5'*

The respective claims 1 of these requests differ from claim 1 of the main request merely in the deletion of the term "preventing".

The deletion of the term "preventing" does not change the argument provided in points 3.1.1 to 3.1.7 above, which consequently also applies to the subject-matter of claims 1 of auxiliary requests 1, 4, 4', 5 and 5', which thus does not fulfil the requirements of Article 123(2) EPC for the same reasons as the main request.

3.2.2 *Auxiliary requests 2 and 3*

Claims 1 of auxiliary requests 2 and 3 are based on claim 1 of auxiliary request 1 and further include the subject-matter of claim 2 of the main request. Consequently, the same argument as given under points

3.1.8 and 3.2.1 applies.

The subject-matter of claims 1 of auxiliary requests 2 and 3 does not fulfil the requirements of Article 123(2) EPC.

3.3 *Auxiliary requests 6 and 6'*

Claim 1 of auxiliary request 6 differs from claim 1 of the main request in that two alternatives, bone marrow paralysis and neutropenia, have been identified to represent the anti-cancer-treatment-induced toxicity of the bone marrow.

The second claimed alternative is a combination of, *inter alia*, the following technical features:
- an immunonutritional composition comprising arginine
- use in transiently reducing neutropenia

As discussed above for the main request (see point 3.1.3), arginine has been described as advantageous in the context of red blood cell count, CD3+ cell modulation and tumour progression. These three aspects are not directly linked to neutropenia, which relates to abnormally low concentrations of neutrophils.

Thus, arginine does not represent the preferred active agent for this type of bone marrow toxicity. Consequently, the second alternative of claim 1 of auxiliary request 6 can only be arrived at by selecting firstly the active agent arginine and secondly neutropenia as a manifestation of a cancer-treatment-induced bone-marrow-related condition.

In view of this double selection necessary to arrive at the combination of technical features defined in claim

1, the subject-matter of claim 1 of auxiliary request 6 extends beyond the disclosure of the application as filed (Article 123(2) EPC).

Claim 1 of auxiliary request 6' is identical to claim 1 of auxiliary request 6. The same argument applies. Consequently, the subject-matter of claim 1 of auxiliary request 6' also extends beyond the disclosure of the application as filed.

4. *Auxiliary request* 7

4.1 *Admission*

The subject-matter of auxiliary request 7 is the result of the deletion of one of the options of claim 1 of auxiliary request 6, namely the option that bone marrow toxicity is neutropenia, and the deletion of two dependent claims. Provided the deletion of an alternative and the deletion of dependent claims do not lead to a fresh case, they have been considered in the case law of the boards to be mere restrictions of the subject-matter that do not constitute an amendment of a party's case within the meaning of Article 13(2) RPBA 2020 (see T 995/18, Reasons, 2, and T 1151/18, Reasons, 2.1). This is the case here. The deletion of the option "or neutropenia" in auxiliary request 7 simply sets aside one of the objections under discussion without shedding new light on the remaining subject-matter and without other consequences on the parties' respective appeal cases. It is thus comparable to the withdrawal of certain objections or lines of attack by an opponent, which has also never been seen as a change of case (see T 995/18, Reasons, 2). A set of claims relating to bone marrow paralysis but not to neutropenia has been on file throughout the proceedings

(as auxiliary request 12 in opposition proceedings, see decision under appeal, and as auxiliary request 10 in appeal proceedings). Furthermore, the board considers that the filing of this request considerably sped up the proceedings by avoiding the discussion of a large number of auxiliary requests and further issues, such as the respondent's objections under Articles 123(3) and 84 EPC.

Thus, Article 13(2) RPBA 2020 does not prejudice the deletions made compared with auxiliary request 6 and the admission of the remaining subject-matter, labelled "auxiliary request 7", into the proceedings.

4.2 *Amendments*

4.2.1 Claim 1 of auxiliary request 7 contains the following technical features:

- an immunonutritional composition comprising:
- at least one immuno-enhancing agent and a pharmaceutically acceptable carrier, said immune-enhancing agent comprising arginine,
- for use in transiently reducing anti-cancer treatment induced toxicity of the bone marrow, wherein the bone marrow toxicity is bone marrow paralysis,
- wherein said immunonutritional composition is used as part of neoadjuvant treatment, and
- wherein said immunonutritional composition is enterally administered.

The subject-matter of claim 1 of auxiliary request 7 derives from claim 1 as filed in combination with claims 6 and 10 and example 2 (for arginine and the omission of the functional definition of the immuno-enhancing agent and the term "transiently"). The

subject-matter has been limited to one of the disclosed options for bone marrow toxicity, namely bone marrow paralysis (see point 3.1.4). In this context, it is noted that the discussion of the activities of arginine in example 2, i.e. the prevention of a marked fall of erythrocytes and the modulation of CD3+ cells, is in line with bone marrow paralysis (whereas it is not linked to neutropenia). The transient treatment of bone marrow paralysis by arginine is thus directly derivable from the application as filed.

The presence of a pharmaceutically acceptable carrier is disclosed on page 33, lines 24 to 26.

The replacement of the term "moderating" with "reducing" is based on page 60, penultimate paragraph. This replacement has to be seen as a mere rewording which is not a selection for the following reasons. From the application as filed, it can be clearly derived that the treatment aims to ameliorate immune cell function and red blood cell count. With this in mind, it is clear that the terms "moderating" or "mitigating" (bone marrow paralysis) are to be understood as synonyms of "reducing" the paralysis. This is also in line with the information given for arginine in example 2. The omission of the term "preventing" is a mere deletion not resulting in a further selection.

Neoadjuvant treatment is described on page 58, first paragraph; page 59, first paragraph; and in the paragraph bridging pages 60 and 61. Furthermore, it is defined in claims 26 and 37. Claim 37 is an independent claim that relates to the use of the compositions of claims 1 to 13 as filed in neoadjuvant treatment. It is thus disclosed in a general way (see also point 3.1.5

above).

Enteral administration is disclosed as the preferred mode of administration on page 30, penultimate paragraph.

Claim 1 as filed does not define that the bone marrow is exposed to the immunonutritional composition.

Claim 1 of auxiliary request 7 is thus a combination of technical features which are either generally disclosed or preferred. Consequently, it is directly and unambiguously derivable from the application as filed.

4.2.2 The subject-matter of claim 2 of auxiliary request 7 is disclosed in claims 34 to 36 as filed. As the galenic forms defined in claim 2 are, in the case under consideration, not directly linked to the actual choice of active agent and are in line with the preferred mode of administration, which is enteral, these galenic forms, which are also described in the description (see page 30, penultimate paragraph, and page 33, paragraph 4 to page 34, paragraph 2) do not add subject-matter.

4.2.3 Concerning the correction of the obvious error in claim 1 of auxiliary request 7 from "immunotritional" to "immunonutritional", the board notes the following. The term "immunotritional" is clearly erroneous. From the wording of claim 1 of auxiliary request 7, as well as claim 1 as granted, it is obvious that the same composition as defined before is to be administered ("and wherein said [...] composition"). It is thus immediately evident from the wording of claim 1 as granted how the correction of the obvious error is to be made, i.e. by the replacement of the term "immunotritional" with "immunonutritional".

As the correction of the obvious error, made in the set of claims filed on 4 May 2015 which underlies the application documents on which the grant of the European patent is based, concerns auxiliary request 7, Rule 139 EPC rather than Rule 140 EPC applies (see G 1/10, OJ EPO 2013, 194, point 9). As the filing of auxiliary request 7 was occasioned by a ground for opposition under Article 100 EPC, the requirements of Rule 80 EPC are fulfilled. However, these requirements are irrelevant in the context of Rule 139 EPC (see G 1/10, point 13). The correction is thus allowable.

4.3 *Sufficiency of disclosure*

4.3.1 The application as filed discloses that administration of arginine prevents the marked fall of erythrocytes and modulates the loss of CD3+ cells in appropriate animal models. Such activities are in line with the treatment of bone marrow paralysis and are thus suitable to initially establish that a successful treatment is plausible.

4.3.2 Initial plausibility being established, the burden of proof that enteral administration of arginine is not suitable to achieve the claimed effect is on the respondent. However, the respondent merely stated that there was no data in the patent showing that the tested immunonutritional compositions were effective in preserving the innate and adaptive immune functions and the normal physiology of immune cells. It alleged that at least fully normalised blood parameters were to be expected.

The board cannot accept this argument. In view of the initial plausibility derivable from the data present

for arginine in the application as filed, a mere statement not supported by any evidence cannot establish a lack of sufficiency of disclosure.

4.3.3 Concerning the respondent's second point, that there is a lack of information on how to determine whether an immuno-enhancing agent or an immunonutritional composition is effective in reducing bone marrow paralysis, the following applies. It is obvious for the person skilled in the art to check blood parameters, especially parameters relating to the immune functions/ blood cell counts, to gauge bone marrow vitality/ paralysis. Suitable blood parameters can be found in the examples.

4.3.4 In its reply to the statement of grounds of appeal, the respondent briefly referred to document (1). However, it has not provided any arguments pointing to specific passages of document (1). The decision under appeal is silent on document (1). The board is thus not in a position to come to a finding on lack of sufficiency of disclosure based on this document.

4.3.5 In view of the initial plausibility given by the data of the application as filed for arginine and the lack of substantiation of serious doubts by the respondent, the subject-matter of claim 1 of auxiliary request 7 is considered to be sufficiently disclosed.

4.4 *Remittal*

The decision under appeal was confined to the allowability of amendments, clarity and sufficiency of disclosure. The grounds of appeal under Article 100(a) EPC were not addressed. Accordingly, pursuant to Article 111(1), second sentence, EPC, the

board has discretion over whether to exercise any power within the competence of the department which was responsible for the decision appealed or to remit the case to that department for further prosecution. Having regard to the board's function to review the decision under appeal and given that the appellant has explicitly requested remittal and that the respondent has not objected to remittal in the context of issues arising under Article 100(a) EPC, the board considers that it is appropriate to remit the case to the opposition division for further prosecution.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division for further prosecution on the basis of the seventh auxiliary request as submitted during the oral proceedings.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated