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Datasheet for the decision of 1 October 2020

Case Number: T 1879/15 - 3.3.02

Application Number: 09715865.3

Publication Number: 2257562

IPC: C07H3/04, C07H3/06

Language of the proceedings: EN

Title of invention:
OLIGOSACCHARIDE INGREDIENT

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
N.V. Nutricia

Headword:

Relevant legal provisions:
EPC Art. 87(1), 54(3), 56

Keyword:
Priority - partial priority (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
G 0001/15

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1879/15 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 1 October 2020

Appellant: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (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 15 July 2015 revoking European patent No. 2257562 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	P. O'Sullivan
	L. Bühler

Summary of Facts and Submissions

I. European patent 2 257 562 was opposed under Article 100(a) (novelty and inventive step) and 100(b) EPC.

II. The appeal of the patent proprietor (hereinafter appellant) lies from the decision of the opposition division to revoke the patent.

The contested decision was based on the patent as granted (main request) and auxiliary requests 1 to 7. According to the decision, the set of claims of the main request (patent as granted) lacked inventive step.

III. The following evidence *inter alia* was cited during opposition proceedings and invoked by the parties in appeal proceedings:

D1 EP 2 096 115 A1
D4 Pouliot *et al.*, J. Membrane Sci., 80 (1993), 257-264
D7 WO 2006/089921 A1
D9 Sarney *et al.*, Biotechnology and Bioengineering, 69 (2000), 462-467
D10 US 6,454,946 B1
D14 US 2005/0096295 A1

IV. Final requests

The appellant requests that the decision of the opposition division be set aside and that the patent be maintained as granted, or alternatively, maintained on the basis of one of the sets of claims of auxiliary

requests 1 or 2, filed with the statement of grounds of appeal.

The opponent (respondent) requested in writing that the appeal be dismissed, i.e. that the opposition division's decision to revoke the patent in its entirety be upheld.

V. A communication of the board pursuant to Article 15(1) RPBA 2020 was sent in preparation for oral proceedings.

VI. The independent claims of the main request (the patent as granted) read as follows:

"*1. An oligosaccharide ingredient comprising glycosylated amino acids and peptides of the general formula* R_nSac_m *where R is an amino acid residue, Sac is a monosaccharide selected from the group comprising N-acetyl-neuraminic acid, N-acetyl galactosamine and galactose, n has a value between 1 and 10 with the proviso that if n has the value 1 R is a threonine residue or a serine residue and if n has a value between 2 and 10 the peptide contains at least one threonine or serine residue, m has a value between 2 and 4, and wherein said oligosaccharide ingredient comprises 15 to 25 mol% N-acetyl galactosamine, 15 to 25 mol% galactose, 20 to 50 mol% N-acetyl-neuraminic acid and 15 to 25 mol% threonine or serine or a mixture thereof.*

7. A process for producing an oligosaccharide ingredient as claimed in any of claims 1 to 3 comprising the steps of hydrolysing caseinoglycomacropeptide with an exoprotease and an endoprotease to obtain a mixture of free amino acids

and peptides with a chain length between 2 and 10 and subjecting the hydrolysed mixture to nanofiltration so as to retain the fraction having a molecular weight between 1000 and 2000 Daltons."

VII. Oral proceedings before the board were held on 1 October 2020 in the absence of the respondent as announced by letter dated 24 September 2020.

VIII. The respondent's arguments, insofar as relevant to the present decision, may be summarised as follows:

Main request (claims as granted)

Novelty - Articles 100(a) and 54(3) EPC

The question of novelty for the subject-matter of claim 1 *vis à vis* D1 was dependent on the outcome of Enlarged Board of Appeal decision G 1/15.

Interpretation of claim 1

Claim 1 was directed to an oligosaccharide ingredient *comprising* relative amounts of the components recited therein in terms of the molar percentage thereof. The molar percentages recited applied to relative amounts of said components both inside and outside the formula R_nSac_m, i.e. it included embodiments wherein the molar percentages recited were obtained (partially) from ingredients other than R_nSac_m. The claim therefore did not impose any constraint on the origin of N-acetyl galactosamine, galactose, N-acetyl-neuraminic acid and threonine and/or serine, in particular not within compounds of the formula R_nSac_m. There was nothing unclear or ambiguous about the wording of the claim, which was therefore to be interpreted as it would be

understood by the skilled person, without consulting the description.

Inventive step - Articles 100(a) and 56 EPC

D14 (example 8) was the closest prior art for the subject-matter of claim 1. The alleged distinguishing features of the claimed subject matter over example 8 of D14 were the amounts of the ingredients (expressed in mol%) recited in the claim, or alternatively, certain process features. If the amounts of the ingredients were to be considered as a distinguishing feature, they were merely arbitrarily chosen and could not contribute to inventive step. On the other hand, the product of claim 1 was not distinguished from the product of example 8 of D14 by virtue of the steps of the preparation process employed, since the process had no bearing on the nature of the product and was not reflected in any of the product features of claim 1. Hence, the differing process steps in example 8 of D14 versus the process of the contested patent were irrelevant for assessing inventive step.

The technical problem was the provision of further ingredients for use in infant formulae.

The solution to this problem, namely the parameters proposed in claim 1 was merely the result of arbitrary selections. Even if processing conditions were considered to imply a distinguishing feature in claim 1, those process steps would have been contemplated by the skilled person practicing in the field of caseinoglycomacropeptide (CGMP) processing, in particular in the light of disclosures D4, D7, D9, or D10.

The subject-matter of claim 1 consequently lacked inventive step.

IX. The proprietor's arguments, insofar as relevant to the present decision, may be summarised as follows:

Main request (claims as granted)

Novelty - Article 100(a) and 54 EPC

The question of novelty for the subject-matter of claim 1 *vis à vis* D1 was dependent on the outcome of Enlarged Board of Appeal decision G 1/15.

Inventive step - Article 100(a) EPC

D14 (example 8) was the closest prior art for the subject-matter of claim 1. A distinguishing feature of claim 1 was at least the presence in the oligosaccharide ingredient of glycosylated amino acids and peptides of the general formula R_nSac_m as defined in the claim. The definition of R_nSac_m was a consequence of the process of preparation according to claim 7. The technical problem underlying claim 1 was the provision of an alternative CGMP-derived oligosaccharide ingredient enriched in sialic acid. The solution provided in claim 1 involved an inventive step in view of D14 as closest prior art. The same conclusion applied to independent claim 7, directed to the process for producing the product of claim 1.

Reasons for the Decision

Main request (claims as granted)

1. Novelty - Articles 100(a) and 54(3) EPC

1.1 D1 was cited by the respondent in opposition proceedings as state of the art pursuant to Article 54(3) EPC. D1 is the A1 publication of European patent application 08101975.4 from which the contested patent claims the priority date of 26 February 2008, and was published on 2 September 2009. Thus, if this priority date were to be deemed invalid, the effective date of the contested patent would be its filing date, 25 February 2009, in which case D1 would be prior art pursuant to Article 54(3) EPC.

1.2 It is undisputed that there is overlap between the molar percentage ranges recited for the listed components in claim 2 of D1 and claim 1 of the patent, the latter, broader ranges fully encompassing the former (contested decision, paragraph 7.5.2.1, table).

1.3 The appellant was of the opinion that granted claim 1 was entitled to partial priority for the parts of the broader ranges recited in claim 1 at issue overlapping with the ranges disclosed in D1.

1.4 According to G 1/15(order):

"*Under the EPC, entitlement to partial priority may not be refused for a claim encompassing alternative subject-matter by virtue of one or more generic expressions or otherwise (generic "OR"-claim) provided that said alternative subject-matter has been disclosed for the first time, directly, or at least implicitly,*

unambiguously and in an enabling manner in the priority document. No other substantive conditions or limitations apply in this respect".

1.5 G 1/15 therefore clearly establishes that the generic "or" alternatives in claim 1 at issue, disclosed for the first time in the priority document D1, i.e. the molar percentage ranges falling within the scope of claim 1 at issue and corresponding to the ranges recited in D1, claim 2, are entitled to the claimed priority date. D1 is consequently not prior art pursuant to Article 54(3) EPC for these ranges and is thus irrelevant to the novelty of the claimed subject-matter.

1.6 It follows that the ground for opposition under Article 100(a) EPC in combination with Article 54 EPC does not prejudice the maintenance of the patent as granted.

2. Interpretation of claim 1

2.1 Claim 1 refers to an *"oligosaccharide ingredient* ***comprising*** *glycosylated amino acids and peptides of the general formula* R_nSac_m *where R is an amino acid residue, Sac is a monosaccharide selected from the group comprising N-acetyl-neuraminic acid, N-acetyl galactosamine and galactose, [...] and wherein said oligosaccharide ingredient* ***comprises*** *15 to 25 mol% N-acetyl galactosamine, 15 to 25 mol% galactose, 20 to 50 mol% N-acetyl-neuraminic acid and 15 to 25 mol% threonine or serine or a mixture thereof."* (emphasis added by the board)

2.2 The parties disagreed on the correct interpretation of claim 1. The respondent was of the opinion that the "comprising" language of claim 1 (see bold type above) was unambiguous, and had the consequence that the molar percentages recited applied to relative amounts of the components N-acetyl galactosamine, galactose, N-acetyl-neuraminic acid (hereinafter "sialic acid") and threonine and/or serine both inside and outside the formula R_nSac_m. The appellant on the other hand, both in written proceedings but in particular during oral proceedings offered various possible interpretations of claim 1, some of which were based on an interpretation of the claim in the light of the description.

2.3 The board is of the view that if a term used in a claim has a clear technical meaning, the description cannot be used to interpret such a term in a different way. The unambiguous claim wording must be interpreted as it would by the person skilled in the art without the aid of the description. Thus, claim 1 describes an oligosaccharide ingredient which both **comprises** glycosylated amino acids and peptides of the general formula R_nSac_m, and **comprises** specific molar percentage ranges of the components recited in the claim. As noted by the respondent, this wording does not impose any constraint on the origin of said components. Said molar percentages must therefore be understood to apply to the components recited, present in the oligosaccharide ingredient both inside and outside the formula R_nSac_m. Thus, the molar percentages recited may also be obtained by adding components other than those defined by the formula R_nSac_m, as submitted by the respondent.

2.4 Most importantly, as will be addressed below, the board came to the conclusion that the interpretation of the

features of claim 1 related to the molar percentage of the components recited is not decisive for the assessment of whether the subject-matter of the claim involves an inventive step. Consequently, a conclusion in this regard is not required in order to assess inventive step (*vide infra*). Specifically, as will be addressed below, the feature related to the presence in the oligosaccharide ingredient of glycosylated amino acids and peptides of the general formula R_nSac_m recited in the claim is sufficient to render the subject-matter of claim 1 inventive.

3. Inventive step - Article 100(a) and 56 EPC

3.1 Leaving aside the feature concerning the molar percentage ranges of the components listed, contested claim 1 concerns an oligosaccharide ingredient which is defined in that it **comprises** glycosylated amino acids and peptides of the general formula R_nSac_m. R is defined as an amino acid residue, Sac is defined as a monosaccharide selected from the group comprising N-acetyl-neuraminic acid (sialic acid), N-acetyl galactosamine and galactose. "n" has a value between 1 and 10 with the proviso that if n has the value 1, R is a threonine residue or a serine residue. If n has a value between 2 and 10, the peptide contains at least one threonine or serine residue. "m" has a value between 2 and 4.

3.2 Closest prior art

3.2.1 The parties agree that D14, and in particular example 8 thereof, represents the closest prior art with regard to the subject-matter of claim 1 at issue. The board sees no reason to differ.

3.2.2 D14 concerns children's nutritional formula containing sialic acid and methods for its manufacture (paragraph [0003]). D14 aims to produce infant formula (e.g. milk powder) comprising caseinoglycomacropeptide(CGMP) having an enhanced concentration of sialic acid (paragraph [0013]).

3.3 Distinguishing features

3.3.1 Example 8 of D14 describes the production of a CGMP product whereby a fraction of cheese whey enriched in GMP is subjected to **partial proteolytic hydrolysis** followed by fractionation using **anion chromatography**. This process differs from the process used in the contested patent to prepare the oligosaccharide ingredient of claim 1 which comprises, according to granted claim 7, the steps of **hydrolysing** CGMP with an **exoprotease and an endoprotease**, followed by **nanofiltration** to retain the fraction having a molecular weight between 1000 and 2000 Daltons.

3.3.2 The respondent submitted that these **process** differences between example 8 of D14 and the process of the contested patent had no bearing on the **product** features recited in contested claim 1. If there was any effect attributable to the difference in processing conditions, it was not part of claim 1.

3.3.3 The board notes that despite the respondent's written argument set out above, no substantiation was offered specifically as to **why** the respective processes of D14 and the contested patent would, as alleged, not lead to different products. It is established jurisprudence that in general, the (not explicitly disclosed) product of a prior art process can be considered identical to a

claimed product if the prior art process discloses starting materials and process conditions identical to those disclosed for preparing said claimed product. In such a situation, the burden of proof to demonstrate the contrary generally lies with the patent proprietor. This however does not apply to the present situation, since the prior art process disclosed in D14 is not identical to the process disclosed in the contested patent. In the present case therefore, the burden of proof remains with the respondent.

3.3.4 In term of the nature of the product of example 8 of D14, it is stated that the process yields a fraction enhanced in sialic acid content (paragraph [0053]). The product of this process is optionally desalted and dried to yield a (commercially available) dry powder product, designated W4733 (paragraph [0054]). The protein content, sialic acid content and amino acid profile of that product is displayed in table 10 (page 8). The listed ingredients include threonine, serine and sialic acid ("SA" in table 10 of D14). Thus the product of example 8 comprises amino acids "R", and sialic acid as monosaccharide "Sac" as required in claim 1. There is however no indication from table 10 of D14 that W4733 comprises glycosylated amino acids and peptides of the general formula R_nSac_m meeting the requirements recited in claim 1 for the values of "n" (1-10) and "m" (2-4), and the associated provisos in terms of the presence of threonine and/or serine residues. There is thus no explicit indication in D14 that the product of example 8 fulfills the requirement of contested claim 1 in terms of comprising glycosylated amino acids and peptides of the general formula R_nSac_m.

3.3.5 In addition to the evidence lacking in D14, it is credible that the process of the contested patent yields a product distinct from that produced in example 8 of D14. The first step of the process in example 8 is "partial proteolytic hydrolysis" (paragraph [0053]). No information is provided in D14 regarding how this hydrolysis was performed, e.g. whether it was performed with an enzyme, or, for example, an acid. In contrast, as set out above, the process of the contested patent requires in a first step hydrolysis with an exoprotease and an endoprotease (claim 7), both proteolytic peptidase enzymes.

3.3.6 The appellant submitted that the definition of R_nSac_m in claim 1 was a consequence of the way in which the process is carried out: endoproteases hydrolysed CGMP by breaking the peptide bonds of non-terminal amino acids, while exoproteases cleaved peptide bonds at or close to the amino- or carboxy-terminal end of the protein. The combination of said enzymes provided the highest chance of degrading CGMP into its amino acid monomers and smaller oligomers (along with a glycosylated side chain), as specified in claim 1.

3.3.7 The board finds the appellant's explanation entirely reasonable and credible. Furthermore, nanofiltration to retain a fraction having a molecular weight of between 1000 and 2000 Daltons, employed in the second step of the process of the contested patent (claim 7), is a purification method based on molecular size. In contrast, anion chromatography, employed as the second step in the process of example 8 of D14, functions by separating molecules on the basis of charge. Thus, not only the first step, but also the second step of the process of example 8 of D14 provides a justification for the conclusion that the product of example 8 of D14

is different from that resulting from the process of the contested patent.

3.3.8 In view of the foregoing, it must be concluded that subject-matter of claim 1 is distinguished from D14 **at least** in that the latter does not disclose an oligosaccharide ingredient having glycosylated amino acids and peptides of the general formula R_nSac_m.

3.4 Problem solved

3.4.1 Example 2 of the patent describes the preparation of the claimed oligosaccharide ingredient. Table 1 shows the mass balance and sialic acid ("NeuAc") content during and after the filtration step. Here, the desired retentate product of the filtration (c.f. claim 7) comprised 14.4 mass% sialic acid, representing an enrichment compared to the 7.5 mass% sialic acid comprised within the starting material. Thus, the process of claim 7 leads to enrichment of sialic acid in the CGMP derived product. As set out above, the process of D14 leads to a different sialic acid-enriched, CGMP-derived product.

3.4.2 It follow that the objective technical problem underlying the subject-matter of claim 1 is the provision of an alternative CGMP-derived oligosaccharide ingredient enriched in sialic acid.

3.5 Obviousness

3.5.1 The solution to the problem outlined above is the provision according to claim 1 of an oligosaccharide ingredient.

3.5.2 As set out above, the board will examine whether in the light of the technical problem it would have been obvious for the skilled person to prepare an oligosaccharide ingredient comprising at least glycosylated amino acids and peptides of the general formula R_nSac_m.

3.5.3 According to the respondent, the process features of the contested patent addressed above would have been derivable by the skilled person from the disclosures of D4, D7, D9 or D10. Accordingly, the skilled person would have adjusted the process of D14 in order to solve the problem posed, thus arriving at the subject-matter of claim 1. These documents are addressed individually in the following.

3.5.4 D4 is a journal article and concerns the fractionation and characterisation of "casein hydrolysates" using ultrafiltration membranes (abstract). The starting material of the hydrolysis of D4 is a caseinate solution (abstract), which is different from CGMP (patent, paragraph [0006]). The enzymes employed in the hydrolysis, chymotrypsin or trypsin, are both endoproteases (page 259, second paragraph). Thus, for this reason alone, even if the skilled person were to take D4 into account, for which the board also sees no motivation, it would not lead him to the process of the contested patent and thus to the oligosaccharide ingredient of claim 1.

3.5.5 D7 is a patent document, the aim of which is to prepare IPP (IIe-Pro-Pro), a blood-pressure lowering compound (title). D7 discloses that GMP from Kappa-Casein (i.e. the same starting material used in the patent, paragraph [0006])) could be used to make a fraction comprising this compound (page 4, lines 10-21).

According to D7, the relevant composition may also be used in a food product, e.g. for the prevention of obesity (page 6, lines 21-24). As noted by the respondent, D7 discloses the treatment of CGMP with "Flavourzyme", the same exo- and endoprotease employed in the examples of the contested patent (D7, page 12, lines 3-5). However, the aim of D7, the preparation of IPP, is different to that of D14. D7 also states that the choice of enzyme dosage and pH is important to obtain the desired IPP product (page 12, lines 7-10). Furthermore, although nanofiltration is mentioned among other techniques as an optional further technique to purify "bioactive ingredients" (page 13, line 22 - page 14, line 5), it is only in the context of isolating IPP, and not specifically to provide a retentate having a molecular weight of 1000 to 2000 Daltons. More importantly however, even if the skilled person wishing to solve the technical problem underlying claim 1 were to look to D7, it fails to provide any motivation whatsoever to choose any specific process steps in order to solve the problem posed.

3.5.6 D9 is a journal article and concerns enzymatic hydrolysis of lactose (abstract) to recover "biologically active oligosaccharides", followed by nanofiltration. It was found that the hydrolysis significantly improved the efficiency and selectivity of the nanofiltration. Thus D9 reports a preparative recovery of oligosaccharides from human milk using a combination of enzyme treatment and nanofiltration (first page, right hand column, last paragraph). D9 fails to disclose the use of both an exo- and endoprotease as required by the process of the contested patent, nor specifically the separation by nanofiltration to provide a fraction having a molecular weight of 1000 to 2000 Daltons. Thus, for this reason

alone, even if the skilled person were to take D9 into account, it would not lead to the process of the contested patent and thus to the oligosaccharide ingredient of claim 1. Furthermore, even if the skilled person wishing to solve the technical problem underlying claim 1 were to look to D9, it fails to provide any motivation whatsoever to choose any specific process steps in order to solve the problem posed.

3.5.7 D10 concerns carbohydrate purification using ultrafiltration, reverse osmosis and nanofiltration (title), and is concerned with the production of carbohydrate molecules of defined structure such as sialyl lactose, of interest as neutralisers for enterotoxins from certain bacteria (D10, column 1, lines 20-25). Further sialic acid containing carbohydrates are mentioned for treatment of e.g. arthritis, autoimmune diseases, ulcers, etc. (column 1, lines 28-37). D10 is concerned with using nanofiltration or reverse osmosis to purify said compounds from a feed having a contaminant (column 2, lines 48-55). Oligosaccharides comprising Gal, sialic acid and GalNac are mentioned (column 2, lines 55-67). The possibility of using nanofiltration to collect oligosaccharides in the retentate is mentioned (paragraph bridging columns 9 and 10). However, there is no disclosure in D10 of a hydrolysis step, let alone a hydrolysis with an exoprotease and an endoprotease as required by the process of the contested patent. Thus, for this reason alone, even if the skilled person were to take D10 into account, for which the board nevertheless sees no motivation, it would still not lead to the process of the contested patent and thus to the oligosaccharide ingredient of claim 1.

3.5.8 Thus, starting from D14 as closest prior art and seeking to solve the technical problem as set out above, none of D4, D7, D9 or D10 provide the skilled person with the teaching or motivation to arrive to the subject-matter of claim 1 without exercising an inventive step.

3.5.9 It follows that faced with the technical problem as set out above, the incorporation into an oligosaccharide ingredient of glycosylated amino acids and peptides of the general formula R_nSac_m according to contested claim 1 would not be an obvious measure for the skilled person starting from D14 as closest prior art.

Consequently, the subject-matter of claim 1 involves an inventive step. For the same reasons, the subject-matter of dependent claims 2 and 3, of the product of claim 4 comprising the oligosaccharide ingredient of any of claims 1 to 3 and of dependent claims 5 and 6 involves an inventive step.

3.6 Independent claim 7

3.6.1 Although the respondent did not directly argue that independent process claim 7 lacked an inventive step, the objection is implicit given the respondent's view that the differences between the process of D14, example 8, and that of the contested patent were obvious in view of D4, D7, D9 or D10.

3.6.2 Claim 7, as set out above, is directed to a process for producing the oligosaccharide ingredient of *inter alia* claim 1 comprising the steps of hydrolysing caseinoglycomacropeptide with an exoprotease and an endoprotease and subjecting the hydrolysed mixture to

nanofiltration so as to retain the fraction having a molecular weight between 1000 and 2000 Daltons.

3.6.3 Analogously to the technical problem set out above for contested claim 1, the problem underlying claim 7 may be seen as the provision of an alternative process for the preparation of a CGMP derived oligosaccharide ingredient enriched in sialic acid.

3.6.4 For the same reasons provided above with respect to claim 1, there is no teaching or motivation in any of D4, D7, D9 or D10 for the skilled person to adjust the process of example 8 of D14 in the manner described in claim 7 in order to solve this problem.

3.7 It follows that the subject-matter of claim 7 involves an inventive step.

3.8 In view of the foregoing, the ground for opposition under Article 100(a) EPC in combination with Article 56 EPC does not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairman:

N. Maslin M. O. Müller

Decision electronically authenticated