Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 16 July 2024

Case Number: T 2199/22 - 3.3.04

Application Number: 07765188.3

Publication Number: 2046312

IPC: A61K31/122, A61K31/231, A61K31/232, A61K35/60, A61P9/00, A61P19/00

Language of the proceedings: EN

Title of invention:
Pharmaceutical and nutraceutical products comprising vitamin K2

Patent Proprietor:
Lesaffre et Compagnie

Opponent:
Kappa Bioscience As

Headword:
PUFA and MK-7/LESAFFRE

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

Keyword:
Grounds for opposition - added subject-matter (yes) - insufficiency of disclosure (yes)
Amendments - added subject-matter (yes)
Amendment after summons - exceptional circumstances (no)

Decisions cited:
T 0609/02, T 1599/06, T 0966/18

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2199/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 16 July 2024

Appellant I: (Patent Proprietor)	Lesaffre et Compagnie 41, rue Etienne Marcel 75001 Paris (FR)
Representative:	Weickmann & Weickmann PartmbB Postfach 860 820 81635 München (DE)
Appellant II: (Opponent)	Kappa Bioscience As Silurveien 2 0380 Oslo (NO)
Representative:	Dehns St. Bride's House 10 Salisbury Square London EC4Y 8JD (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 15 July 2022 concerning maintenance of the European Patent No. 2046312 in amended form.**

Composition of the Board:

Chairman	L. Bühler
Members:	O. Lechner
	A. Chakravarty

Summary of Facts and Submissions

I. European patent No. 2 046 312 ("patent") was granted based on application No 07 765 188.3. The application was filed as an International patent application and published as WO 2008/006607 ("application as filed").

II. The patent proprietor and the opponent filed appeals against the opposition division's interlocutory decision that European patent No. 2 046 312 amended according to auxiliary request 3 met the requirements of the EPC. Both parties will be referred to according to their role in the opposition proceedings.

III. In its decision the opposition division held that the claims of the patent as granted and set of claims of auxiliary requests 1 and 2 (filed on 13 April 2021) contained subject-matter which extended beyond the content of the application as filed (Articles 100(c) and/or 123(2) EPC). Auxiliary request 3 (filed on 13 April 2021) was found to comply with the requirements of the EPC.

IV. With its statement of grounds of appeal, the opponent maintained objections under Articles 54, 56, 83, 100(c) and 123(2) EPC and filed documents D9 to D11.

V. With its statement of grounds of appeal, the patent proprietor requested maintenance of the patent as granted as its main request and re-submitted the sets of claims of auxiliary requests 1 to 16 (originally filed on 13 April 2021, with the observations to the notice of opposition).

VI. Both parties replied to the respective statements of grounds of appeal and subsequently provided further submissions.

VII. The board issued a summons to oral proceedings and subsequently a communication under Article 15(1) RPBA, setting out its preliminary opinion on matters of particular significance for the decision.

VIII. Oral proceedings before the board took place on 16 July 2024.

During the oral proceedings, the patent proprietor submitted a set of claims of a new auxiliary request 17.

At the end of the proceedings, the Chairman announced the board's decision.

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

"1. A pharmaceutical or nutraceutical product for oral administration comprising menaquinone-7 (MK-7) in combination with at least one of a polyunsaturated fatty acid, either purified or in the form of a marine oil, wherein said product is a tablet formulation or a capsule formulation and wherein MK-7 is in the range of between 1-10 µg.

2. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in

humans and animals, wherein the dosage of MK-7 is in the range of between 1-10 µg per day."

X. Independent claims 1 and 2 of auxiliary request 1 read as follows:

"1. A pharmaceutical or nutraceutical product for oral administration comprising menaquinone-7 (MK-7) in combination with at least one of a polyunsaturated fatty acid, either purified or in the form of a marine oil, wherein said product is a tablet formulation or a capsule formulation and wherein MK-7 is in the range of between 1-10 µg, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders.

2. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals, wherein the dosage of MK-7 is in the range of between 1-10 µg per day."

XI. Independent claims 1 and 2 of auxiliary request 2 read as follows:

"1. A pharmaceutical or nutraceutical product for oral administration comprising menaquinone-7 (MK-7) in combination with at least one of a n-3 polyunsaturated fatty acid, either purified or in the form of a marine oil, wherein said product is a tablet formulation or a capsule formulation and wherein MK-7 is in the range of between 1-10 µg, for use in a method for preventing or

treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders.

2. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals, wherein the dosage of MK-7 is in the range of between 1-10 µg per day."

XII. The sole independent claim 1 of auxiliary request 3 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals, wherein the dosage of MK-7 is in the range of between 1-10 µg per day."

XIII. The sole independent claim 1 of auxiliary request 4 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals, wherein the dosage of MK-7 is in the range of between 1-10 µg per day."

XIV. The sole independent claim 1 of auxiliary request 5 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method of prophylaxis or treatment of at least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis or an inflammatory or degenerative disease of the cartilage, wherein the dosage of MK-7 is in the range of between 1-10 µg per day."

XV. The sole independent claim 1 of auxiliary request 6 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method of prophylaxis or treatment of at least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis or an inflammatory or degenerative disease of the cartilage, wherein the dosage of MK-7 is in the range of between 1-10 µg per day."

XVI. The sole independent claim 1 of auxiliary request 7 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid in the form of a marine oil, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals,

wherein the dosage of MK-7 is in the range of between 1-10 µg per day."

XVII. The sole independent claim 1 of auxiliary request 8 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid in the form of a marine oil, for use in a method of prophylaxis or treatment of at least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis or an inflammatory or degenerative disease of the cartilage, wherein the dosage of MK-7 is in the range of between 1-10 µg per day."

XVIII. The sole independent claim 1 of auxiliary request 9 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals, wherein the dosage of MK- 7 is in the range of between 1-10 µg per day, and wherein the dose of marine oil is 5 g per day, or wherein the product is a tablet formulation or a capsule formulation, wherein the amount of MK-7 in one tablet or capsule is between 1 and 10 µg and the amount of unsaturated fatty acid in each tablet or capsule is between 300 and 1200 mg."

XIX. The sole independent claim 1 of auxiliary request 10 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method of prophylaxis or treatment of at least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis or an inflammatory or degenerative disease of the cartilage, wherein the dosage of MK-7 is in the range of between 1-10 µg per day, and wherein the dose of marine oil is 5 g per day, or wherein the product is a tablet formulation or a capsule formulation, wherein the amount of MK-7 in one tablet or capsule is between 1 and 10 µg and the amount of unsaturated fatty acid in each tablet or capsule is between 300 and 1200 mg."

XX. The sole independent claim 1 of auxiliary request 11 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid in the form of a marine oil, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals, wherein the dosage of MK-7 is in the range of between 1-10 µg per day and wherein the dose of marine oil is 5 g per day."

XXI. The sole independent claim 1 of auxiliary request 12 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid in the form of a marine

oil, for use in a method of prophylaxis or treatment of at least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis or an inflammatory or degenerative disease of the cartilage wherein the dosage of MK-7 is in the range of between 1-10 µg per day, and wherein the dose of marine oil is 5 g per day."

XXII. The sole independent claim 1 of auxiliary request 13 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals, wherein the dosage of MK-7 is in the range of between 1-10 µg per day, and wherein the product is a tablet formulation or a capsule formulation, wherein the amount of MK-7 in one tablet or capsule is between 1 and 10 µg and the amount of unsaturated fatty acid in each tablet or capsule is between 300 and 1200 mg."

XXIII. The sole independent claim 1 of auxiliary request 14 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in combination with at least one of a n-3 polyunsaturated fatty acid, either purified or in the form of a marine oil, for use in a method of prophylaxis or treatment of at least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis or an inflammatory or degenerative disease of the cartilage, wherein the dosage of MK-7 is

in the range of between 1-10 µg per day, and wherein the product is a tablet formulation or a capsule formulation, wherein the amount of MK-7 in one tablet or capsule is between 1 and 10 µg and the amount of unsaturated fatty acid in each tablet or capsule is between 300 and 1200 mg."

XXIV. The sole independent claim 1 of auxiliary request 15 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in a soft gel capsule in combination with at least one of a polyunsaturated fatty acid (PUFA) in the form of fish oil, containing 35% eicosapentaenoic acid (EPA), 25% docosahexaenoic acid (DHA) and 10% other n-3 PUFA, for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals, wherein the dosage of MK-7 is 10 µg per day, and wherein the dosage of fish oil is 5 g per day."

XXV. The sole independent claim 1 of auxiliary request 16 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in a soft gel capsule in combination with at least one of a polyunsaturated fatty acid (PUFA) in the form of fish oil, containing 35% eicosapentaenoic acid (EPA), 25% docosahexaenoic acid (DHA) and 10% other n-3 PUFA, for use in a method of prophylaxis or treatment of at least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis or an inflammatory or degenerative disease of the cartilage, wherein the dosage of MK-7 is

10 µg per day, and wherein the dosage of fish oil is 5 g per day."

XXVI. The sole independent claim 1 of auxiliary request 17 reads as follows:

"1. A pharmaceutical or nutraceutical product comprising MK-7 in a soft gel capsule in combination with at least one of a polyunsaturated fatty acid (PUFA) in the form of fish oil, containing 35% eicosapentaenoic acid (EPA), 25% docosahexaenoic acid (DHA) and 10% other n-3 PUFA, for use in a method for preventing or treating vascular calcification, hypertension, myocardial infarction and cardiovascular death, wherein the dosage of MK-7 is 10 µg per day, and wherein the dosage of fish oil is 5 g per day."

XXVII. The patent proprietor's arguments, relevant to the decision, are summarised as follows:

(a) Main request - claim 2 - Article 100(c) EPC

Dosage of MK-7 in the range of between 1 to 10 µg/day

The combination of end-points of the ranges 1 to 500 µg and 10 to 20 µg, as provided in claim 23 or page 13, lines 15 to 19 of the application as filed, was permissible, as evidenced by e.g. decision T 1170/02, Reasons, point 4.5.2. Based on statements on page 10, lines 33 ff. and page 13, lines 28 to 30 of the application as filed, which disclose an MK-7 dose range of 1 to 10 µg, the skilled person would have seriously considered working within this range.

Additionally, the passages on page 8, lines 22 ff., and page 9, lines 15 ff. also provided a basis for a range of 1 to 10 µg per day of MK-7.

Page 8, lines 22 ff. made a clear factual distinction: the first part reported that, in dosages typically between 1 and 10 µg/day, MK-7 did not affect the extrinsic thrombin potential (ETP), while the second part stated that, in doses of 100 µg MK-7 and higher, MK-7 completely reversed the ETP-lowering effects of marine oils, and these doses of MK-7 relate to a marine oil intake of 5 grams per day. The different terminology used in this paragraph clearly indicated this separation: "*dosages typically between 1 and 10 µg/day, MK-7*" (line 23) *versus* "*doses of 100 µg MK-7*" (line 27).

It was evident, particularly from the passages in claim 23 and on page 10, lines 33 ff. of the application as filed, that the MK-7 dose range did not need to be combined with any specific polyunsaturated fatty acid (PUFA) dose. Claims 3 and 7 but also page 8, line 25 of the application as filed disclosed PUFA in general and there was also no requirement derivable that the PUFA must be an n-3 PUFA.

The disclosure as a whole made it apparent that reversing the mild anti-coagulant effects of PUFA was not intended.

Claim 23 of the application as filed, including its reference to "any one of the preceding claims", as well as to the description provided a basis for the remaining features of claim 2.

The medical use of a pharmaceutical or nutraceutical product comprising MK-7 in combination with a PUFA or marine oil was further supported by claims 2, 5 to 7 and page 5, lines 19 to 23 of the application as filed.

Especially claims 3 and 7 as well as page 5, paragraph 1 of the application as filed provided a generic disclosure for PUFA.

The prevention or treatment of cardiovascular, bone, and cartilage-related diseases was also disclosed in claims 5 to 8, and on pages 1, lines 5 to 9; page 5, lines 27 to 29; and page 7, lines 26 ff. Claims 4 to 8 and pages 1, lines 5 to 9, and page 9, line 10 of the application as filed also provided a clear basis for the medical use of vitamin K2 in combination with a PUFA, either purified or as a marine oil, for these conditions.

The preference for MK-7 as a vitamin K2 compound was supported by claims 2, 5, 7, and page 7, lines 26 ff.; page 8, line 22; or page 14, lines 17 to 18 of the application as filed. Specific effects of MK-7 were disclosed on page 8, lines 22 to 23 of the application as filed. Experiments 2, 3 and 9 also used exclusively MK-7.

Thus, the skilled person would have directly and unambiguously derived the subject-matter of claim 2 from the above teachings in the application as filed.

(b) Auxiliary requests 1 and 2 - Article 123(2) EPC

Support for the amendment in claim 1 could be found, e.g., on page 5, lines 27 to 29; page 7, lines 26 to

32; page 13, lines 28 to 30; and original claim 8 of the application as filed.

Additionally, auxiliary request 2 had been amended to specify that the PUFA in claim 1 are n-3 PUFA. Basis for this additional amendment in auxiliary request 2, could be found, e.g. on page 7, lines 8 to 13; page 12, lines 11 to 13 and 20 to 22; and in claims 16 and 22 of the application as filed.

(c) Auxiliary request 3 - Article 123(2) EPC

Support for the reference of previous claim 4 to previous claim 2 (now claims 2 and 1) could be found, e.g., on page 5, lines 31 to 35 of the application as filed. Support for making previous claim 5 dependent on previous claim 2 (now claims 3 and 1) could be found, e.g., on page 5, lines 24 to 30 of the application as filed.

(d) Auxiliary requests 4 to 8 - Article 123(2) EPC

Claim 1 of auxiliary requests 4 differed from (claim 2 of) the main request in the same features as claim 1 of auxiliary request 3. Further, the PUFA in claim 1 were specified to be n-3 PUFA. Claim 4 (corresponding to claim 7 as granted) had been amended in an analogous way.

Claim 1 of auxiliary request 5 differed from (claim 2 of) the main request in the same features as (claim 1 of) auxiliary request 3. Further, the medical indications were specified to those of dependent claim 4 as granted, i.e., to "prophylaxis or treatment of at least one of atherosclerosis, arteriosclerosis,

osteoporosis, osteoarthritis or an inflammatory or degenerative disease of the cartilage".

The subject-matter of claim 1 of auxiliary requests 6 and 7 differed from (claim 2 of) the main request in the same features as auxiliary request 4.
In auxiliary request 6 the medical indications were further amended to those of dependent claim 4 as granted.
In auxiliary request 7 the PUFA was specified to PUFA in the form of a marine oil.

The subject-matter of claim 1 of auxiliary request 8 differed from claim 2 of the main request in the same features as claim 1 of auxiliary request 7. Further, the medical indications were specified to those of dependent claim 4 as granted like in auxiliary requests 5 and 6.

(e) Auxiliary requests 9 and 10 - Article 123(2) EPC

The preference for n-3 PUFA was disclosed in claims 4, 5, 7 in combination with claim 16; page 7, lines 8 to 13; page 12, lines 11 to 13 and 20 to 22 of the application as filed.

The dose of marine oil being 5 g/day found basis, e.g., on page 13, lines 26 to 30 of the application as filed.

The feature wherein the amount of MK-7 in one tablet or capsule is between 1 and 10 µg and the amount of unsaturated fatty acid in each tablet or capsule is between 300 and 1200 mg found basis, e.g., on page 13, lines 15 to 19 (for the MK-7 dose) and lines 22 to 25 (for the unsaturated fatty acid dose) of the application as filed.

The range of between 1 and 10 µg MK-7 resulted from an allowable selection of two endpoints of the ranges as also disclosed in claim 23 of the application as filed.

In auxiliary request 10, the medical indications were those of dependent claim 4 as granted, which had been deleted for consistency reasons. Basis for this amendment could be found, e.g., in claims 9 and 22 as well as on page 5, lines 31 to 35 of the application as filed.
Page 9, line 2 to 3 and line 14 and page 10, line 30 provided basis for the conditions to be treated or prevented according to claim 1 of auxiliary request 10.

(f) Auxiliary request 11 - Article 83 EPC

The application as filed disclosed that PUFA have beneficial effects on cardiovascular (page 7, lines 36 ff.; page 8, lines 32 ff.), bone (page 9, lines 23 ff.), and cartilage health (page 10, lines 13 ff.). These effects were partly attributed to a reduction in vitamin K-dependent protein production in the liver, leading to a mild hypocoagulant effect and a decrease in extrinsic thrombin potential (ETP), the most sensitive thrombosis risk measure (page 8, lines 22 ff.).

The inventors had discovered that low-dose MK-7 (1 to 10 µg/day) stimulated matrix gamma glutamic acid protein (MGP)/osteocalcin (OC) carboxylation without affecting ETP (page 8, lines 13 ff.; page 9, lines 15 ff.; page 10, lines 32 ff.). This showed that combining 1 to 10 µg/day MK-7 with PUFA synergistically enhanced the benefits of both compounds, as the MK-7 dose prevented interference between the two (page 8, paragraph 3). The increased MGP/OC carboxylation was

beneficial for cardiovascular, bone, and cartilage health, making the claimed subject-matter suitable for the prevention and treatment of related medical conditions.

Additionally, the patent application provided experimental proof of the efficacy of the claimed products, including *in vitro* experiments (Experiments 5 to 9) and small-scale human studies (Experiments 2 and 3).

At least one way enabling the skilled person to perform the claimed invention had been shown and there was no evidence on file that any of the claimed diseases could not be treated by the claimed combination.

(g) Auxiliary request 12 - Article 123(2) EPC

Auxiliary request 12 represented a combination of the amendments carried out in auxiliary request 6 and auxiliary request 11, the medical use having been restricted to a method of prophylaxis or treatment of at least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis or an inflammatory or degenerative disease of the cartilage using a dosage of 1 to 10 µg/day MK-7 and 5 g/day marine oil.

Basis for the specific medical indications recited in claim 1 could be found on page 5, lines 31 to 35; page 7, lines 8 to 13; page 12, lines 11 to 13 and 20 to 22; and claims 9 and 22 of the application as filed.

(h) Auxiliary requests 13 and 14 - Article 123(2) EPC

It was explicitly disclosed in the application as filed that capsules and tablets were the preferred dosage

forms according to the invention (e.g., page 12, lines 31 to 32), and that they contained between 1 and 500 µg of a vitamin K2 class compound (e.g., page 13, lines 15 to 17). Given this, and the preference for MK-7 as the vitamin K2 class compound, it logically followed that the preferred daily dose of MK-7 would be between 1 and 10 µg, meaning that the tablet or capsule would ideally contain this amount.

It was further literally disclosed that the amount of PUFA in each tablet was typically between 300 and 1200 mg (page 13, lines 22 to 25), and that preferred PUFA were n-3 PUFA (page 12 lines 20 to 22; page 7, lines 11 to 13).

(i) Auxiliary requests 15 and 16 – Article 123(2) EPC

Support for the amendments in claim 1 of auxiliary requests 15 and 16 could be found, for example, in Experiments 2 and 3 of the application as filed. The formulation administered to the participants in these studies was identical to the one described in claim 1 of auxiliary requests 15 and 16. Additionally, it was evident that the administration of this exact formulation resulted in a significant effect on ETP levels, as well as MGP and OC carboxylation. Furthermore, express reference to these experiments was made in the general part of the application as filed, which disclosed that MK-7 is an essential ingredient to maximise the benefits of marine oil and n-3 PUFA-containing foods and supplements for cardiovascular (page 9, line 19) and bone health (page 10, line 9). Since the four-month treatment period mentioned in Experiments 2 and 3 were not inextricably linked to the formulation used, its omission did not represent an intermediate generalisation.

The medical indications of claim 1 of auxiliary request 16 were those of dependent claim 4 as granted and as provided in claim 22 of the application as filed.

(j) Auxiliary requests 17 - Admission - Rule 13(2) RPBA

Claim 1 of auxiliary request 17 was based on claim 1 of auxiliary request 15 but limited to the prevention and treatment of vascular calcification, hypertension, myocardial infarction and cardiovascular health, i.e. the specific therapeutic indications mentioned in the description on page 9, lines 13 to 14, just before the paragraph disclosing the effects observed in Experiment 2.

It had not been possible to file this auxiliary request earlier. The opposition division had found auxiliary request 3 to be allowable. Only during the oral proceedings before the board did it become clear that the rationale behind the board's preliminary opinion, as expressed in its communication pursuant to Article 15(1) RPBA, concerning an intermediate generalisation, was related to the broad scope of the medical indications in auxiliary requests 15 and 16. Therefore, the late filing was justified under Article 13(2) RPBA and represented a *bona fide* attempt to narrow the scope to indications specifically related to diminished MGP carboxylation. The amendments were not complex.

XXVIII. The opponent's arguments, relevant to the decision, can be summarised as follows:

(a) Main request – claim 2 – Article 100(c) EPC

Dosage of MK-7 in the range of between 1 to 10 µg/day

Claim 23 of the application as filed did not disclose the 1 to 10 µg/day MK-7 dosage range independently of PUFA intake. Moreover, there was no general disclosure of the range of 1 to 10 µg/day of MK-7, especially not in combination with a use in a method for preventing or treating cardiovascular disease in general, let alone bone and cartilage-related diseases. The disclosed range was always tied to specific PUFA dosages, such as 5 g/day marine oil, or particular conditions, as evidenced by passages on page 8, lines 28 to 29; page 13, lines 26 to 27; or Experiments 2 and 3 of the application as filed. The surprising effects of MK-7 of not reversing the beneficial anti-coagulant effect of marine oils depended on a specific vitamin K2:PUFA ratio and would be eliminated by variations in PUFA levels. Page 5, lines 2 to 4 and 24 to 26 were not relevant, as these did not refer to specific MK-7 dosages.

Moreover, pages 8, line 13 ff.; page 19, line 17; page 10, lines 7; page 10, lines 34 to 35; and page 13, lines 26 to 28 disclosed an anti-coagulant effect for marine oils only and not PUFA in general.

Claim 23 did not relate to the combination of vitamin K2 and PUFA and thus could not provide a suitable basis. The claim dependency recited at least one compound within the vitamin K2 class of compounds as claimed in any one of the preceding claims. Thus, it

only served to characterise the vitamin K2 aspect but did not refer to the pharmaceutical or nutraceutical product of original claims 1 and 2 or 14 to 21, nor did it refer to the kit of claim 13, which may have included other components.

(b) Auxiliary requests 1 and 2 - Article 123(2) EPC

At least claims 2 of auxiliary requests 1 and 2 did not overcome the added matter objections raised in the context of claim 2 of the main request.

(c) Auxiliary request 3 - Article 123(2) EPC

Claim 1 of auxiliary request 3 was identical to claim 2 of the main request and thus added matter in the sense of Article 123(2) EPC for the same reasons as discussed for claim 2 of the main request.

(d) Auxiliary requests 4 to 8 - Article 123(2) EPC

N-3 PUFA were disclosed but not in combination with the claimed dosage of MK-7. The passages to which the patent proprietor had referred as a basis for n3-PUFA made no reference to the claimed dosage of the MK-7. Claim 22 of the application as filed was only concerned with specific conditions to which auxiliary request 4 was not limited.

The only passage in which the limitation to 1 to 10 µg/day of MK-7 was disclosed in context of a n-3 PUFA was page 8, lines 22 to 25. However, page 8, lines 28 to 29 associated the dose of 1 to 10 µg/day of MK-7 to an amount of marine oil of 5 g/day, not to any amount of n-3 PUFA.

The range of 1 to 10 µg/day of MK-7 could thus not be used without a limitation to an amount of marine oil of 5 g/day.

Claim 1 of auxiliary request 5 added matter as narrowing the disease list did not address the concerns found with claim 2 of the main request regarding the dosage level.

Claim 1 of auxiliary request 6 included a list of specific diseases. If auxiliary request 4 added matter then so did auxiliary request 6.

Claim 1 of auxiliary request 7 introduced the feature that a marine oil is present. However, a basis existed only for 5 g/day of marine oil and not any level of marine oil given the dosage requirement in claim 1 of auxiliary request 7. The passage cited by the patent proprietor on page 12, lines 6 to 8 of the application as filed referred to the stability tests of Experiment 4 only.

Claim 1 of auxiliary request 8 included a list of specific diseases. If auxiliary request 7 added matter then so did auxiliary request 8.

(e) Auxiliary requests 9 and 10 - Article 123(2) EPC

There was no basis in the application as filed for a tablet or capsule comprising an amount of between 1 and 10 µg MK-7. The application disclosed the 1 and 10 µg MK-7 range only in the context of a per day dosage as evidenced by page 10, line 30, and the entire context of page 13, lines 17 to 19, 26 to 28, and line 14. Additionally, there was no basis in the application as

filed for n-3 PUFA in its purified form, only in the form of a marine oil.
Due to the introduced "or" connector a dosage of 5 g/day of n-3 PUFA was not a requirement.

(f) Auxiliary request 11 - Article 83 EPC

The were significant doubts about the efficacy of the claimed medical uses across their full scope, as the data provided did not support achieving therapeutic effects for all claimed ranges. Specific dosages of vitamin K2 were necessary for the desired outcomes, as shown in, e.g., Experiments 2 to 3 and 5 to 9. The hypocoagulant effect of marine oil and n-3 PUFA was noted as a key benefit, with MK-7 counteracting some negative effects and restoring MGP and OC levels.

There was no evidence that this combination could treat all cardiovascular, bone, and cartilage-related diseases or disorders. The claims should be limited to medical uses in which the observed technical effect was a relevant one.

Experiments 2 and 3 demonstrated the effects of the claimed PUFA and MK-7 combination on healthy humans but did not show any therapeutic effect for even one of the broadly claimed conditions. Without specific and clear data supporting the treatment across the entire range of these broadly defined conditions, the claims lacked the credibility needed to justify their wide scope.

(g) Auxiliary request 12 - Article 123(2) EPC

There was no basis in the application as filed for the specific combination of 1 to 10 µg/day MK-7 and 5 g/day n-3 PUFA for use in the prophylaxis or treatment of at

least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis, or an inflammatory or degenerative disease of the cartilage. This combination of specific dosages was only disclosed in the context of counteracting the negative effects of n-3 PUFA on ETP levels in healthy patients. ETP levels were relevant only in the context of thrombosis, and no link to the aforementioned diseases could be deduced.

(h) Auxiliary requests 13 and 14 - Article 123(2) EPC

Claim 1 of auxiliary requests 13 and 14 contained the same MK-7 content limitation without the "per day" requirement. Thus, these auxiliary requests added matter without even considering whether there was support for the other limitations in this claim.

(i) Auxiliary requests 15 and 16 - Article 123(2) EPC

The subject-matter of claim 1 of auxiliary requests 15 and 16 was allegedly based on Experiments 2 and 3. However, Experiments 2 and 3 used 5 g/day of fish oil (containing 35% EPA, 25% DHA and 10% other n-3 PUFA) during 4 months for treating healthy humans. Claim 1 of both auxiliary requests, however, failed to mention the 4 months treatment period and thus represented an intermediate generalisation.

(j) Auxiliary requests 17 - Admission - Rule 13(2) RPBA

Article 123(2) EPC issues had been discussed from the beginning of the appeal, and the board's preliminary opinion pursuant to Article 15(1) RPBA had also been negative on that matter. During the oral proceedings, the board confirmed its preliminary negative opinion and provided a rationale for its decision. This would

not have been exceptional; the patent proprietor could have responded by filing additional auxiliary requests or, at the very least, announced its intention to introduce the now-claimed specific conditions.

XXIX. The parties' requests relevant to the decision were as follows.

(a) The patent proprietor requested that
- the decision under appeal be set aside and that the patent be maintained as granted, or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1 to 16 (as filed on 13 April 2021) or of auxiliary request 17 (as submitted during oral proceedings); and
- auxiliary request 17 as filed during oral proceedings be admitted.

(b) The opponent requested that
- the decision under appeal be set aside and that the patent be revoked; and
- auxiliary request 17 not be admitted.

Reasons for the Decision

Main request - claim 2 - Article 100(c) EPC

1. The opponent argued that the dosage range of 1 to 10 µg/day MK-7 was disclosed in the application as filed only in the context of co-administration with 5 g/day of marine oil. Isolating the MK-7 dosage from the specific marine oil dosage amounted to an intermediate generalisation.

Dosage of MK-7 in the range of between 1 to 10 µg/day

2. From the disclosure in the application as filed on page 8, line 22; page 9, line 15; page 10, lines 5 and 34; and especially page 14, lines 17 to 18 it is evident that MK-7 is the preferred vitamin K2 to be included in the pharmaceutical or nutriceutical product.

3. However, the board considers that page 8, paragraph 3; page 9, paragraph 2; page 10, second paragraph; page 13, lines 26 to 28; and Experiments 2 and 3 of the application as filed do not provide a general disclosure for the dosage range of MK-7 of between 1 to 10 µg/day for any intended use of claim 2 in combination with any amount of any PUFA. This is because all these passages disclose, either directly or by reference to Experiments 2 and 3, an MK-7 dosage between 1 to 10 µg/day only in combination with n-3 PUFA in the form of 5 g/day marine oils (consisting of 70% of n-3 PUFA). No other passage mentioning the required dosage range refers to n-3 PUFA.

4. The board does not agree with the patent proprietor's view that paragraph 3 on page 8 of the application as filed is to be read as consisting of two independent parts. The statement "*these doses of MK-7 relate to a marine oil intake of 5 grams per day*" (page 8, lines 28 to 29) refers not only to the higher dosage range of 100 µg or more MK-7 per day, but also to the lower dosage range (1 to 10 µg/day) mentioned earlier in the same paragraph. Since the effect of n-3 PUFA or marine oil intake is discussed in the context of its interaction with different MK-7 dosages, the skilled person would reasonably conclude that the 5 g/day of

marine oil intake applies to both dosage ranges for MK-7, i.e. 1 to 10 µg/day and 100 µg/day or more.

5. The board fails to see any technically significant distinction in terminology between "*dosages typically between 1 and 10 µg/day, MK-7*" (line 23) and "*doses of 100 µg MK-7 per day and higher*" (line 27). Both passages refer to a given amount (or range of amounts) and a time interval, and thus clearly relate to a dosage.

Conditions to be prevented or treated

6. Claim 23 of the application as filed, was cited by the patent proprietor as disclosing the combination of features in claim 2, except for the MK-7 dosage range. However, claim 23 neither discloses a combination of vitamin K2 and a PUFA, nor the prevention or treatment of at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals.

The board acknowledges that the back-reference in claim 23 ("as claimed in any one of the preceding claims") relates to the "use" or "method of treatment or prophylaxis", rather than to the feature "vitamin K2 or at least one compound within the vitamin K2 class of compounds" which is found twice in the claim and further defines the "use" or "method of treatment or prophylaxis". Nevertheless, preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders has to be selected from the uses and methods in claims 4 to 6, 8, 9, and 22. To arrive at the subject-matter claimed further selections are necessary, including specifying MK-7 as the form of vitamin K2, its dosage, a combination with PUFA, as

well as the particular conditions to be prevented or treated.

7. The patent proprietor argued that preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals with a pharmaceutical or nutraceutical product comprising MK-7 in combination with a PUFA or marine oil was further supported by claims 2, 5 to 7 and page 5, lines 19 to 23 of the application as filed.

However, all these passages relate to the promotion of at least one of cardiovascular health, bone health and cartilage health in humans and animals but not the use of MK-7 in combination with at least one of a PUFA in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals.

8. The combined disclosure of 1 to 10 µg/day MK-7 and 5 g/day marine/fish oil (see page 8, paragraph 3; page 9, paragraph 2 together with Experiment 2; page 10, paragraph 2 together with Experiment 3, page 13, paragraph 4) is limited to the teaching that this combination does not reverse the beneficial effect of marine oil in terms of maintaining the marine/fish oil-induced lower endogenous thrombin potential (ETP) while inhibiting decarboxylation of matrix gamma carboxyglutamic acid protein (MGP) and osteocalcin (OC) caused by the reduction of vitamin K status due to the administration of marine/fish oil. The disclosure does not extend to purified n-3 PUFA at this dosage and does not relate to the treatment of a condition as claimed.

Conclusion

9. The omission of a marine/fish oil dosage of 5 g/day combined with an MK-7 dosage of 1 to 10 µg/day, as well as the combination of these dosages with the therapeutic purpose of treating cardiovascular, bone, and cartilage-related diseases or disorders in humans and animals, is considered to result in an intermediate generalisation. Consequently, the subject-matter of claim 2 extends beyond the content of the application as filed.

Auxiliary requests 1 and 2 - Article 123(2) EPC

10. Claim 2 of auxiliary request 1 is identical to claim 2 of the main request. Claim 2 in auxiliary request 2 has been amended to specify that the PUFA are n-3 PUFA.

11. The subject-matter of claim 2 of auxiliary requests 1 and 2 contain subject-matter which extends beyond the content of the application as filed for the same reasons as set out for claim 2 of the main request (see points 1. to 9. above).

Auxiliary request 3 to 8 - Article 123(2) EPC

12. Auxiliary requests 3 to 8 differ from the main request *inter alia* in that product claim 1 of the main request has been deleted. However, the subject-matter of claim 1 of all these requests corresponds to either that of claim 2 of the main request (auxiliary requests 3, 4 and 7) or to that of claim 4 of the main request (auxiliary requests 4, 5, and 8) which include the dosage range of MK-7 between 1 to 10 µg/day but omit the dosage of 5 g/day of marine oil.

13. Thus, at least for the reasons provided in points 1. to 9. above in the context of claim 2 of the main request, the subject-matter of claim 1 of auxiliary requests 3 to 8 is considered to extend beyond the content of the application as filed.

Auxiliary requests 9 and 10 - Article 123(2) EPC

14. Claim 1 of auxiliary request 9 is based on claim 2 of the main request but has been limited to n-3 PUFA, and a product for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals wherein the dosage used are 1 to 10 µg/day MK-7 and 5 g/day marine oil or wherein the product is a tablet formulation or a capsule formulation, wherein the amount of MK-7 in one tablet or capsule is between 1 and 10 µg and the amount of unsaturated fatty acid in each tablet or capsule is between 300 and 1200 mg.

Claim 1 of auxiliary request 10 differs from claim 1 of auxiliary request 9 in that the therapeutic purpose has been amended to the prophylaxis or treatment of at least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis of an inflammatory or degenerative disease of the cartilage.

15. The subject-matter of claim 1 of auxiliary requests 9 and 10 relates to a product for use in a method for preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals with two different pharmaceutical or nutraceutical products defined by (i) comprising a MK-7 dose of 1 to 10 µg/day in combination with at least one n-3 PUFA, or (ii) a product defined as being a tablet formulation or a capsule formulation with an amount of

1 to 10 µg MK-7 and 300 to 1200 mg PUFA, i.e. without indication of the dosing frequency.

Tablet or capsule containing an amount between 1 to 10 µg MK-7

15.1 The patent proprietor indicated page 13, lines 15 to 19 and claim 23 (for the MK-7 dose) and page 13, lines 22 to 25 (for the amount of unsaturated fatty acid in each tablet or capsule) as well as claim 23 in the application as filed as providing a basis for the feature relating to a tablet formulation or a capsule formulation with an amount of 1 to 10 µg MK-7 and 300 to 1200 mg PUFA.

15.2 Page 13, lines 15 to 17 of the application as filed disclose a capsule containing a vitamin K2 compound in an amount between 1 and 500 µg.

15.3 The passages on either side of lines 15 to 17 on page 13, also fail to disclose a tablet or capsule containing an amount between 1 to 10 µg MK-7.

Page 13, lines 17 to 19 discloses vitamin K2, notably MK-7, at **dosages** "*between 2 and 300 µg, more preferably 5-50 µg, and most preferably between 10-20 µg per day*", i.e. it does not relate to the tablet or capsule (see also claim 23 of the application as filed).

Page 13, line 26 also does not disclose tablets or capsules but discloses "[...] *that at dosages as high as 10 µg per day[,] marine oil (at a dose of about 5 g) and MK-7 can be combined* [...]".

The sentence on page 13, lines 28 to 33, refers to **dosages** (i.e. dose and frequency) as high as 10 µg/day and states that "[d]*osages as high as 100 µg per day*

are not applicable for the purpose described here, because these dosages were found to counteract the effect of warfarin, which is an even stronger inhibitor of blood clotting factor carboxylation than n-3 PUFAs are."

15.4 Claim 23 of the application as filed also does not provide a basis for the amounts of MK-7 and PUFA in one tablet or capsule as it relates only to a vitamin K2 dosage and does not mention PUFA at all. Also none of the other claims of the application as filed mentions the amount of PUFA to be comprised in a tablet or capsule.

15.5 As can be taken from the above cited passages, there is no direct and unambiguous disclosure for a tablet or capsule containing an amount between 1 to 10 µg MK-7 and 300 to 1200 mg PUFA. Consequently, the subject-matter of claim 1 of auxiliary requests 9 and 10 extends beyond the content of the application as filed.

Auxiliary request 11 - Article 83 EPC

16. Claim 1 of auxiliary request 11 relates to a pharmaceutical or nutraceutical product comprising MK-7, administered at a dosage of 1 to 10 µg/day, with n-3 PUFA in the form of a marine oil, administered at a dosage of 5 g/day, for preventing or treating cardiovascular, bone, or cartilage diseases or disorders in both humans and animals. Claim 1 is thus drafted as purpose-related product claim pursuant to Article 54(5) EPC.

17. The requirement of sufficiency of disclosure must be satisfied at the effective date of the patent, i.e. on the basis of the information provided in the patent

application as filed together with the common general knowledge then available to the skilled person.

18. For the requirement of sufficiency of disclosure to be met in the case of a claim pursuant to Article 54(5) EPC, the application as filed, when read by a person skilled in the art having the common general knowledge in mind, must establish the functional technical link between the claimed product and the claimed specific use within the meaning of Article 54(5) EPC, namely the prevention or treatment of at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals (Case Law of the Boards of Appeal, 10th ed., 2022, II.C.7.2.2; especially decisions T 609/02, T 966/18, or T 1599/06).

19. The application as filed does not provide direct evidence that the claimed pharmaceutical or nutraceutical product is suitable for preventing or treating diseases such as atherosclerosis, osteoporosis, or osteoarthritis.

The effect reported in the relevant sections of the application as filed discussing the health effects of fish oil, krill oil and n-3 PUFA on cardiovascular, bone health, and/or cartilage health (page 7, last paragraph to page 11, paragraph 1 and Experiments 2 and 3 of the application as filed), is that the combined treatment of human patients with MK-7 plus marine oil comprising n-3 PUFA prevents the negative side-effects of marine oils and n-3 PUFA, such as OC carboxylation, while preserving the mild anti-coagulant effect of the marine oil and n-3 PUFA.

The mechanistic rationale provided is that poor carboxylation of MGP and OC is a known risk factor for these conditions.

Other passages in the application as filed relate to cell culture experiments investigating vitamin K uptake and metabolism under various conditions (page 11, lines 6 to page 12, line 2) and the formulation of products and dosages (Page 12, line 4 to page 14, lines 23, as well as Examples 1 to 8).

It can be taken from the application as filed, that marine oil and n-3 PUFA were known to reduce vitamin K dependent clotting factors in the liver but also to decrease the extrahepatic vitamin K status and thus to decrease the activation (by glutamate carboxylation) of extra-hepatic vitamin K-dependent proteins including MGP and OC. A poor vitamin K status was known as a risk factor for e.g. vascular calcification which was closely associated with atherosclerosis (paragraph bridging pages 8 and 9)), development and progression of osteoporosis (page 9, last paragraph). Poor MGP carboxylation has been associated with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis (page 10, penultimate paragraph).

20. Experiments 2 and 3 in the application as filed demonstrate an ETP-lowering effect in healthy humans after one month of supplementation with 5 g/day fish oil and 10 µg/day MK-7. Figures 1 and 2 show that after an initial drop in MGP and OC carboxylation, the levels normalised after 3 to 4 months of supplementation, indicating a normalisation of vascular vitamin K status.

21. While the disclosure and evidence in the application as filed (as discussed in paragraphs 19. and 20.) may suggest a potential health benefit in terms of prophylaxis or prevention after a longer period of treatment for certain physical conditions, there is no evidence that the claimed combination affects the full range of cardiovascular, bone, and cartilage-related diseases or disorders, such as bone cancer.

22. In view of the above considerations, taking into account the disclosure of the application as filed and the common general knowledge at the relevant date, the board concludes that the skilled person would not have considered that the claimed product achieves prevention or treatment of cardiovascular, bone, and cartilage-related diseases or disorders over the whole scope of the claim.

Auxiliary request 12 - Article 123(2) EPC

23. For the subject-matter of claim 1 of auxiliary request 12, claim 9 of the application as filed may be considered the basis, as it relates to the prophylaxis or treatment of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis, or an inflammatory or degenerative disease of the cartilage. This is disclosed as being achieved by administering to a human or animal an effective amount of vitamin K2 or at least one compound within the vitamin K2 class of compounds, optionally in combination with an effective amount of at least one PUFA, either purified or in the form of a marine oil.

24. The following additional passages in the application as filed were cited by the patent proprietor to provide a basis for the claimed subject-matter:

24.1 Page 5, lines 31 to 35 discloses in a(n) (fourth) aspect the intention to prevent or treat at least one of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis or an inflammatory or degenerative disease of the cartilage, comprising administering to a human or animal a pharmaceutical or nutraceutical product or medicament as defined herein - a specific medication is not specified in this paragraph.

The following (fifth) aspect relates to counteracting certain negative aspects of fish oil, krill oil and PUFA containing foods and food supplements.
Only in the specific context of this fifth aspect it is mentioned that the negative effects can be counteracted by combining 1 to 10 µg/day MK-7 with a 5 g/day marine oil dosage (page 8, lines 22 ff.; page 9, line 15 ff; page 10, line 5 ff.; Experiments 2 and 3).

24.2 Page 7, lines 8 to 13 and page 12, lines 11 to 13 and 20 to 22 of the application as filed provide further definitions for PUFA and discloses that a compound within the vitamin K2 class of compounds referred to a single menaquinone. These passages do neither concern the claimed PUFA and MK-7 dosages nor the claimed prophylactic or therapeutic goals.

24.3 Claim 22 of the application as filed refers to the use of vitamin K2 or at least one compound within the vitamin K2 class of compounds and at least one of a n-3 PUFA for the preparation of a medicament for the prophylaxis or treatment of atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis, or another inflammatory or degenerative disorder of the cartilage.

25. However, none of the above passages in the application as filed provide a direct and unambiguous disclosure of the claimed combination of n-3 PUFA/marine oil and MK-7 dosages and conditions to be treated. Avoiding side effects due to a specific food supplement may be somehow linked to prevention or prophylaxis but not a therapeutic treatment.

26. The application as filed only discloses that 1 to 10 µg/day of vitamin K2 can counteract the poor vitamin K status induced by prolonged administration of marine/fish oil and n-3 PUFA. A link between a combination of 1 to 10 µg/day MK-7 and 5 g/day marine/fish oil is only provided in the specific context of ETP levels (page 8, lines 15 to 21; Experiments 2 and 3 and Figures 1 and 2). Specific conditions hinging on these ETP levels might be considered to have a basis in the sense of Article 123(2) EPC.

27. Other passages in the application as filed relating to more general therapeutic purposes do not disclose the claimed dosage combination.

27.1 Page 9, line 5 ff. of the application as filed refers to prior art and states that atherosclerosis and vascular calcification are closely associated with poor vitamin K status of the vessel wall, and that high-dose vitamin K supplementation (1 mg/day) showed major advantages for vascular elasticity.

27.2 Page 13, paragraph 2 of the application as filed also fails to provide a basis for the claimed combination. It generally states that the amount of vitamin K2 or vitamin K2 compounds in each tablet or capsule may vary widely, depending on factors such as the severity and

nature of the disease, and the condition, sex, and age of the patient. It further specifies that the amount of vitamin K2 or a compound within the vitamin K2 class typically ranges from 1 to 500 µg per tablet or capsule, although higher amounts are also possible. The preferred dosages of vitamin K2, particularly MK-7, are between 2 and 300 µg, with more specific preferences of 5 to 50 µg, and most preferably between 10 to 20 µg/day.

28. None of the cited passages provides a direct and unambiguous disclosure of a dosage of 1 to 10 µg/day MK-7 in combination with n-3 PUFA in the form of 5 g/day marine oil for use in treating atherosclerosis, arteriosclerosis, osteoporosis, osteoarthritis, or inflammatory or degenerative diseases of the cartilage.

Consequently, the subject-matter of claim 1 extends beyond the content of the application as filed.

Auxiliary requests 13 and 14 - Article 123(2) EPC

29. Auxiliary requests 13 and 14 relate to the medical use of a product comprising MK-7 and n-3 PUFA, wherein the dosage of MK-7 is in the range of 1 to 10 µg/day and wherein the amount of MK-7 in one tablet or capsule is between 1 and 10 µg and the amount of PUFA is between 300 and 1200 mg.

30. As discussed in the context of claim 2 of the main request (see points 3. to 5. above, the application as filed discloses an MK-7 dosage between 1 to 10 µg/day only in combination with a fish or marine oil intake of 5 g/day. Moreover, there is no direct and unambiguous disclosure in the application as filed for a tablet or capsule containing an amount between 1 to 10 µg MK-7

and 300 to 1200 mg PUFA (see 15.1 to 15.5 points above).

31. Consequently, the subject-matter of claim 1 of auxiliary requests 13 and 14 extends beyond the content of the application as filed.

Auxiliary requests 15 and 16 - Article 123(2) EPC

32. The subject-matter of claim 1 of auxiliary request 15 and 16 is limited to the dosages used in Experiment 2 and 3 of the application as filed, i.e. 5 g/day of fish oil containing 35% EPA, 25% DHA and 10% other n-3 PUFA and 10 µg/day MK-7.

33. However, as already discussed in the context of claim 1 of auxiliary request 12 (see points 23. to 28. above), there is no direct and unambiguous disclosure in the application as filed of the combination of (i) the compositions from Experiment 2 and/or Experiment 3 with (ii) the therapeutic use in preventing or treating at least one of cardiovascular-, bone- and cartilage-related diseases or disorders in humans and animals. Examples 2 and 3 focus on healthy individuals, and the compositions are used to counteract negative (side) effects of PUFA supplementation (like reduced carboxylation of MGP and OC), not to treat or prevent diseases.

34. Therefore, the subject-matter of claim 1 of auxiliary requests 15 and 16 extends beyond the content of the application as filed.

Auxiliary requests 17 - Admission - Article 13(2) RPBA

35. Claim 1 of auxiliary request 17, which was filed during oral proceedings before the board, is identical to claim 1 of auxiliary request 15, except that the therapeutic aim has been amended to relate to the prevention and treatment of "vascular calcification, hypertension, myocardial infarction, and cardiovascular death". These specific therapeutic indications are mentioned in the description on page 9, lines 13 to 14, just before the paragraph disclosing the effects observed in Experiment 2.

36. Points 9 and 10 of the opponent's statement of grounds of appeal already raised the objection that there was no general disclosure of the range of 1 to 10 µg/day of MK-7, especially not in combination with a use in a method for preventing or treating cardiovascular disease in general, let alone bone and cartilage-related diseases. The board's preliminary opinion pursuant to Article 15(1) RPBA (see points 25, 26, and 55) also expressed concerns that claim 2 of the main request, which is similar to claim 1 of auxiliary request 17, added matter.

37. Moreover, the specific diseases/conditions to be prevented or treated according to claim 1 of auxiliary request 17 were taken from the description and combined with the formulations used in Experiments 2 and 3. Thus, the specific disclosure in Experiments 2 and 3 was generalised to a broader range of conditions.

38. Since the patent proprietor failed to put forward exceptional circumstances justified by cogent reasons, the board decided not to admit auxiliary request 17 into the proceedings (Article 13(2) RPBA).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

I. Aperribay L. Bühler

Decision electronically authenticated