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Datasheet for the decision of 20 February 2024

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Title of invention:
PROPHYLACTIC USE OF INULIN AGAINST SINUSITIS

Patent Proprietor:
Südzucker AG

Opponent:
Dehmel & Bettenhausen Patentanwälte PartmbB

Headword:
PROPHYLACTIC USE OF INULIN AGAINST SINUSITIS/Südzucker AG

Relevant legal provisions:
RPBA 2020 Art. 12(4), 12(6)
EPC Art. 56

Keyword:
Main request - Inventive step (Yes)

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Case Number: T 0959/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 20 February 2024

Appellant: (Opponent)	Dehmel & Bettenhausen Patentanwälte PartmbB Herzogspitalstr. 11 80331 München (DE)
Representative:	Rückerl, Florian Dehmel & Bettenhausen Patentanwälte PartmbB Herzogspitalstraße 11 80331 München (DE)
Respondent: (Patent Proprietor)	Südzucker AG Maximilianstrasse 10 68165 Mannheim (DE)
Representative:	Schrell, Andreas Gleiss Große Schrell und Partner mbB Patentanwälte Rechtsanwälte Leitzstrasse 45 70469 Stuttgart (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 15 February 2022 rejecting the opposition filed against European patent No. 3331537 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	Y. Podbielski

Summary of Facts and Submissions

I. European patent No. 3 331 537 B1 was granted on the basis of a set of 15 claims.

Independent claim 1 as granted read as follows:

"1. An inulin composition comprising GF_n- and F_m-compounds which composition comprises 25 to 40 wt.-% (dry matter, based on total mass of carbohydrates) of compounds having a DP ≥ 11 (degree of polymerization), 15 to 30 wt.-% (dry matter, based on total mass of carbohydrates) of F_m compounds with m=2 to 9, wherein the DP_{Av} (average degree of polymerization) of the inulin composition is 6.5 to 9."

II. The patent was opposed under Article 100 (a) EPC on the grounds that the subject-matter of the granted patent lacked novelty and inventive step.

III. The present appeal lies from the decision of the opposition division to reject the opposition.

IV. The documents cited during the opposition proceedings included the following:

D1: EP 1125507 A1
D1b: Analysis and calculation of DPAV, F2-9 and DP of Synergy 1 products of D1
D2: EP 2060257 A1
D14: Closa-Monasterolo et al., Clinical nutrition 32 (2013), 918-927
D19a: Product sheet Beneo Orafti Synergyl (2011)

D19b: Productsheet Beneo Orafti Synergyl (2020)
D21: WO 96/01849 A1
D22: WO 98/05793 A1
D23: Franck et al., "Inulin, Chemical Structure and Analysis" Biopolymers, 2004, pages 439 - 448
D26: Product sheet of RAFTILINE®HP (Orafti) dated February 1998
D27: Product sheet of RAFTILINE®HP (Orafti) dated June 1999
D29: Demigne et al., 2008, Eur J Nutr, 47, 366-374
D30: Durieux et al., 2001, Biotechnology Letters, 23, 1523-1527
D31: Taipale et al., 2011, British Journal of Nutrition, 105, 409-416.

V. According to the decision under appeal, the subject-matter of the claims was novel over D1, since this document did not disclose the presence of 15-30 wt% of F_m compounds with m=2 to 9 and an inulin composition with a DP_{Av} of 6.5 to 9.

D29-D31 were admitted into the proceedings.

D1 was considered to be the closest prior art, rather than D19, D2 or D14. The problem was defined as the provision of an alternative composition able to improve the immune system, especially effective in the prophylaxis of sinusitis. The claimed solution was not obvious in view of D1, D30, D31 and D14.

VI. The opponent (hereinafter the appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal dated 21 June 2022, the appellant submitted the following items of evidence:

D32: 3D graph representing the inulin compositions of claim 1
D33: 3D graph representing the inulin compositions of claim 1

VII. With its reply to the grounds of appeal dated 25 October 2022, the patent proprietor (hereinafter the respondent), filed auxiliary requests 1-3 and submitted the following evidence:

D34: Neumer et al. , Nutrients, 2021, 13, 1276, pp.1-16
D35: Study protocol for D34
D36: Jackson et al. (submitted), Comparative fermentation study, Manuscript, (2022).

VIII. A communication from the Board, dated 6 November 2023, was sent to the parties. In it, the Board expressed its preliminary opinion that D34-D36 should not be admitted into the appeal proceedings and that the claimed subject-matter appeared to be inventive.

IX. Oral proceedings took place on 20 February 2024 by videoconference.

X. The arguments of the appellant may be summarised as follows:

Main request - Inventive step

D1 was the closest prior art; it disclosed a prebiotic composition with short and long chains inulins which had a positive effect on the immune system. There was no requirement that the specific problem of the contested patent be mentioned in the closest prior art; moreover, the stimulation of the immune system had necessarily a prophylactic effect on sinusitis. In any

case, the claimed invention had to be obvious over any starting point.

When starting from the disclosed EFI/HFI ratio of 65/35, the only difference was the 15 to 30 wt.-% of F_m compounds with m=2 to 9 and the claimed DP_{Av} . Since no comparison had been done over D1, and since there was no evidence that an effect was linked with the distinguishing features, the problem was the provision of an alternative inulin composition.

The skilled person would have arrived at the claimed subject-matter without effort, there was no need for a pointer to the differences. D30 showed that inulin compositions with a DP_{Av} comprised between 7 and 9 was known.

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

Main request - Inventive step

D1 was the closest prior art. Contrary to the appellant's argument, this document did not disclose directly and unambiguously a composition with an EFI/ HFI ratio of 65/35, which should be a further distinguishing feature. D1 did not describe any effect on the immune system, while the contested patent did.

The problem over D1 was the provision of a composition effective to reduce the frequency of occurrence of sinusitis. The claimed solution could not be obvious over D1. The same conclusion would apply if the problem was defined as an alternative.

XII. Requests

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed and the patent be maintained as granted (main request) and, in case the decision under appeal is set aside, that the patent be maintained on the basis of one of auxiliary requests 1-3 filed with the reply dated 25 October 2022.

Reasons for the Decision

1. Main request (claims as granted) - Inventive step

1.1 The claimed invention relates to an inulin composition comprising GF_n- and F_m- compounds for decreasing the risk of sinusitis. The composition is in particular able to improve the performance of the immune system of children at the age of 3 to 6 years (see the specification par. [0021]).

As explained in paragraph [0023] of the patent, inulin is a mixture of oligo- and polysaccharides which are composed of fructose (F) units and which oligo- and polysaccharides may or may not comprise a starting glucose moiety (G).

Claim 1 of the main request is characterised by the following essential technical features:
A) an inulin composition comprising GF_n- and F_m - compounds, which composition comprises:

B) 25 to 40 wt.-% (dry matter, based on total mass of carbohydrates) of compounds having a DP≥11 (degree of polymerization),
C) 15 to 30 wt.-% (dry matter, based on total mass of carbohydrates) of F_m compounds with m=2 to 9,
D) wherein the DP_{Av} (average degree of polymerization) of the inulin composition is 6.5 to 9.

1.2 D1 was considered to represent the closest prior art by the opposition division in its decision. The appellant also took this document as closest prior art. The Board agrees that D1 can be a suitable starting point for the assessment of inventive step.

D1 relates to inulin products consisting of a mixture of an easily fermentable inulin (EFI) and a hardly fermentable inulin (HFI) in a EFI/HFI weight ratio from 10/90 to 70/30, preferably from 35/65 to 65/35, preferably from 40/60 to 45/55, and about 50/50 (see claims 1 and 2, and par. [0039]). Hence, D1 discloses compositions comprising GF_n- and F_m -compounds, which corresponds to feature A) of claim 1 of the main request (see also point 3.2.1 of the decision of the opposition division, 2nd paragraph).

In D1, EFI are short-chain inulin, i.e. inulin with a DP<10, ranging mainly from 2 to 7, and agave inulin (cf. par. [0040] and [0042]). Products suitable as EFI are Raftilose® L85, Raftilose® L95 and Raftilose® P95 (cf. par. [0053]). Raftilose® L95 and Raftilose® P95 have a content of 95% oligofructose and 5% of glucose, fructose and sucrose, with a DP_{Av} from 2 to 9, while Raftilose® L85 has a content of about 85% oligofructoses, with a DP_{Av} of 2-9 (cf. par. [0014] and [0053]).

HFI are long-chain inulin with a $DP_{Av} \geq 20$, preferably more than 23 (cf. par. [0041] and [0043]). A product suitable as HFI is chicory inulin Raftline® HP with a DP_{Av} of at least 20 (cf. par. [0011] and [0054]-[0055]).

When selecting the specific upper limit 65/35 EFI/HFI inside the range of 35/65 to 65/35 disclosed in D1, it can be calculated, based on the composition of the HFI Raftline® HP, that the inulin composition of D1 comprises 35% of compounds having a degree of polymerization higher than 11 (see also Figure 3 of D21), which corresponds to feature B) of claim 1 of the main request. Hence, as concluded by the opposition division (see point 3.3.6) feature B is anticipated by D1 as far as a 65/35 EFI/HFI is selected and the HFI is Raftline® HP.

In case Raftilose® L95 is taken as EFI, and by taking Table 1 of D22 as the basis for the composition of the commercially available Raftilose® L95, the inulin composition of D1 would comprise 65% x 38%, namely about 25% by weight by weight of F2 to F9 (see also D1b). However, when taking Table 2 of D23 as the basis for the composition of the same product Raftilose® L95 , the inulin composition of D1 would comprise 65% x 78%, namely about 50% of F2 to F9 in the inulin composition, which does not fall under the scope of the claimed feature C) of claim 1 of the main request. Already in view of the uncertainty as to the composition of Raftilose® L95, it is not possible to conclude that feature C) of claim 1 of the main request, namely a content of 15 to 30 wt.-% of F2 to F9, has been disclosed directly and unambiguously in D1. This was also the conclusion of the opposition division in its decision (see points 3.4.2-3.4.6 of the

decision) which was not disputed by the appellant (see statement of grounds of appeal, page 11, 4th paragraph).

D1b provides a calculation of the DP_{Av} values of some EFI/HFI mixtures as disclosed in D1. The calculations give various results for the combination of 65/35 EFI/HFI which can fall within or outside the claimed feature D) of claim 1, namely a DP_{Av} of the inulin composition comprising between 6.5 to 9. However, these calculations are not conclusive, since they are based on hypothetical DP_{Av} of each EFI and HFI, which are not given in D1, as well as on the composition of Raftilose® L95 given in D22, for which there is no certainty of accuracy. Moreover, even when taking these assumptions into account, it was found in D1b that only 2 compositions among 8 of EFI/HFI at a weight ratio of 65/35 could possibly have a DP_{Av} between 6.5 and 9. Consequently, the Board concurs with the appealed decision (see point 3.5.4) that it is not possible to conclude that feature D) is disclosed directly and unambiguously in D1.

The examples of D1 use an inulin product comprising oligofructose of DP between 2 to 7 in mixture with long chain chicory inulin with a DP_{Av} of 25 in a weight ratio of 45/55, which also does not correspond to the amounts claimed in claim 1 of the main request.

The compositions disclosed in D1 are used for their nutritional effects and benefits in several diseases. Claim 16 mentions the following "effects/benefits": dietary fibre effects, modulation of gut function, bifidogenicity, increased mineral absorption, increased absorption of calcium and/or of magnesium and/or of iron, bone mineral density increase, bone mineral

content increase, peak bone mass increase, improvement of the bone structure, reduction of bone mineral density loss, reduction of loss of bone structure, modulation of lipid metabolism, stimulation of the immune system, prevention or reduction of the risk of cancer, prevention or reduction of the risk of colon cancer and prevention or reduction of the risk of breast cancer. The use for stimulating the immune system, in particular in relation to the reduction of the risk of cancer, is mentioned in claim 16 or paragraphs [0024] and [0070]. Sinusitis is not mentioned in D1, even less its prophylactic use in children between 3 and 6 years of age. Moreover, the examples of D1 show inulin compositions used only for improving the absorption of calcium or magnesium, as well as the lipid metabolism.

It follows from the above that the inulin composition of claim 1 of the patent differs from the product of D1 at least on account of the features C) and D) as defined in point 1.1 above.

1.3 The problem was defined by the opposition division in its decision as the provision of an alternative composition able to improve the immune system, especially effective in the prophylaxis of sinusitis. A similar technical problem is proposed by the respondent.

The appellant defines the problem as the provision of an alternative inulin composition.

1.4 The solution to any of these problems is the provision of an inulin composition defined in particular by features C) and D) given above, namely comprising 15 to 30 wt.-% (dry matter, based on total mass of

carbohydrates) of F_m compounds with m=2 to 9, and wherein the DP_{Av} (average degree of polymerization) of the inulin composition is 6.5 to 9.

1.5 The example of the patent and D14 were cited in relation to the assessment of technical effect provided by the compositions of claim 1.

1.5.1 The unique example of the contested patent shows in a credible way that a prebiotic composition according to claim 1 as granted reduces significantly the risk of sinusitis episodes in children aged from 3 to 6 years. Thus, the patent demonstrates that the claimed composition has a beneficial effect on the immune system and is especially effective in the prophylaxis of sinusitis.

1.5.2 D14 studies the safety and efficacy of a prebiotic composition of oligofructose enriched inulin, i.e. the commercial product Orafti® Synergy 1 in infants of less than 4 months; the product Orafti® Synergy 1 is a chicoran-derived fructan comprising approximately 50% oligofructose with a DP less than 10 and 50% long-chain inulin with a DP higher than 10 (see point 2.2 of D14). Hence, the product is different from the claimed inulin composition, but falls under the preferred weight ratio of EFI/HFI disclosed for the compositions of D1.

Newborns fed with Orafti® Synergy 1 were compared with newborns receiving a comparative formula and with breastfed infants. D14 mentions in paragraph 3.2.3 that there were no significant differences in the mean number of infections between formula groups. At the end of paragraph 4.1 the authors of D14 furthermore state that "a longer-term follow-up of the infants in our study would help to elucidate the possibility of

preventing infections by prebiotic supplementation in infants".

In summary, D14 relates to a different inulin composition than the claimed subject-matter, but corresponding however to the compositions disclosed in D1 with a 50/50 weight ratio between long and short chains of inulin. D14 does not relate to the treatment of children from 3 to 6 years of age and does not mention any efficacy in the prophylaxis of sinusitis. Therefore D14 is of no relevance in establishing the technical effects over D1.

1.5.3 In conclusion, the contested patent shows a technical effect whereas D1 does not provide any evidence or suggestion that the compositions disclosed therein have an efficacy in the prophylaxy of sinusitis; the only evidence present in D1 relates to intestinal absorption of calcium and magnesium and the effect on the lipid metabolism. Moreover, D1 mentions the stimulation of the immune system exclusively in the context of an effect on cancer and not on sinusitis (see D1, par. [0024]), and it is questionable whether a stimulation of the immune system may systematically be translated in a prophylactic effect on sinusitis.

Accordingly, in the Board's view the technical problem can be defined as the provision of a composition capable of improving the immune system, especially effective in the prophylaxis of sinusitis.

1.6 It remains to be considered whether the skilled person faced with this technical problem would have arrived at the subject-matter of claim 1 in an obvious manner. In this context, the following documents illustrating the prior art concerning inulin products, namely documents

D1, D14, D22, D23, D29 and D30 were discussed by the parties.

1.6.1 The closest prior art D1 does not present a composition comprising EFI/HFI at a weight ratio of 65/35 as a preferred option and all examples of D1 show compositions having a EFI/HFI weight ratio of 45/55. Moreover, the examples of D1 evaluate the effects of the disclosed inulin product either on the calcium or magnesium absorption (see examples 1-3), or on the lipid metabolism, hence not on a possible stimulation of the immune system. There is furthermore no disclosure or suggestion in D1 of simultaneously choosing a EFI/HFI ratio of 65/35 and choosing the appropriate EFI for obtaining an inulin composition wherein the final DP_{Av} is between 6.5 to 9 and contining 15 to 30 wt.-% of F_m compounds with m=2 to 9, even less for stimulating the immune system; the combination of a composition with a weight ratio of 65/35 with Raftilose® L95 as EFI appears indeed to be a further selection, with a further uncertainty as to the exact composition of Raftilose® L95, which might not be corresponding to Table 1 of D22.

The appellant argued on the basis of D32 and D33 that there was a possible partial overlap between the compositions of D1 and the claimed compositions. The Board notes however that this overlap does not correspond to the most preferred compositions of D1, and that no compositions falling in this region of overlap is disclosed or suggested in D1. Moreover, the data shown in D32 and D33 are based on the inulin composition of Raftilose® L95 given in D22, which give an amount of about 25% by weight of F2 to F9, while a calculation based on D23 gives an amount of about 50% of F2 to F9 in the inulin composition. This excludes

the product Raftilose® L95 as being a product falling under the scope of the claim. For these reasons, the graphs shown in D32 and D33 cannot be considered as relevant. Finally, there is no indication in D1 that inulin compositions falling in the area of overlap would provide any beneficial effect to the immune system.

Consequently, the skilled person faced with the technical problem defined above would not find in D1 any suggestion to prepare the inulin compositions defined in claim 1.

1.6.2 D14 discloses an inulin product different from the claimed inulin composition, and is a prebiotic composition used in infants of less than 4 months (see point 2.5.2 above).

1.6.3 D29 relates to a study comparing, in a growing rat model, the effects on digestive fermentations and mineral metabolism of diets containing 7.5% inulin, using either a purified native inulin (NATinulin), a reformulated inulin based on a combination of short and long chain fructans (REFinulin), or dehydrated chicory (D29, abstract). The REFinulin batch contained 91.8% inulin, the NATinulin batch 93.0% and the 'Chicory' batch 51.7% (D29, p. 368). The exact composition of the inulin products does not appear to have been disclosed in D29.

1.6.4 D30 relates to Chicory fructooligosaccharides (FOS), i.e. Fibrulose F97 and Fibruline Instant. Fibrulose F97 contains oligofructoses FOS for which 70% presents a degree of polymerization (Dp) between 2 and 10 and maximum of 5% presents a Dp higher than 20. Fibruline Instant is composed of oligofructoses presenting a Dp

between 2-60, with a mean Dp of 10. These products appear to be different from the inulin composition of claim 1 of the main request.

1.6.5 Consequently, none of the prior art documents teaches the use of inulin products characterized by the features C) and D) as defined in claim 1 for stimulating the immune system and decreasing the risk of sinusitis.

1.7 Accordingly, the claimed solution is not obvious and the subject-matter of claim 1 meets 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