Internal distribution code:

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

Datasheet for the decision of 17 September 2024

Case Number: T 2173/22 - 3.3.07

Application Number: 16733314.5

Publication Number: 3307290

IPC: A61K9/00, A61K9/14, A61K33/26, A61K35/741, A23L33/135, A61K9/107, A61K33/42, A61K35/747, A23L33/00, A23L33/16, A61P7/06, A61P3/02, A61P3/10

Language of the proceedings: EN

Title of invention:
DIETARY SUPPLEMENT

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
FrieslandCampina Nederland B.V.
N.V. NUTRICIA
Morinaga Milk Industry Co., Ltd.

Headword:
Probiotic-ferric pyrophosphate/NESTLE

Relevant legal provisions:
EPC Art. 56

Keyword:
Public prior use as closest prior art (yes)
Inventive step - (no)

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

Case Number: T 2173/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 17 September 2024

Appellant: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Karlstraße 7 80333 München (DE)
Respondent: (Opponent 01)	FrieslandCampina Nederland B.V. Stationsplein 4 3818 LE Amersfoort (NL)
Representative:	FrieslandCampina IP Department Bronland 20 6708 WH Wageningen (NL)
Respondent: (Opponent 02)	N.V. NUTRICIA Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Wohlfahrt, Jan Günther Gleiss Große Schrell und Partner mbB Patentanwälte Rechtsanwälte Leitzstraße 45 70469 Stuttgart (DE)
Respondent: (Opponent 03)	Morinaga Milk Industry Co., Ltd. 33-1, Shiba 5-chome Minato -ku Tokyo 108-8384 (JP)

Representative: Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 9 August 2022 concerning maintenance of the European Patent No. 3307290 in amended form**

Composition of the Board:

Chairman A. Usuelli
Members: J. Molina de Alba
A. Jimenez

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's interlocutory decision rejecting the main request (patent as granted) and auxiliary request 1, and concluding that European patent No. 3307290 as amended according to auxiliary request 2, and the invention to which it relates, met the requirements of the EPC.

Claim 1 as granted read as follows:

"*1. An oral composition comprising:*
- *at least one probiotic bacteria selected from the genera:* Lactobacillus, *and* Bifidobacterium, *and*
- *ferric pyrophosphate*

wherein, said composition is in the form of a maternal supplement."

Claim 1 of auxiliary request 1 read as follows:

"*1. An oral composition for use in the treatment or prevention of gestational diabetes, the treatment or prevention of iron deficiency and/or the treatment or prevention of anaemia in a pregnant and/or lactating female subject, or to a female subject prior to pregnancy, said composition comprising:*
- *at least one probiotic bacteria selected from the genera:* Lactobacillus, *and* Bifidobacterium, *and*
- *ferric pyrophosphate*

wherein, said composition is in the form of a maternal supplement,

wherein the ferric pyrophosphate is microparticulate and wherein, the ferric pyrophosphate has a particle size distribution D_{90} of: 200 microns or less."

Claim 1 of auxiliary request 2 was derived from claim 1 of auxiliary request 1 by limiting the use to the treatment or prevention of gestational diabetes.

II. In the decision under appeal, the opposition division concluded, among other things, that:

- the subject-matter of the patent as granted was not novel,
- D30 belonged to the prior art,
- document D47 was not admitted into the proceedings,
- the subject-matter of auxiliary request 1 lacked an inventive step starting from D30 as the closest prior art, and
- the subject-matter of auxiliary request 2 met the requirements of the EPC.

III. The following documents were cited in the decision under appeal:

D9 EP 0 974 269 A1

D15a Machine translation of JPWO2013141139A1

D24 M.C. Fidler et al., British Journal of Nutrition, 2004, 91, 107-112

D25 L. Rossi et al., Food Chemistry, 2014, 151, 243-247

D26 N. Sakaguchi et al., Int. J. Vitam. Nutr. Res., 2004, 74(1), 3-9

D27 R. Wegmüller et al., J. Nutr., 2004, 134, 3301-3304

D30 "Vanilla Mango Flavoured Formulated Milk for Pregnant Women", Mintel GNDP, Record ID: 2577737, July 2014

D30a Enlarged, colour images of D30

D47 Declaration of E. Habeych dated 10 May 2022

IV. The patent proprietor (appellant) filed an appeal against the opposition division's decision.

In the statement of grounds of appeal, the appellant requested that the patent be maintained in amended form on the basis of the claims of auxiliary request 1 on which the decision under appeal was based (main request in these appeal proceedings).

V. Opponent 3 (respondent 3) filed an appeal that it withdrew before filing any statement of grounds of appeal. Subsequently, respondent 3 did not make any substantive submissions.

VI. Opponents 1 and 2 (respondents 1 and 2) replied to the statement of grounds of appeal.

VII. The board scheduled oral proceedings, in line with the parties' requests, and issued a communication with its preliminary opinion on the case. The board noted, among other things, that the patent proprietor being the sole appellant, the maintenance of the patent in the form held allowable by the opposition division could not be challenged due to the principle of prohibition of *reformatio in peius*.

VIII. With a reply to the board's preliminary opinion, respondent 1 filed additional documents that were not admitted by the board at the subsequent oral proceedings.

IX. Oral proceedings were held before the board on 17 September 2024 in the form of a mixed-mode hearing. The appellant and respondents 1 and 3 attended in person. Respondent 2 attended by videoconference. At the end of the oral proceedings, the board announced its decision.

X. The appellant's arguments, where relevant to the present decision, can be summarised as follows:

Admittance of D47

The opposition division was wrong not to admit D47 as suitable evidence of a technical prejudice in the prior art against combining micronised ferric pyrophosphate and probiotic bacteria. Therefore, D47 should be admitted into the appeal proceedings.

Admittance of the inventive-step objection based on the public prior use allegedly demonstrated by D30

The respondents' inventive-step objection based on the fact that the closest prior art was the prior use allegedly demonstrated by D30 should not be admitted. The respondents' position in the opposition proceedings and in their replies to the statement of grounds of appeal was that the entry "Date Published" in D30 was the date on which D30 was published in the database Mintel GNDP, rather than the date on which the product described in D30 was purchased in a supermarket. Thus, the respondents' case was based on the consideration that D30 was prior art instead of evidence of public prior use. In addition, contrary to Rule 76(2)(c) EPC, the respondents had not substantiated the objection within the opposition period because they had not

provided all the details on the circumstances under which the alleged public prior use had occurred. The inventive-step objections in the notices of opposition were not based on public prior use as the closest prior art, either.

Validity of D30 as evidence of public prior use

D30 was not valid evidence of public prior use because it did not contain all the information generally required for that purpose. It failed to prove the alleged facts beyond reasonable doubt.

Inventive step

Starting from the product described in D30 as the closest prior art, the subject-matter of claim 1 differed in that ferric pyrophosphate was present as microparticles having a particle size distribution D_{90} of 200 microns or less.

The micronisation of ferric pyrophosphate provided higher iron dispersibility and bioavailability. However, contrary to what might be expected, Example 1 of the patent showed that the higher iron bioavailability provided by micronised ferric pyrophosphate did not impair the viability of probiotic bacteria. Therefore, the objective technical problem was to provide an improved maternal supplement.

The solution proposed in the claims was not obvious. As explained in the patent (paragraphs [0012], [0044] and [0080]) and confirmed by D28 (page 13, lines 22 to 24), the skilled person expected that a more active form of iron would result in a greater loss of viability of the probiotic bacteria. In view of this technical

prejudice, the skilled person would not follow the suggestion in D24 to D27 to reduce the particle size of ferric pyrophosphate, since that would impair the viability of the probiotic bacteria in the product of D30. Therefore, it was surprising that micronisation enhanced the dispersibility and bioavailability of ferric pyrophosphate without adversely affecting the viability of probiotic bacteria.

XI. The respondents' arguments, where relevant to the present decision, can be summarised as follows:

Admittance of D47

The opposition division was right in not admitting D47, since it was established case law that a declaration from an inventor could not prove the existence of a prejudice in the prior art. Therefore, this point of the decision should not be reversed. There were also no reasons to admit D47 into the appeal proceedings under Article 12(6) RPBA.

Admittance of the inventive-step objection based on the public prior use demonstrated by D30

The consideration of D30 as evidence of public prior use that could be taken to be the closest prior art was part of the decision under appeal and was also brought up by respondents 1 and 2 in their replies to the statement of grounds of appeal (reply of respondent 1, page 8, section "Status of D6 and D30, last two paragraphs; reply of respondent 2, page 7, second paragraph). Contrary to the appellant's view, all the evidence required to demonstrate public prior use was contained in D30, which had been filed during the opposition period.

Validity of D30 as evidence of public prior use

D30 was suitable evidence of public prior use. It disclosed all the information required on the circumstances under which the public prior use had occurred. Furthermore, as D30 was a publicly accessible document, the standard of proof was not beyond reasonable doubt but a balance of probabilities.

Inventive step

Starting from the product disclosed in D30 as the closest prior art, the oral composition of claim 1 differed in that ferric pyrophosphate was present as a microparticulate while the particle size of ferric pyrophosphate in D30 was unknown.

There was no evidence on file that micronisation improved the dispersibility and bioavailability of ferric pyrophosphate. There was also no direct comparison of a composition according to claim 1 with the product of D30. Therefore, the objective technical problem was to provide an alternative composition. The solution proposed in claim 1 was obvious in light of D24 to D27, which taught that micronisation improved the dispersibility and bioavailability of ferric pyrophosphate in food compositions.

Even if the objective technical problem was defined as providing an improved maternal supplement, the subject-matter of claim 1 was obvious in view of D24 to D27. Contrary to the appellant's contention, there was no prejudice in the prior art against combining micronised ferric pyrophosphate and probiotic bacteria in a food product. This was clear from D9, D15a, D24 and D27,

which disclosed yogurt products containing micronised ferric pyrophosphate. Neither the patent nor D28 were suitable pieces of evidence for showing that there was a prejudice in the prior art.

XII. The parties' final requests relevant to the present decision were as follows:

- The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the claims of auxiliary request 1 on which the decision is based, filed as main request with the statement of grounds of appeal.

  The appellant also requested that document D47 be admitted into the appeal proceedings.

- The respondents requested that the appeal be dismissed.

  In addition, respondents 1 and 2 requested that D47 not be admitted into the appeal proceedings.

Reasons for the Decision

1. Admittance of D47

D47 is a declaration by one of the inventors of the patent filed by the appellant two months before the oral proceedings before the opposition division. It was intended to demonstrate, in the discussion on inventive step, that there was a technical prejudice in the prior

art against combining micronised iron sources with probiotic bacteria.

The opposition division considered that D47 was late filed and, at first glance, not relevant because an inventor's declaration could not prove the presence of a prejudice in the prior art (decision, page 6, third paragraph). In this context, the opposition division referred to Case Law, tenth edition, 2022, I.D.10.2.

In its communication in preparation for the oral proceedings, the board gave its preliminary opinion that the opposition division had not exercised its discretion to disregard D47 under Article 114(2) EPC in an unreasonable way. Therefore, the board was not minded to reverse that point of the decision. In addition, the board considered that the circumstances of the appeal case did not justify the admittance of D47 under Article 12(6) RPBA. First, there had been no change of case with respect to the admittance of D47. Second, the decision and respondents 1 and 2 were right that, in general, a mere declaration by an inventor is not valid evidence of a prejudice in the prior art at the priority date.

At the oral proceedings before the board, the appellant did not wish to make any further comment on the admittance of D47 and referred to its written submissions. Therefore, the board confirmed its position that the opposition division's decision not to admit D47 should not be overruled and that D47 was not to be admitted under Article 12(6) RPBA.

2. Admittance of the inventive-step objection based on the public prior use of the product disclosed in D30.

2.1 The appellant argued that the consideration of D30 as evidence of public prior use was a change to the respondents' case. In the opposition proceedings and in their replies to the statement of grounds of appeal, the respondents position had always been that the entry "Date Published" in D30 was the date on which D30 was published rather than the date on which the product described therein was purchased in a supermarket. Thus, the respondents considered D30 to be a prior-art document rather than evidence of public prior use. Therefore, the inventive-step objection starting from the product purchased according to D30 as the closest prior art should not be admitted into the appeal proceedings.

2.2 The appellant's request has to be rejected. The consideration that D30 was evidence of public prior use and that the public prior use constituted the closest prior art was discussed during the opposition proceedings and was dealt with in the decision under appeal.

As noted by the appellant in the statement of grounds of appeal (page 3, last two paragraphs), the opposition division acknowledged in point 2.3 of the decision that the appellant had argued that the date indicated in D30 could be the date of purchase of the described product rather than the date on which D30 had been published. Based on this argument, the opposition division concluded that D30 proved that the product described therein was publicly available in July 2014, i.e. before the priority date of the patent.

In other words, the decision was based on the fact that D30 was evidence of public prior use rather than a prior-art document. Subsequently, this evidence was taken to be the closest prior art for the assessment of inventive step in relation to auxiliary request 1, which is the main request in these appeal proceedings (decision: page 19, lines 25 and 26, and page 21, second paragraph).

Therefore, the inventive-step objection starting from the public prior use of the product described in D30 is part of the appeal proceedings in accordance with Article 12(1)(a) and (2) RPBA and cannot be excluded.

3. Validity of D30 as evidence of public prior use

3.1 The appellant contested the validity of D30 as suitable evidence of public prior use. It argued that public prior use had to be proven beyond reasonable doubt and that D30 did not meet this standard, especially with regard to the date on which the product of D30 had been made available to the public.

3.2 The board disagrees. D30 is a record extracted from the Mintel GNPD database. It was not disputed that Mintel GNPD is generally acknowledged in the field of nutritional compositions to be a reliable database of commercially available products. D30 reproduces the information on the packaging of a product purchased in a public establishment. The record is also accompanied by images of the packaging, which were provided in colour and higher quality in D30a. An inspection of the images in D30a confirms that the product description and the ingredients disclosed in D30 truly reflect the information on the purchased product. In addition, D30

discloses that the product was purchased by one of Mintel's shoppers in a supermarket called "Village Grocer" in Petaling Jaya 47810, Malaysia. The parties disputed the meaning of the entry "Date Published" in D30, which was July 2014. According to the respondents, this date indicated when the record had been published in the Mintel database. In contrast, the appellant contended that it could be the date on which the product had been purchased. This issue can be left unresolved, since in either case no doubts arise as to the public availability of the product in July 2014, i.e. nearly one year before the priority date of the patent.

Therefore, D30 is a valid piece of evidence of public prior use. The information it contains demonstrates beyond reasonable doubt that the product described therein was publicly available before the priority date of the patent.

4. Inventive step - main request

4.1 The patent (paragraphs [0001], [0006] and [0008]) is directed to a maternal supplement for pregnant and lactating women that contains probiotic bacteria and an iron source. The probiotic bacteria are intended to reduce the development of gestational diabetes while the iron source prevents iron deficiency. According to the patent (paragraph [0013]), the gist of the invention is the finding that ferric pyrophosphate is an iron source that does not impair the viability of probiotic bacteria. This is the case even when ferric pyrophosphate is provided in a finely divided form to increase iron bioavailability (paragraphs [0036] and [0044]). Accordingly, the patent shows in Example 1 (tables in paragraphs [0071] and [0079]) that three

different forms of ferric pyrophosphate, namely an emulsion (Preparation 2), a micronised powder (Preparation 3) and a non-micronised powder (Preparation 4), do not cause a substantial loss of bacterial viability compared with compositions containing other iron sources, such as ferrous bisglycinate (Preparation 1) and ferric ammonium citrate (Preparation 5). The viability of probiotic bacteria in the preparations containing ferric pyrophosphate remained at the level of the control (Preparation 6), which did not contain any iron source.

4.2 The commercial product photographed and described in D30 can be regarded as the closest prior art. Like the oral composition of claim 1, the product of D30 is a maternal supplement for pregnant and lactating women that contains ferric pyrophosphate and the probiotic *Bifidobacterium lactis*. The product of D30 indicates on its packaging that iron and vitamin B12 are factors in red blood cell formation for supporting the 50% increase in blood volume that occurs during pregnancy. Therefore, like the maternal supplement of claim 1, the product of D30 is intended, among other things, to treat or prevent iron deficiency during pregnancy.

4.3 It was common ground between the parties that the maternal supplement of claim 1 differs from that of D30 in that claim 1 specifies that ferric pyrophosphate is present in the form of a microparticulate having a particle size distribution D_{90} of 200 microns or less. The form of ferric pyrophosphate in the product of D30 is unknown.

4.4 With regard to the technical effect produced by this difference, the appellant argued that micronisation increased ferric pyrophosphate dispersibility and iron

bioavailability. However, the higher iron bioavailability provided by micronised ferric pyrophosphate did not impair the viability of the probiotic bacteria present in the maternal supplement, as demonstrated in Example 1 of the patent (tables in paragraphs [0071] and [0079]). Based on this technical effect, the appellant defined the objective technical problem as that of providing an improved maternal supplement.

The respondents did not dispute the fact that, in view of Example 1 of the patent, micronised ferric pyrophosphate does not impair the viability of the probiotic bacteria in the maternal supplement. However, they denied that the ferric pyrophosphate in the composition of claim 1 had higher dispersibility and bioavailability than the one in the product of D30. First, the particle size of ferric pyrophosphate in the maternal supplement of D30 was unknown and there was no direct comparison between the maternal supplements of claim 1 and D30. Second, there was no evidence on file that micronisation improved the dispersibility and bioavailability of ferric pyrophosphate. Therefore, the objective technical problem could not be defined in terms of an improvement, but as an alternative.

4.5 The board agrees with the respondents that there are no comparative data showing that the maternal supplement of claim 1 is improved compared with the one of D30. However, finding the product purchased and described in D30 to provide comparative data may be difficult, if not impossible. Therefore, the board considered that in this particular situation and in the appellant's favour, it could be assumed that ferric pyrophosphate was not micronised in the product of D30. In view of the outcome of the assessment of inventive step below

(point 4.8), the respondents are not adversely affected by this assumption.

With regard to the evidence on the technical effect produced by micronising ferric pyrophosphate, documents D24 (abstract), D25 (page 243, right-hand column, first paragraph), D26 (abstract) and D27 (abstract) support the appellant's argument that reducing the particle size of ferric pyrophosphate to the micron range can improve its dispersibility and bioavailability in food products.

Therefore, in the board's view, the objective technical problem can be defined as that of providing a maternal supplement having higher iron dispersibility and bioavailability without impairing the viability of probiotic bacteria.

4.6 The solution to this problem proposed in claim 1 is the provision of ferric pyrophosphate as a microparticulate with a particle size distribution D_{90} of 200 microns or less. In preferred embodiments, the ferric pyrophosphate microparticulate is in the form of a colloid or an emulsion, such as the emulsified form commercially available as SunActive Fe® (see patent, claim 2 and paragraph [0041], last two sentences).

4.7 This solution was obvious to the skilled person in view of documents D24 to D27.

D24 (abstract) is concerned with the bioavailability and dispersibility of ferric pyrophosphate used to fortify food products. The document teaches that ferric pyrophosphate is difficult to absorb because it is insoluble in water. The document therefore proposes micronising ferric pyrophosphate to an average particle

size of 0.3 microns and mixing it with emulsifiers to improve its dispersibility in liquid products. This form of ferric pyrophosphate remained in suspension and was well absorbed. It was designated as SunActive Fe™.

D25 (page 243, left-hand column, last sentence and right-hand column, first paragraph) also deals with the poor solubility and bioavailability of ferric pyrophosphate in food supplements. It teaches that decreasing the particle size of ferric pyrophosphate to nanoscale colloidal particles significantly enhances iron bioavailability and absorption.

D26 (abstract and page 8, last paragraph) discloses a micronised, dispersible form of ferric pyrophosphate with a sharp particle size distribution at a nanometre level (0.3 microns, see page 5, right-hand column, last paragraph, and Figure 1). This form of ferric pyrophosphate was completely dispersible in liquid form and had higher bioavailability than the form regularly used for food fortification. It was commercially available as SunActive Fe™.

Similarly, D27 (abstract) teaches that reducing the particle size of ferric pyrophosphate significantly enhances its bioavailability and makes it useful for food fortification. This is particularly the case when ferric pyrophosphate has an average particle size of about 0.5 microns and is combined with emulsifiers.

4.8 The appellant did not deny that reducing particle size was an obvious measure to increase the dispersibility and bioavailability of ferric pyrophosphate in food products. In fact, the appellant relied on this principle to justify that the technical effect produced by the particle size distribution defined in claim 1

was increased dispersibility and iron bioavailability, since this effect was not supported by experimental evidence in the patent. The appellant's position on obviousness was rather that the skilled person would not reduce the particle size of ferric pyrophosphate because there was a prejudice in the prior art against it: micronisation of ferric pyrophosphate would increase iron activity and this could be expected to adversely affect the viability of the probiotic bacteria in the maternal supplement.

4.8.1 As evidence of this prejudice in the prior art, the appellant cited the patent (paragraphs [0036] and [0044]) and D28 (page 13, lines 22 and 23). The patent states in paragraphs [0036] and [0044] that it was surprising that the finely divided forms of ferric pyrophosphate of the invention do not decrease bacterial viability, since the high bioavailability of an iron form is usually correlated with high reactivity. D28 states on page 13, lines 22 and 23, that iron is a potent oxidising agent and that, when a soluble form of iron comes into contact with food, it can change the colour, taste and smell of the food.

4.8.2 It is established case law that the presence of a prejudice in the prior art has to be established by demonstrating that there was a preconceived idea universally or at least widely held by experts in the field (Case Law, tenth edition, 2022, I.D.10.2). A typical way of proving a prejudice is the citation of common technical knowledge published before the priority date, although other ways cannot be excluded. However, statements in the patent that are not accompanied by the citation of specific evidence of the alleged prejudice are not a suitable way of demonstrating a prejudice. Similarly, a mere statement

in a patent application, such as D28, cannot prove the presence of a prejudice, either. This is even more the case considering that D28 does not even make the link between the oxidising properties of iron and the viability of bacterial probiotics.

In addition to the missing evidence of the alleged prejudice, documents D9, D15a, D24 and D27 show that the skilled person was not deterred from preparing food products containing micronised ferric pyrophosphate and bacterial probiotics.

D9 (paragraph [0031] and Examples 1 to 3) and D15a (paragraphs [0001], [0010], [0054] and [0056]) disclose the preparation of fermented milk products containing *Lactobacillus* or *Bifidobacterium* strains in combination with dispersed coated ferric pyrophosphate microparticles. D24 (paragraph bridging pages 107 and 108) and D27 (page 3303, right-hand column, lines 8 to 10) disclose the use of micronised ferric pyrophosphate for fortifying a yogurt drink.

4.8.3 In conclusion, the appellant did not convincingly show that the skilled person would not apply the teaching of D24, D25, D26 and D27 to the product of D30 when seeking to solve the objective technical problem.

4.9 Therefore, the main request does not involve an inventive step and fails to meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated