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Language of the proceedings: EN

Title of invention:
Vitamin k2 containing food product

Patent Proprietor:
NattoPharma ASA

Opponent:
Kappa Bioscience As

Headword:

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13

Keyword:
Inventive step - (no)
Late-filed auxiliary requests - admitted (no)

Decisions cited:

Catchword:

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Case Number: T 0533/12 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 15 May 2014

Appellant: (Patent Proprietor)	NattoPharma ASA Henrik Ibsen gate 100 0230 Oslo (NO)
Representative:	Weiss, Wolfgang Weickmann & Weickmann Patentanwälte Postfach 86 08 20 81635 München (DE)
Respondent: (Opponent)	Kappa Bioscience As Forskningsparken i Oslo Gaustadallèen 21 N-0349 Oslo (NO)
Representative:	Campbell, Neil Boyd Dehns St Bride's House 10 Salisbury Square London EC4Y 8JD (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 13 February 2012 revoking European patent No. 1153548 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman W. Sieber
Members: J. Jardón Álvarez
E. Kossonakou

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the proprietor of European patent No. 1 153 548, NattoPharma ASA, against the decision of the opposition division to revoke the patent.

II. The opponent, Kappa Bioscience AS, had requested revocation of the patent in its entirety on the grounds that the claimed subject-matter lacked novelty and inventive step (Article 100(a) EPC), that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC), and that the patent contained subject-matter which extended beyond the content of the application as originally filed (Article 100(c) EPC).

The documents cited during the opposition proceedings included:

D2: H. Kawashima *et al.*, "Effects of Vitamin K_2 (Menatetrenone) on Atherosclerosis and Blood Coagulation in Hypercholesterolemic Rabbits", Jpn. J. Pharmacol. 75 (1997), pages 135-143;

D3: EP 0 679 394 A2;

D9: L.J. Schurgers *et al.*, "Nutritional Intake of Vitamins K_1 (Phylloquinone) and K_2 (Menaquinone) in The Netherlands", Journal of Nutritional & Environmental Medicine 9 (1999), pages 115-122; and

D15: J.M. Geleijnse *et al.*, "Inverse Association of Dietary Vitamin K-2 intake with Cardiac Events and

Aortic Atherosclerosis; The Rotterdam Study" (undated; 26 pages).

III. In its decision the opposition division held that:

- the subject-matter of claim 1 of the main request (claims as granted) extended beyond the content of the application as filed (Article 100(c) EPC);

- document D2 was novelty-destroying for the subject-matter of the claims of the first auxiliary request; and

- the subject-matter of the claims of the second auxiliary request lacked inventive step in view of the data presented in D15.

IV. This decision was appealed by the patent proprietor (in the following: the appellant). The appellant no longer pursued the requests it had presented to the opposition division; instead, on 15 June 2012 it filed new requests together with the statement setting out the grounds of appeal, namely a main request and auxiliary requests I to V. It also filed the following further document:

D16: G.C.M. Gast *et al.*, "A high menaquinone intake reduces the incidence of coronary heart disease", Nutrition, Metabolism & Cardiovascular Diseases (2008), pages 1-7.

V. With its reply dated 2 November 2012 the opponent (in the following: the respondent) disputed the arguments submitted by the appellant and requested that the appeal be dismissed.

VI. In a communication issued prior to oral proceedings, the board indicated the points to be discussed at those oral proceedings. It also expressed its preliminary view that the subject-matter of claim 1 of the main request lacked inventive step.

VII. By letter dated 15 April 2014 the appellant filed further auxiliary requests VI to X.

VIII. During the oral proceedings held before the board on 15 May 2014, the appellant filed auxiliary request XI. The respondent raised objections under Articles 123(2), 83 and 56 EPC against the claims of all requests. Additionally, it contested the admissibility of auxiliary requests VI to XI.

IX. Claim 1 of the main request reads as follows:

"1. Use of menaquinone in the preparation of a food product for maintaining, optimising, strengthening or promoting cardiovascular health of human beings, wherein the food product is not an egg, wherein menaquinone is added to the food product such that the level of menaquinone is 5 to 5000 µg per 100 g of product, with the proviso that if the menaquinone is a MK-n menaquinone then the food product is not a cheese or natto."

Claim 1 of auxiliary request I is based on claim 1 of the main request wherein the level of menaquinone has been limited to "5 to 1000 µg per 100 g of product".

Claim 1 of auxiliary request II reads as follows:

"1. Use of menaquinone in the preparation of a food product for maintaining, optimising, strengthening or

promoting cardiovascular health of human beings, wherein the food product is not an egg, wherein menaquinone is added to the food product such that the level of menaquinone is 5 to 1000 µg per 100 g of product, wherein the menaquinone is a MK-n menaquinone, n is greater than 4, and the food product is not a cheese or natto."

Claim 1 of auxiliary request III is based on claim 1 of auxiliary request II with the following further feature added at the end of the claim: "and wherein part or all of the food product containing the menaquinone ingredient is heat treated."

Claim 1 of auxiliary request IV is based on claim 1 of the main request wherein the level of menaquinone has been limited to "50 to 1000 µg per 100 g of product".

Claim 1 of auxiliary request V is based on claim 1 of auxiliary request II wherein the level of menaquinone has been limited to "50 to 1000 µg per 100 g of product"

Claim 1 of auxiliary requests VI to X corresponds to claim 1 of auxiliary requests I to V, respectively, except that in each case the feature "wherein the menaquinone levels in food products are less than 5mg/day" has been added after the word "egg".

Lastly, claim 1 of auxiliary request XI reads as follows:

"1. Use of menaquinone in the preparation of a food product for maintaining, optimising, strengthening or promoting cardiovascular health of human beings, wherein the food product is not an egg, wherein the

menaquinone level in the food product is 50 to 5000 µg per day, wherein menaquinone is added to the food product such that the level of menaquinone is 50 to 1000 µg per 100 g of product, and wherein the menaquinone is a MK-n menaquinone, n is greater than 4, and the food product is not a cheese or natto."

X. The arguments of the appellant, insofar as they are relevant for the present decision, may be summarised as follows:

- The invention was based on the surprising finding that there was no need for the levels of menaquinone suggested so far in the prior art to get the desired cardiovascular health effects. The post-published evidence filed during the examination and appeal proceedings confirmed this finding, which was already disclosed in the application as filed. What was relevant for obtaining the beneficial effect of vitamin K_2 was the increase of the daily vitamin K_2 intake. Documents D15 and D16 experimentally confirmed this finding that a minimal increase of the daily intake reduced coronary risk for human beings.

- This unexpected improvement was achieved by the claimed use of fortified food containing menaquinone in the specified amounts. Moreover, since the claimed fortified products would usually replace non-fortified food products, the total amount of vitamin K_2 ingested by humans eating the fortified food products according to the invention would be increased.

- This effect was not suggested by any of the documents cited by the respondent. Neither D2 nor

D3 disclosed fortified foods and were therefore not relevant for the present invention.

- The auxiliary requests should be admitted into the proceedings. The amendments were supported by the application as originally filed and restricted the daily dosage to be consumed. In its view, interpretations it regarded as illogical should be excluded from the scope of the claim. The skilled person would understand that the claimed menaquinone levels of "less than 5 mg per day" referred to the daily dosage achieved using the fortified food because the claim was directed to a medical indication for promoting cardiovascular health. The skilled person would disregard other interpretations of the claim.

XI. The arguments of the respondent may be summarised as follows:

- Claim 1 of the main request included added subject-matter because there was no support for the term "optimising" in combination with the claimed range of menaquinone and with the use for "human beings". The patent lacked sufficiency of disclosure because there was no evidence in the application as filed that the claimed use indeed promoted cardiovascular health.

- The claimed subject-matter lacked inventive step starting from the teachings of any of D2, D3 or D9 as closest prior-art document. The distinguishing features of the claim could not justify an inventive step. The claimed level of menaquinone was arbitrary and the addition of a vitamin to a

food product was routine for the skilled person once the use was known.

- Auxiliary requests VI to IX should not be admitted into the proceedings *inter alia* because the added feature introduced serious clarity issues. The definition of the amount of menaquinone in a food product as an "amount per day" was meaningless.

XII. The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form in accordance with either the main request or, subsidiarily, one of auxiliary requests I to XI. The main request and auxiliary requests I to V were filed on 15 June 2012 with the statement of grounds of appeal, auxiliary requests VI to X were filed with letter dated 15 April 2014, and auxiliary request XI was filed on 15 May 2014 during the oral proceedings.

XIII. The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

MAIN REQUEST

2. The respondent raised substantive objections against the claims of the main request under Articles 123(2), 100(c), 83 and 56 EPC. However, as this request is not allowable due to lack of inventive step (see below point 3.6), there is no need for the board to deal with the other objections of the respondent.

3. Inventive step

3.1 The invention relates to food products comprising added menaquinone for promoting cardiovascular health of human beings (see paragraph [0001] of the patent specification).

3.2 Claim 1 is drafted in the "Swiss-type" format and thus concerns a therapeutic indication of a known product. The subject-matter of claim 1 relates to this use and comprises the combination of the following features:

(a) use of menaquinone in the preparation of a food product for maintaining, optimising, strengthening or promoting cardiovascular health,

(b) of human beings,

(c) wherein the food product is not an egg,

(d) wherein menaquinone is added to the food product such that the level of menaquinone is 5 to 5000 µg per 100 g of product,

(e) with the proviso that if the menaquinone is a MK-n menaquinone then the food product is not a cheese or natto.

3.2.1 Features (a) and (b) define the claimed use of menaquinone, namely to reduce coronary heart disease risk in humans. Features (c) and (e) are provisos to exclude foods with a naturally high menaquinone content.

3.2.2 The key feature of the invention is said to be feature (d) because the level of menaquinone is related to the desired cardiovascular effect (see [0016]).

3.2.3 Interpretation of feature (d)

It was the understanding of the parties that this feature ensures that the products covered by the claims are products fortified with menaquinone. As the claim requires the addition of menaquinone to the food product, for products already containing more than 5 µg of menaquinone per 100 g of product, the final level of "5 to 5000 µg per 100 g of product" represents the sum of the menaquinone naturally present in the food product and the menaquinone added.

Feature (d) defines a level of menaquinone "per 100 g of [food] product", but is entirely silent about the actual amount of menaquinone, or food product, to be ingested. It gives no indication whatsoever as to how much product is to be eaten to obtain any cardiovascular benefit.

Thus, claim 1 does not require that a particular amount of menaquinone be actually consumed. However, the desired cardiovascular effect to be achieved is dependent on how much menaquinone is ingested, not on how much menaquinone is in the food product itself.

3.3 Closest prior art

3.3.1 As acknowledged in the patent specification, menaquinone, also known as vitamin K_2, represents a family of 2-methyl-1,4-naphthoquinone derivatives having a side-chain composed of a varying number of isoprenoid residues (see figure 1 of the patent). It is

characterised by the number of isoprenoid residues and also abbreviated as MK-n, where M stands for menaquinone, K stands for vitamin K and n represents the number of isoprenoid side chain residues. Protein-rich products such as meat, fish, cheese and other dairy products as well as fermented soy-beans are known to contain some menaquinone (see paragraphs [0002] and [0003]).

3.3.2 The respondent relied on any of documents D2, D3 or D9 as closest prior art. D2 relates to the effects of vitamin K_2 on atherosclerosis and blood coagulation in hypercholesterolemic rabbits (see abstract), D3 to the use of menaquinone as an antiarteriosclerotic agent (claim 3) and D9 provides data regarding the nutritional intake of vitamins K_1 and K_2 in the Netherlands (see abstract).

3.3.3 Any of these documents could be used as the starting point for the assessment of inventive step. In the following, the board will use D9 because it is also acknowledged in the patent specification (see paragraph [0004]).

3.3.4 In D9 the vitamin K content of several foods was measured (see Table 1) and these data were used to calculate the intake of vitamin K in the population participating in the "Rotterdam Study", namely subjects aged 55 years and over in the Netherlands (see Tables 2 and 3).

The study recognises that low nutritional vitamin K intake is a risk factor for calcification of the abdominal aorta (page 120, lines 4 to 6 from the bottom) and recommends a significant increase in the daily intake of vitamin K, namely 370 µg per day of

vitamin K_1 and 45 µg per day of menaquinones. These amounts correspond to a daily consumption of about 100 g of green vegetables and 100 g of cheese (see page 121, last paragraph before "Acknowledgements").

3.4 Problem to be solved and its solution

3.4.1 However, a high intake of products like cheese in order to achieve the recommended amount of menaquinone suggested in D9 is not acceptable, because it either does not fit in the desired diet or may be bad for overall health. In particular, cheese has a high caloric content and a high degree of saturated fatty acids that promote cardiovascular disease (see paragraph [0004] of the patent specification).

For this reason the prior art had proposed adding menaquinone to food products so as to increase the menaquinone intake per day. Relatively high levels of menaquinone were believed to be necessary to promote cardiovascular health effectively (see paragraph [0006]).

3.4.2 The technical problem underlying the patent in suit in the light of D9 can be seen only in the provision of food products fortified with menaquinone. No other elements can be taken into account when formulating the objective technical problem, and in particular not elements relating to a lower dosage regime of menaquinone, because, as explained above, what is relevant to obtain the cardiovascular effect is not the added level of menaquinone in the food product but the amount of menaquinone ingested, a feature not present in the claim.

3.4.3 As a solution to this problem, claim 1 of the main request proposes the use of fortified food products wherein menaquinone is added to the food product such that the level of menaquinone is 5 to 5000 µg per 100 g of product.

3.4.4 It is self-evident that the above-defined objective technical problem is solved by the features of claim 1.

3.5 Obviousness

3.5.1 It remains to be decided whether this solution is obvious for the skilled person.

3.5.2 Basically, the subject-matter of claim 1 differs from the teaching of D9 in that the intake of menaquinone is made using a food product wherein menaquinone has been added, that is to say a fortified food product.

3.5.3 This difference cannot justify an inventive step. The fortification of food with vitamins is common general knowledge and has been carried out for years. This has not been disputed by the appellant. Although in higher amounts, even menaquinone has been added to food products, as acknowledged by the patent specification itself (see paragraphs [0006] and [0007]).

3.5.4 As regards the actual amount of menaquinone per 100 g of the food product, this amount is arbitrary. As already mentioned, what matters for cardiovascular health benefits is how much menaquinone a person actually ingests per day and not the amount of menaquinone in 100 g of food product. Therefore also the specific amount of menaquinone in 100 g of the food product cannot contribute to inventive step.

3.5.5 The appellant tried to justify an inventive step on the basis of the surprising finding that there was no need for the high levels of menaquinone suggested in the prior art to get the desired health benefits. In this context it also relied on post-published documents D15 and D16 which show a statistically significant decrease in coronary heart disease risk when the daily intake of menaquinone is increased. In particular, it relied on tables 4 and 5 of D16 showing a lower incidence of coronary heart diseases with a relatively small menaquinone intake increase (10 µg in table 4 or 1 µg in table 5).

3.5.6 However, the board cannot accept this line of argument, because, as explained above, the added level of menaquinone in a food product is not relevant to obtaining any cardiovascular effect. The effect is dependent on the amount of menaquinone ingested, a feature not present in the claim. Thus, even if an unexpected effect could be deduced from the evidence provided by D15 and/or D16, this effect could not justify any inventive step for the claimed subject-matter.

3.6 For these reasons, the subject-matter of claim 1 of the main request lacks inventive step.

AUXILIARY REQUESTS I TO V

4. Inventive step

4.1 As admitted by the appellant during the oral proceedings, none of auxiliary requests I to V overcomes the above objections against the main request.

4.1.1 In claim 1 of all these auxiliary requests, as in the main request, the amount of menaquinone refers to the level of menaquinone added to the food product to achieve a given level of menaquinone "per 100 g of product" and does not limit the claim to any daily intake.

4.1.2 Claim 1 of auxiliary requests II and V is further limited to menaquinone MK-n "wherein n is greater than 4". However, the presence of higher menaquinones in natural food was already known from D9 (see, for instance page 120, lines 3 to 9) and therefore cannot change the assessment of inventive step.

4.1.3 Lastly, claim 1 of auxiliary request III further requires that "part or all of the food product containing the menaquinone ingredient is heat treated". There is no information on file that this feature gives rise to any technical effect, let alone an unexpected one, and therefore it cannot contribute to inventive step.

4.1.4 Consequently, the reasoning above for the main request applies *mutatis mutandis* to the subject-matter of claim 1 of auxiliary requests I to V which therefore also lacks inventive step.

AUXILIARY REQUESTS VI TO XI

5. Admissibility

5.1 Auxiliary requests VI to X were filed by the appellant one month before the oral proceedings as a direct reaction to the preliminary opinion in the board's communication that the claims did not specify any daily intake of menaquinone. Auxiliary request XI was filed

towards the end of the oral proceedings after the board had deliberated upon the allowability of the previous requests, *i.e.* at the very last moment.

Auxiliary requests filed at such a late stage of the proceedings are usually only admitted into the appeal proceedings under exceptional circumstances, namely in particular, if it can be quickly ascertained that they overcome all the outstanding issues without raising new ones.

5.2 The appellant justified the late filing of auxiliary requests VI to X as being a result of the negative preliminary finding of the board concerning the main request and auxiliary requests I to V. The amendments present in auxiliary requests VI to X only concerned a more restricted definition of the feature objected to. They were thus simple and clear enough to be readily understood by the skilled person. Auxiliary request XI was a last try to overcome the clarity objection against the feature added to auxiliary requests VI to X and should also be admitted into the proceedings.

5.3 The board cannot agree. The amendment to claim 1 of auxiliary requests VI to X, namely the feature "wherein the menaquinone levels in food products are less than 5 mg/day" does not overcome the objections raised by the board against the previous requests.

5.3.1 The claim still does not indicate any dose of menaquinone to be ingested. Moreover, the amendment is not clear (Article 84 EPC). The feature added defines the menaquinone level in food products as "less than 5 mg per day". However, the amount of a compound in a product cannot be defined "per day", it can only be defined in relation to the total amount of product (or

as a percentage). A definition of the menaquinone level in the food product in "mg per day" is unclear.

5.3.2 The board can also not follow the argument of the appellant that the skilled person would exclude any illogical interpretation of the claim and understand that the above amount is the daily dosage to be consumed by the human being. Firstly, the amended claim is simply not drafted to cover the administration of a low amount of vitamin K_2 to a patient over a certain period of time. Secondly, there is no basis anywhere in the patent specification for such an interpretation of the added feature. The patent is entirely silent about any daily dosage of menaquinone; it always defines the amount of menaquinone in relation to the weight of product.

5.3.3 The same considerations apply to auxiliary request XI, which still defines the menaquinone level in the food product as "50 to 5000 µg per day"(emphasis by the board). The clarity objection above also applies to this request.

5.4 Consequently, the board exercised its discretion not to admit auxiliary requests VI to XI into the proceedings because the amendments made raise new clarity issues and do not overcome the deficiencies of the previous requests (Article 13 RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated