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**Datasheet for the decision
of 13 February 2019**

Case Number: T 1186/16 - 3.3.09

Application Number: 03772878.9

Publication Number: 1568285

IPC: A23L1/30, A61K31/70, A23L1/236,
A61P3/10, A61P3/04

Language of the proceedings: EN

Title of invention:

AGENT FOR INHIBITING RISE IN BLOOD GLUCOSE LEVEL AND FOOD
COMPRISING IT

Patent Proprietor:

Mitsui Sugar Co., Ltd.

Opponents:

Fresenius Kabi Deutschland GmbH
N.V. Nutricia

Headword:

Relevant legal provisions:

EPC Art. 53(c), 54(3), 54(5), 100(a)
RPBA Art. 12(2), 12(4)
EPC R. 116(1)

Keyword:

Claims encompassing non-therapeutic embodiments (Yes)
Novelty (No, all requests)

Decisions cited:

G 0005/83, G 0002/08, T 0292/04, T 1286/05, T 1278/12

Catchword:



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Case Number: T 1186/16 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 13 February 2019

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 18 March 2016
rejecting the opposition filed against European
patent No. 1568285 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman W. Sieber
Members: A. Veronese
 A. Jimenez

Summary of Facts and Submissions

- I. Appeals were filed by the opponents against the decision of the opposition division rejecting the oppositions filed against European patent No. 1 568 285.
- II. With their notices of opposition the opponents had requested the revocation of the patent in its entirety on the grounds under Article 100(a) EPC (subject-matter excluded from patentability, lack of novelty and lack of inventive step), Article 100(b) and 100(c) EPC.
- III. Claims 1 and 3 of the granted patent read:

"1. Use of palatinose in the manufacture of a reducer of blood glucose level increase comprising palatinose as an active ingredient, wherein said reducer is ingested before or after or simultaneously with consuming a foodstuff comprising a carbohydrate having an α -1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides and wherein said reducer reduces an increase in blood glucose level caused by consuming said carbohydrate."

"3. A food material comprising palatinose and a foodstuff composed of a carbohydrate having an α -1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, for use in a method of reducing blood glucose level increase, characterised by having an individual ingest said food material wherein said food material reduces blood glucose level increase caused by consuming said foodstuff."

IV. The documents submitted during the opposition proceedings included, among others:

- D1: EP 1 424 074 A1
- D4: JP 2000-300212 A
- D4a: Machine translation of D4
- D5: B.A.R. Lina et al. Food and Chemical Toxicology, Vol. 40(10), 2002, pp. 1375-1381
- D6: US 4,587,119 A
- D7: JP 63-112963 A
- D17: Palatinose™ in beverages; Beneo Inc.
- D18: Palatinose™ the next generation sugar, Beneo Inc.

V. The decision of the opposition division can be summarised as follows.

The claimed subject-matter did not extend beyond the disclosure of the original application as filed and was sufficiently disclosed.

Claim 1 and 3 related to a therapeutic method for reducing an increase in blood glucose level caused by the consumption of certain types of carbohydrates and were drafted, respectively, in the Swiss-type and Article 54(5) EPC format. As such, they did not violate Article 53(c) EPC and were novel over the prior art, which did not disclose the relevant therapeutic use of palatinose.

The results shown in the patent proved that palatinose induced the therapeutic effect specified in the claims. None of the available prior art documents gave any hint towards the use of palatinose to attain this effect. Thus, the claimed subject-matter involved an inventive step.

D17 and D18 were late-filed and not *prima facie* relevant, and thus not admitted into the proceedings.

- VI. This decision was appealed by opponent I (appellant I) and opponent II (appellant II), which requested that the decision be set aside and the patent be revoked in its entirety. Appellant I also requested that D17 and D18 be admitted into the appeal proceedings.
- VII. In its reply, the proprietor (respondent) requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained on the basis of one of the eight auxiliary requests filed during the opposition proceedings (auxiliary requests 1 to 6 filed by letter dated 9 October 2014 and auxiliary requests 7 and 8 filed by letter dated 22 January 2016). All auxiliary requests contain a claim which corresponds to claim 3 as granted. The respondent further requested that D17 and D18 not be admitted into the appeal proceedings.
- VIII. In a communication issued in preparation for the oral proceedings, the board drew attention to the points to be discussed during the hearing. Oral proceedings took place before the board on 13 February 2019. At the end of the debate, the chairman announced the decision.
- IX. The arguments of the appellants relevant for the decision were as follows:

Claims 1 and 3 related to a method for reducing an increase in blood glucose levels caused by the consumption of certain types of carbohydrates. This effect was not, as such, therapeutic. Neither the claims nor the description of the patent defined a patient group in need of therapeutic treatment. Only

healthy individuals were mentioned. Furthermore, no reference was made to hyperglycaemia, and no evidence was provided that the claimed method was effective for treating this condition. Conversely, the alleged effect could be exploited for non-therapeutic purposes in healthy subjects, e.g. athletes, as evidenced by D4/D4a, D17, D18 and D21. As far as claims 1 and 3 related to these non-therapeutic purposes, they could not be construed as purpose-limited Swiss-type and Article 54(5) EPC claims, and the claimed subject-matter was not novel over D1, D4-D7 and D12, which disclosed compositions comprising palatinose and other carbohydrates as defined in the claims, which were suitable for inducing the effect specified in the claims.

These objections applied to all auxiliary requests.

- X. The arguments of the respondent relevant for the decision were as follows:

The claimed invention aimed at achieving a therapeutic effect in subjects who needed assistance with glycaemic control and were vulnerable to hyperglycaemia. The treatment of healthy patients was not contemplated, because in these patients the glucose level was already controlled by the insulin system. Thus, the claims were to be construed as purpose-limited Swiss-type and Article 54(5) EPC claims, irrespective of the fact that the term "therapy" was not used and that the tests described in the patent were conducted in healthy subjects. The feature requiring palatinose to reduce an increase in blood glucose level caused by the consumption of certain carbohydrates was an essential feature characterising the claimed subject-matter. D1 disclosed compositions comprising palatinose and maltodextrin, which induced lower blood sugar levels

than other commercially available compositions, eg "Glucerna" and "Meibalance". However, the teaching of D1 was that palatinose could be used to replace other carbohydrates which induced bigger increases in glucose levels, when preparing nutritional compositions for patients in need of blood glucose level control. A similar teaching could be found in D4, D17 and D18, describing the use of palatinose in sport drinks, and in D5-D7 and D12, describing foods comprising palatinose. However none of these documents disclosed the idea underlying the claimed invention, to use palatinose as an active agent to modify the metabolism of other carbohydrates and to reduce the glycaemic increase caused by their ingestion. Thus, the claimed subject-matter of the main request and the auxiliary requests was novel.

Reasons for the Decision

1. *Admission of documents D17 and D18*
 - 1.1 D17 and D18 were filed by appellant I (then opponent I) on 17 February 2016, shortly before the oral proceedings before the opposition division and after expiry of the time limit set under Rule 116(1) EPC. The opposition division did not consider these late-filed documents *prima facie* relevant and decided not to admit them into the opposition proceedings. In its statement of grounds of appeal appellant I contested this finding and requested their admission into the appeal proceedings.
 - 1.2 D17 and D18 describe sport drinks containing palatinose and their use for providing sustained energy supply to

athletes and active people practising sports. Since they focus specifically on the use of palatinose in healthy people and discuss more clearly than the other documents on file (e.g. D4/D4a) the non-therapeutic uses of this sugar, D17 and D18 are *prima facie* highly relevant in the context of the contentious issue of how the claims have to be construed and whether the claimed subject-matter is novel over the prior art.

Furthermore, appellant I relied on these documents to contest the decision of the opposition division finding that the claimed subject-matter is novel.

For these reasons, the board saw no reasons to hold these documents inadmissible under Rule 12(4) RPBA, despite the opposition division having previously decided not to admit them into the opposition proceedings. Accordingly, D17 and D18 form part of appellant I's case under Rule 12(2) RPBA.

Main request

2. *The gist of the invention*

2.1 The gist of the invention underlying the patent in suit consists essentially in using palatinose to reduce the increase in blood glucose level caused by the consumption of certain types of carbohydrates. These carbohydrates, which have an α -1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides are, for example, sucrose, wheat flour, starch, dextrin and high fructose corn syrup. As explained in paragraphs [0014] and [0015] of the patent, the invention is based upon the recognition that when palatinose is ingested before, after or simultaneously with these carbohydrates, it can reduce the blood glucose level increase induced by them.

3. *Claim construction*

3.1 Claims 1 and 3 as granted essentially refer to:

- the use of palatinose in the manufacture of a reducer of blood glucose level increases, wherein the reducer reduces the increase of blood glucose level caused by consuming certain specified carbohydrates (claim 1), and
- a food material comprising palatinose and a foodstuff composed of certain types of carbohydrates for use in a method of reducing the blood glucose level increase caused by consuming the foodstuff (claim 3).

3.2 According to the respondent, the invention relates and is limited to a medical use of palatinose. Consequently, claims 1 and 3 have to be construed, respectively, as Swiss-type and Article 54(5) EPC type claims.

3.3 By virtue of a legal fiction, Article 54 (5) EPC acknowledges the notional novelty of substances or compositions even when they are as such already comprised in the state of the art, provided they are claimed for a new use in a therapeutic method of the human or animal body which Article 53(c) EPC excludes as such from patent protection. In such cases the notional novelty is not derived from the substance or composition as such but from its intended therapeutic use (see G 2/08 point 5.10.9 of the reasoning). A similar derivation of novelty applies to Swiss-type claims, i.e. claims drafted in the form "use of substance X for the manufacture of a medicament for

therapeutic application Y". In this case, it is the process of manufacture of the medicament defined in the claims which derives its novelty from the new therapeutic use of the medicament, irrespectively of whether a pharmaceutical use of the medicament was already known (G 5/83 point 21 of the reasoning).

3.4 It is, however, clearly understood that the application of this specific approach to the derivation of novelty can be applied only to claims (under Article 54(5) EPC and Swiss-type claims) relating to the use of substances or compositions in methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body (G 5/83 last sentence of point 21 of the reasoning and G 2/08 points 7.1.1 and 7.1.2 of the reasoning). These criteria have been applied consistently by the boards of appeal (see eg T 292/04, T 1286/05 and T 1278/12). In T 292/04, the contested claim was directed to the use of haloperoxidase in the manufacture of an antimicrobial agent for selectively killing pathogenic bacteria while selectively preserving normal flora. Although it was apparently drawn up in the Swiss-type form, the board found that this claim related not only to therapeutic but also to non-therapeutic applications of that agent, such as the cleaning of contact lenses. As far as this was the case, the claim was not construed as a Swiss-type claim.

3.5 According to the respondent, the inventive concept underlying the invention defined in claims 1 and 3 as granted is inherently therapeutic. Furthermore, since the invention must be practised on the human or animal body, it may not be claimed as a method or a (direct) use but only with claims drawn, as the ones above, to a

manufacturing use or a composition "for use" in a particular method. The requirement that palatinose or the foodstuff containing it reduce blood glucose level increases caused by consuming certain carbohydrates becomes the essential feature characterising the therapeutic method of treatment defined in those claims. The respondent further argued that, when reading the claims, the skilled person would have promptly recognised that the claimed method concerns exclusively individuals vulnerable to hyperglycaemia who require a therapeutic control of blood glucose levels. Since in healthy individuals blood glucose is already controlled by the insulin system, external intervention is not necessary. Thus, in the respondent's opinion, the claims inherently exclude the treatment of healthy individuals and non-therapeutic embodiments.

- 3.6 The board cannot accept the respondent's line of argument. First, fluctuations of glucose blood levels are physiologic, and glycaemia typically increases after consumption of carbohydrates, such as sucrose (table sugar). This natural phenomenon occurs in healthy individuals without being associated to any pathological condition. Furthermore, as evidenced by D17 and D18, controlling glycaemia and preventing sharp increases and subsequent drops in blood glucose levels caused by the ingestion of carbohydrates is advantageous for non-therapeutic purposes. Individuals performing sports rely on carbohydrates as an essential source of energy for physical performance. However, they benefit the most from the consumption of palatinose, which provides a steady and sustained release of glucose in the blood. Unlike sucrose, palatinose does not cause large spikes in blood glucose levels. For this reason palatinose is

included in sport drinks used by athletes to supply a constant stream of energy to the muscles over a long time and, as a result, to enhance endurance performance (D17, see sections entitled "Matching today's athletic expectations using the full potential of functional carbohydrates" and "How exactly can Palatinose™ help athletes go the distance ? "; D18, see sections entitled "Nature premium carbohydrate" and "Palatinose™ - Smart calories for balanced and longer energy"; and D4/D4a, see claims and paragraphs [0010-0012], [0015-0017], [0024-0026] of the machine translation).

- 3.7 The respondent argued that these documents do not disclose, as the opposed patent, the use of palatinose to reduce increases of blood glucose levels caused by other carbohydrates. However, this is irrelevant. The relevant teaching conveyed by these documents is that healthy individuals benefit from a prevention of increases of blood glucose levels caused by the ingestion of carbohydrates and that the achievement of this effect serves non-therapeutic purposes.
- 3.8 Neither the claims nor the opposed patent as a whole have been drafted to limit the claimed invention to a therapeutic method of treatment of the human or animal body. Remarkably, the patent does not mention the words "therapy", "therapeutic treatment", "disease" or "patient". Also none of the diseases or pathological conditions typically caused by or associated with a dysfunction of glucose metabolism, such as diabetes, hyperglycaemia, metabolic syndrome and obesity, are referred to in the patent. All tests reported in the patent were carried out on healthy individuals.

3.9 For these reasons, the respondent's argument that the skilled person would promptly understand that the claimed method is limited to the treatment of subjects requiring a therapeutic control of blood glucose levels and that there would be no reason to treat healthy individuals in which blood glucose is already controlled by the insulin system cannot be accepted. Lastly, the respondent has not provided any argument or evidence indicating that healthy individuals, such as healthy athletes practising sport, would inevitably enjoy a therapeutic benefit from the claimed method. Consequently, claims 1 and 3 encompass uses of palatinose and food materials containing it which are not therapeutic. As far as this is the case, these claims cannot derive their novelty from the allegedly newly discovered technical effect of reducing the blood glucose level increase caused by consuming the specified types of carbohydrates. To this extent these claims are to be understood as directed to (i) the use of palatinose for the manufacture of an agent which is suitable for reducing increases of blood glucose level caused by consuming the types of carbohydrates specified in the claims (claim 1) and (ii) a food material comprising palatinose and a foodstuff composed of those types of carbohydrates, which is suitable for reducing increases of blood level caused by these carbohydrates (claim 3).

4. *Novelty*

4.1 Since a claim drafted like independent claim 3 of the main request is present in all the auxiliary requests on file, the novelty analysis focuses on this claim.

4.2 D1 is a European patent application filed under the PCT on 6 September 2002, i.e. before the earliest priority

date claimed in the opposed patent. It describes a food material comprising palatinose and other carbohydrates such as trehalose, maltodextrin, fructose and processed starch, which have, as specified in the claims of the opposed patent, an α -1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides (D1, tables 1-3 and paragraphs [0024-0025, 52]). D1 teaches that palatinose is hydrolysed at a slower rate than other carbohydrates such as sucrose and that for this reason it can be included in nutritional compositions which do not cause significant postprandial increases of blood glucose. Relying on this teaching, D1 proposes the use of palatinose in food materials to completely or partially replace other carbohydrates that typically induce postprandial increases of blood glucose levels. D1 does not disclose the use of palatinose as an active agent to modify the metabolism of other carbohydrates. In particular, it does not disclose its use to reduce blood glucose level increases caused by other carbohydrates. However, since they comprise considerable amounts of palatinose and the carbohydrates defined in claim 3 of the opposed patent, the food materials described in this document are necessarily suitable for inducing the technical effect specified in this claim. No technical evidence to the contrary has been put forward by the respondent. For these reasons, these food materials fall within the definition of claim 3 of the main request. It follows that the subject-matter of this claim is not novel (Article 54(3) EPC).

- 4.3 D5 describes diets comprising palatinose and sucrose in considerable amounts (abstract and page 1377 last paragraph) whereas D6 discloses foods in the form of biscuits and marzipan comprising palatinose (referred

to as "isomaltulose") in combination with caster sugar or icing sugar (examples 2, 3a, 3b). It was not contested that, as far as the ingredients are concerned, these diets and foods fall within the definition of the food materials specified in claim 3. As such, these diets and foods are suitable for inducing the desired technical effect. Also in this case, no evidence to the contrary was presented by the respondent. Thus, for the reasons already outlined when dealing with D1, the subject-matter of claim 3 of the main request is not novel over the foods described in D5 and D6 (Article 54(2) EPC).

Auxiliary requests 1 to 8

5. *Novelty*

Auxiliary requests 1 to 8 each contains a claim which corresponds to claim 3 of the main request. Thus, for the reasons put forward when dealing with claim 3 of the main request, the subject-matter of these corresponding claims of auxiliary requests 1 to 8 lacks novelty over the foods and the diets disclosed in D1 (Article 54(3) EPC) and in D5 and D6 (Article 54(2) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside
2. The patent is revoked

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated