

Internal distribution code:

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

**Datasheet for the decision
of 24 April 2024**

Case Number: T 1057/22 - 3.3.09

Application Number: 14726214.1

Publication Number: 2991507

IPC: A23L5/00, A61K35/00

Language of the proceedings: EN

Title of invention:

USE OF A COMPOSITION COMPRISING FISH OIL AND JUICE FOR THE
TREATMENT AND/OR POST TREATMENT OF CANCER

Patent Proprietor:

Smartfish AS

Opponent:

N.V. Nutricia

Headword:

Fish oil and juice for the treatment of cancer/SMARTFISH

Relevant legal provisions:

EPC Art. 56, 83, 100(a), 100(b), 123(2)
RPBA 2020 Art. 12(4)

Keyword:

Auxiliary request 24 - admitted (yes)
Amendments - added subject-matter (no)
Therapeutic use - applicability of T 609/02
Sufficiency of disclosure - (yes)
Inventive step - (yes)

Decisions cited:

G 0002/21, T 0609/02, T 0117/04, T 0950/13, T 2059/13,
T 2627/17

Catchword:

The facts underlying T 609/02 should be taken into account when considering its findings for its applicability to the case at hand (Reasons 3.2.8 to 3.2.12).



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 1057/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 24 April 2024

Appellant:
(Patent Proprietor)

Smartfish AS
Gaustadallèen 21
0349 Oslo (NO)

Representative:

Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

Respondent:

(Opponent)

N.V. Nutricia
Eerste Stationsstraat 186
2712 HM Zoetermeer (NL)

Representative:

Nederlandsch Octrooibureau
P.O. Box 29720
2502 LS The Hague (NL)

Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 10 February
2022 revoking European patent No. 2991507
pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman A. Haderlein
Members: M. Ansorge
R. Romandini

Summary of Facts and Submissions

- I. The proprietor (appellant) lodged an appeal against the opposition division's decision revoking the patent.
- II. With its notice of opposition, the opponent had requested that the patent be revoked on the grounds for opposition under Article 100(a) EPC (lack of novelty and lack of inventive step) and Article 100(b) EPC.
- III. The opposition division decided, *inter alia*, that the subject-matter of claim 1 of the then main request met the requirements of Article 123(2) EPC but lacked novelty over D15 (D16 being an English translation of D15). The then auxiliary requests 3 to 6 were not admitted into the proceedings. The subject-matter claimed in the other then auxiliary requests was considered to be insufficiently disclosed.
- IV. With its statement setting out the grounds of appeal, the appellant filed a number of claim requests. In response to the board's communication under Article 15(1) RPBA, it withdrew all but auxiliary requests 24 to 47.
- V. Claim 1 of auxiliary request 24 reads as follows:

"A composition comprising a combination of fish oil and juice in an oil-in-water emulsion, for the use in treatment of cancer, wherein said fish oil is selected from fish oil having a totox value below 20 and omega-3 content above 10% by weight based on the total weight of the fish oil and wherein a suitable emulsifier is used to stabilize the emulsion, wherein the cancer

types treated are selected from the group consisting of pancreatic cancer and neurological cancer."

Claims 2 to 11 are dependent claims.

VI. The following documents were cited in the case at hand:

D12: WO 2009/120091 A1

D14: J. Ferlay et al., "Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012", European Journal of Cancer 49, 2013, 1374-403

D15: "Spis smart ved kreft", an article of Smartfish AS, published on "bramat.no" on 23 November 2013

D16: English translation of D15 having the title "Eat smart with cancer"

D18: Product information "Smartfish Nutrifriend 1100"

D27: Declaration of Janne Sande Mathisen, including cell proliferation tests of pancreatic cancer cells

VII. The parties' relevant arguments, submitted in writing and during the oral proceedings, are reflected in the reasons for the decision below.

VIII. Requests

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of auxiliary requests 24 to 47, filed with the statement setting out the grounds of appeal.

The opponent (respondent) requested that the appeal be dismissed.

Reasons for the Decision

1. Admittance of auxiliary request 24
 - 1.1 The respondent submitted that auxiliary request 24 should not be admitted into the appeal proceedings. The respondent's main argument was that the appellant had many opportunities in the first-instance proceedings to file an auxiliary request having the limitation to the treatment of only pancreatic cancer and neurological cancer as claimed in auxiliary request 24.
 - 1.2 For the following reasons, the board admitted this auxiliary request.
 - 1.2.1 Claim 1 of auxiliary request 24 includes the feature "for the use in treatment of [...] pancreatic cancer and neurological cancer" (see point IV. above). In comparison to the higher-ranking claim requests which were withdrawn after the board had issued its communication under Article 15(1) RPBA, the post treatment of cancer has been deleted, and the number of cancers to be treated by the composition was significantly reduced.
 - 1.2.2 Auxiliary request 24 was not filed in the first-instance proceedings. Filing it with the grounds of appeal is therefore an amendment to the appellant's appeal case within the meaning of Article 12(4) RPBA, the admittance of which is at the discretion of the board.
 - 1.2.3 The board does not consider deleting the post treatment of cancer and limiting the treatment to only two types

of cancer to be complex. Nor does this amendment lead to other complex considerations. On the contrary, these amendments narrow the scope of claim 1 and simplify the contentious issues discussed in the first-instance proceedings. For instance, this amendment restores novelty over D16 and limits the scope of claim 1 to only two types of cancer which are mentioned in tests according to examples 2 and 4 of the patent. The board finds that this amendment is suitable for addressing the issues which led to the decision under appeal, in particular for the assessment of sufficiency of disclosure. In view of the limitation of the scope of claim 1, its admittance is also not detrimental to procedural economy.

- 1.2.4 The board does not see that auxiliary request 24 should have been submitted in the first-instance proceedings. Under the current circumstances, the board does not see that the appellant was prompted by the course of the first-instance proceedings to file auxiliary request 24 before the opposition division.

In view of the above, auxiliary request 24 is admitted into the appeal proceedings.

2. Article 123(2) EPC

Claim 1 of auxiliary request 24 is based on a combination of claims 1 and 2 of the application as filed, where the post treatment of cancer mentioned in claim 1 is deleted, and the list of cancer types targeted by the treatment of cancer mentioned in claim 2 is limited to pancreatic cancer and neurological cancer. This deletion in the list of alternatives in claim 2 is merely the deletion in one

list which is not objectionable under Article 123(2) EPC.

In view of the above, the subject-matter of claim 1 of auxiliary request 24 complies with the requirement under Article 123(2) EPC.

3. Sufficiency of disclosure

3.1 The respondent argued that the claimed subject-matter did not meet the requirement of Article 83 EPC since it was not plausibly demonstrated that the claimed therapeutic effects were achieved over the whole claimed range. It argued that it had not been shown that any type of juice when used in combination with fish oil was suited to providing the claimed therapeutic effects. There was no guidance in the application as filed on which of these juices, when combined with fish oil, promoted anti-cancer effects. It was also problematic that Nutrifriend 1100 as used in example 1 of the patent contained not only fish oil and juice but the additional components (i) protein isolate from milk, (ii) pectin, (iii) aroma from jackfruit, (iv) rosemary extract, (v) vitamin E, (vi) vitamin D and (vii) soya lecithin, which were known to be bioactive. The skilled person did not have any information from the application as filed to render it plausible that the alleged effects were the result of using fish oil and juice only. The respondent agreed with the opposition division that it was impossible to delineate any therapeutic effect induced by fish oil and the mixtures of juices from these additional bioactive components of Nutrifriend 1100, let alone to draw the conclusion that any juice and fish oil combination would provide the alleged therapeutic effects. In view of the above, there were serious

doubts that the invention could be carried out over the whole claimed range. Thus, in its view, the invention could not be carried out by a skilled person over the whole claimed range.

3.2 For the following reasons, the board disagrees.

3.2.1 The board shares the appellant's view that the application as filed contains data on the anti-tumour activity of a composition according to claim 1 (Nutrifriend 2000) on neurological cancer cells (example 2) and on pancreatic cancer cells (example 4). This was confirmed by the opposition division (see point 11.3.2.1, the last eight lines on page 18 of the decision) and was not contested by the respondent.

3.2.2 The respondent substantially criticised the breadth of claim 1 with respect to the feature "juice", which was broadly defined, and it submitted that it was not plausible that any juice was successful in treating the two types of cancer defined in claim 1.

3.2.3 However, there is clear guidance on page 6, lines 11 to 15 of the application as filed (see also paragraph [0025] of the patent) that juices from fruits or berries having a high level of antioxidants, preferably from fruits having a minimum level of metal ions functioning as oxidising agent, may be used in the claimed composition. On page 6, lines 17 to 25 of the application as filed (see also paragraph [0026] of the patent), a comprehensive list of suited juices is given, so a skilled person is provided with ample guidance on the juices which may be used in the claimed composition. Nutrifriend 2000 as used in examples 2 and 4 contains apple, pear, pomegranate and aronia juices. All these juices are indicated in the

application (and in the patent) as filed as preferred juices.

- 3.2.4 Moreover, there is no evidence on file to support the respondent's allegation that choosing any of these explicitly proposed juices might fail to achieve the claimed therapeutic effects. The respondent has not submitted any such evidence, for example, in the form of experimental data. In this context, the board disagrees with the statement given in the decision under appeal that a skilled person would not know which juice to choose. As outlined above, the board is of the opinion that a skilled person is provided with ample guidance as to suitable juices to be used.
- 3.2.5 Even though the additional components protein isolate from milk, pectin, aroma from jackfruit, rosemary extract, vitamin E, vitamin D and soya lecithin, which are present in Nutrifriend 2000 as well, are known to be bioactive and some also possess anti-cancer properties, this alone is not suited to raise serious doubts that the claimed therapeutic effects can be achieved when using only fish oil and juice. In the board's view, the respondent's converse conclusion is an unsubstantiated assertion.
- 3.2.6 In addition, it can be taken from example 4 that an increased apoptosis of pancreatic cancer cells by natural killer (NK) cells is achieved by Nutrifriend 2000 (a composition falling within the scope of claim 1) compared with the control and with the administration of the omega-3 fatty acid docosahexaenoic acid (DHA) alone (see Table 1 of the patent). However, Table 1 also shows that the omega-3 fatty acid DHA alone, which is a crucial ingredient of fish oil, leads to a slight increase in apoptosis of

pancreatic cancer cells by NK cells. Under these circumstances, it is credible from the information given in the application as filed that also the claimed combination of fish oil and juice leads to the claimed therapeutic effects (see G 2/21, Reasons 74).

- 3.2.7 The therapeutic effect in connection with pancreatic cancer cells is further supported by evidence D27, which shows that fish oil alone (Denomega, the same fish oil as used in Nutrifriend 1100) and a combination of fish oil (Denomega) and a juice lead to a slight suppression of cell proliferation of pancreatic cancer cells, whereas a composition falling within claim 1 (Nutrifriend 1100) shows a significant suppression of pancreatic cancer cell proliferation. Evidence D27 filed after the filing date of the patent merely supplements the information provided in the application as filed (see example 4). D27 is not necessary to consider credible the claimed therapeutic effects (see G 2/21, Reasons 77), it only supports that conclusion.
- 3.2.8 The respondent presented two additional submissions that warrant consideration. First, it cited decision T 609/02 to bolster its challenge under Article 83 EPC, claiming its findings should apply to the current case. Second, it argued that the totox value specified in claim 1 is meaningless. However, both submissions are unconvincing for the following reasons.
- 3.2.9 Decision T 609/02 was quoted in G 2/21 (see Reasons 75) and several other decisions of the boards. For therapeutic use claims, the boards have derived from T 609/02 the principle that for Article 83 EPC to be complied with, the suitability for the claimed therapeutic use, unless already known to the skilled person at the priority date, must be disclosed by the

application (see T 609/02, Reasons 9 and the Case Law of the Boards of Appeal, 10th ed. II.C.7.2.1). The reference to this decision cannot, however, change the assessment made by the current board because the facts are different. In the case underlying T 609/02, there was no evidence in the patent (or the application as filed) that the alleged effect took place. Furthermore, the application was also silent on the identification of the compound allegedly providing the effect (Reasons 5).

- 3.2.10 The opposite is true in the current case. The patent (and the application as filed) contains examples of the therapeutic uses claimed (see examples 2 and 4). Additionally, the composition providing the effect is clearly identified (see current claim 1). As a consequence, the board does not find that the invention was "made at a date later than the effective date of the patent" (see T 609/02, Reasons 8).
- 3.2.11 The board also notes that in several decisions of the boards, it was stated that the facts underlying decision T 609/02 differed from the facts underlying the respective cases judged in these decisions (T 117/04, Reasons 25; T 950/13, Reasons 3.9.1; T 2627/17, Reasons 2.1.3). While it is true, as held in T 2059/13, that differences in facts on which decisions are based are normal and the usefulness of case law is not confined to similar or identical facts (see Reasons 4.2.3), the current board is of the opinion that the facts underlying T 609/02 should be taken into account when considering its findings for its applicability to the case at hand.

- 3.2.12 The board thus concludes that the rationale underlying T 609/02 is not at odds with this board's finding of compliance with Article 83 EPC.
- 3.2.13 Concerning the totox value defined in claim 1, the board is of the opinion that a skilled person knows how to determine the totox value of fish oil. The totox value is a feature limiting the fish oil to be selected for the claimed composition. There is clear guidance in the application as filed to select a fish oil having an appropriate quality, i.e. having a low level of oxidation. As can be taken from page 5, lines 30 to 34 of the application as filed, to be of appropriate quality, the level of oxidation given as the totox value (two times the peroxide value added to the anisidine value) should be below 20, preferably below 10. Such fish oils of appropriate quality are usually clear oils with a very mild fishy odour and taste. Thus, even though for fish oil having a strong colour or fish oil containing added flavourings, such as virgin salmon oil containing carotenoids, the p-anisidine test would not be appropriate for measuring secondary oxidation in omega-3 oils, and consequently also the totox value could not be properly determined, there is clear guidance in the patent that clear oils, such as fish oil from cod, should be used, these oils not suffering from this problem.

In view of the above, the subject-matter of claim 1 of auxiliary request 24 meets the requirement of Article 83 EPC.

4. Inventive step
- 4.1 The respondent argued that the claimed subject-matter did not involve an inventive step in view of D12, D16

or D18 as the closest prior art taken in combination with D14.

4.2 The board disagrees for the following reasons.

4.2.1 D12 relates to a therapeutic drink comprising fresh marine oil having a totox value below 10 and further added antioxidants in an oil-in-water emulsion for the production of a medical preparation for the prophylaxis or treatment of diseases associated with elevated oxidative stress, such as cancer (see claim 1 and page 6, lines 11 to 15 of D12). The water phase may be a juice base (see claim 8 of D12).

4.2.2 D16 and D18 both concern a document on the drinkable juice Nutrifriend 1100 (as also used in example 1 of the patent). Nutrifriend 1100 is an oil-in-water emulsion comprising fish oil having a totox value below 20 and an omega-3 content above 10% by weight (based on the total weight of the fish oil) and an emulsifier. Nutrifriend 1100 is proposed for treating colon cancer, prostate cancer and cachexia in D16 and for treating cachexia in D18.

4.2.3 The subject-matter of claim 1 of auxiliary request 24 differs from each of documents D12, D16 and D18 in that none of these documents mention pancreatic cancer or neurological cancer. D12 only mentions the "treatment of cancer" in general, D16 mentions colon and prostate cancer as well as cancer cachexia, and D18 mentions cancer cachexia.

4.2.4 The objective technical problem is the provision of an alternative treatment of cancer.

4.2.5 On obviousness, the board comments as follows.

D12 does not mention pancreatic cancer or neurological cancer. D12 also fails to render it obvious that the composition disclosed in D12 might be suited for treating these types of cancer. A skilled person would not reasonably expect that any type of cancer could be treated by the drink taught in D12. The combination document D14 is a report on cancer incidence and mortality patterns in Europe which would not have taught the skilled person anything about whether the composition of D12 would have been an effective treatment for pancreatic cancer and neurological cancer either.

For similar reasons, the board is not convinced by the respondent's inventive-step objection starting from D16 or D18 as the closest prior art in combination with D14. Neither D16 nor D18 teaches or suggests that the composition Nutrifriend 1100 might be suited for the treatment of pancreatic cancer and neurological cancer. Different types of cancer require different treatments. In the absence of any further technical explanations, a therapeutic effect for one type of cancer cannot be simply extrapolated to other types of cancer. As outlined above, D14 does not provide any teaching which rendered the claimed therapeutic effects obvious for a skilled person.

- 4.2.6 The respondent argued that due to the information given in paragraph [0045] of the patent as granted, the treatment of cancer still included the treatment of cachexia.

The board does not interpret claim 1 in such a way. Claim 1 is limited to the treatment of two types of cancer, and it is no longer directed to the treatment

of cachexia. While the treatment of cachexia was covered by claim 1 of the patent as granted, it is no longer claimed in auxiliary request 24.

In view of the above, the subject-matter of claim 1 of auxiliary request 24 involves an inventive step in view of D12, D16 or D18 as the closest prior art.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the claims according to auxiliary request 24 filed with the statement setting out the grounds of appeal and a description to be adapted and figures possibly to be adapted.

The Registrar:

The Chairman:



K. Götz-Wein

A. Haderlein

Decision electronically authenticated