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Datasheet for the decision of 15 May 2023

Case Number: T 1196/21 - 3.3.09

Application Number: 14808269.6

Publication Number: 3016527

IPC: A23L33/135, A23L33/21, A61K35/74, C12R1/01, A21D13/02, A21D13/04, A23L7/117

Language of the proceedings: EN

Title of invention:

TREATMENT OF OBESITY, THE METABOLIC SYNDROME, TYPE 2 DIABETES, CARDIOVASCULAR DISEASES, DEMENTIA, ALZHEIMER'S DISEASE AND INFLAMMATORY BOWEL DISEASE BY USING AT LEAST ONE BACTERIAL STRAIN FROM PREVOTELLA

Patent Proprietor:

Proprev AB

Opponent:

DuPont Nutrition Biosciences ApS

Headword:

Therapeutic uses of Prevotella strains/PROPREV

Relevant legal provisions:

EPC Art. 83

Keyword:
Main request: sufficiency of disclosure - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1196/21 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 15 May 2023

Appellant: (Patent Proprietor)	Proprev AB Halalid 22 254 40 Helsingborg (SE)
Representative:	Brann AB P.O. Box 3690 Sveavägen 63 103 59 Stockholm (SE)
Respondent: (Opponent)	DuPont Nutrition Biosciences ApS Langebrogade 1 1411 Copenhagen K (DK)
Representative:	DuPont EMEA Langebrogade 1 1411 Copenhagen K (DK)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 10 May 2021 concerning maintenance of the European Patent No. 3016527 in amended form.**

Composition of the Board:

Chairman	M. Ansorge
Members:	A. Veronese
	N. Obrovski

Summary of Facts and Submissions

I. The appeal was filed by the patent proprietor (appellant) against the decision of the opposition division finding that the European patent as amended according to then auxiliary request 9 met the requirements of the EPC.

II. With its notice of opposition, the opponent had requested revocation of the patent in its entirety on the grounds under Article 100(a) (lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.

III. The documents submitted during the opposition proceedings included:

D3: WO 02/07741 A1
D4: WO 2012/089783 A1
D5: WO 2004/009103 A1
D6: WO 2010/122106 A1
D7: WO 2012/142605 A1
D8: P. Kovatcheva-Datchary et al., Cell Metabolism, vol. 22, 2015, 971-82
D21: A. Gonzalez-Chávez et al., Arch. Med. Res., vol. 49(8), 2018, 516-21
D22: K. Alberti et al., Circulation, vol. 120, 2009, 1640-5
D26: I. Salcedo et al., Br. J. Pharmacol., vol. 166(5), 2012, 1586-99
D29: E. Rönnemaa, et al., Diabetologia, vol. 52(8), 2009, 1504-10
D33: H. Zatorski et al., Naunyn-Schmiedeberg's Arch. Pharmacol., vol. 392(11), 2019, 1321-30

D39: S. Grundy et al., Circulation, vol. 109, 2004, 433-8

D40: E. Bonora et al., Diabetologia, vol. 44, 2001, 2107-14

D41: O. Schnell et al., Journal of Interventional Cardiology, vol. 18(6), 2005, 413-6

D42: F. Cosentino et al., European Heart Journal, vol. 41, 2020, 255-323

D43: N. Wærling Hansen et al., International Union of Biochemistry and Molecular Biology, vol. 69(3), 2017, 148-61

D45: F. Wang et al., Front. Aging Neurosci., vol. 10, 2018, Article 376

D49: D. Cibor et al., World J. Gastroenterol, vol. 22(3), 2016, 1067-77

IV. Claim 1 of the patent as granted (main request) reads as follows:

"*1. A product for use in the treatment of obesity, the metabolic syndrome, type 2 diabetes, cardiovascular diseases, dementia, alzheimers disease and inflammatory bowel disease comprising at least one isolated bacterial strain from the species Prevotellaceae, wherein the strain is selected from the group consisting of Prevotella copri and Prevotella ruminicola.*"

V. In its decision, the opposition division found, *inter alia,* that:

- the invention claimed in the main request and in then auxiliary requests 1 to 8 was not sufficiently disclosed because the patent did not disclose the suitability of the claimed composition for treating metabolic syndrome, cardiovascular diseases,

dementia, Alzheimer's disease and inflammatory bowel disease

- the claims of then auxiliary request 9 did not contain added subject-matter; the claimed invention was sufficiently disclosed, was novel over D3 to D6 and involved an inventive step over D7 as the closest prior art

VI. In its statement setting out the grounds of appeal, the appellant contested the opposition division's finding that the invention claimed in the patent as granted was insufficiently disclosed. Furthermore, it filed auxiliary requests 1 to 4 and the following documents:

D50: M. Hjorth et al., Int. J. Obes., vol. 43, 2019, 149-57

D51: M. Gejl et al., Front. Aging Neurosci., vol. 8, 2016, Article 108

VII. The opponent also filed an appeal, but it withdrew it without filing the statement setting out the grounds of appeal. The opponent did not reply to the appellant's statement setting out the grounds of appeal either. After receiving the board's preliminary opinion issued in preparation for the oral proceedings, the opponent (respondent) informed the board that it did not intend to participate at the oral proceedings and that it expected to receive a decision in writing.

The requests

VIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request (the patent as granted) or, alternatively, on the basis of one of auxiliary

requests 1 and 4, filed with the statement setting out the grounds of appeal.

Reasons for the Decision

Main request

1. *Sufficiency of disclosure*

1.1 The board agrees with the appellant that, contrary to the opposition division's finding, the invention claimed in the patent as granted is sufficiently disclosed, as required by Article 83 EPC.

1.2 Claim 1 as granted is formulated in line with Article 54(5) EPC and relates to a product comprising a *Prevotella copri* or a *Prevotella ruminicola* strain for use in the treatment of obesity, metabolic syndrome, type 2 diabetes, cardiovascular diseases, dementia, Alzheimer's disease and inflammatory bowel disease (see point IV, above).

1.3 Under the established case law of the boards, attaining the claimed therapeutic effect is regarded as a functional technical feature of claims for a medical use. In the case of a claim formulated under Article 54(5) EPC, to meet the requirement of sufficiency of disclosure, the therapeutic efficacy of a composition for the claimed therapeutic indication must be credible (see the case law of the Board of Appeal of the European Patent Office, 10th edn., 2022, section II.C.7.2.1).

1.4 The opposition division considered that the patent provided sufficient evidence that the product of claim 1 of the patent as granted was suitable for

treating obesity and type 2 diabetes. It also considered that the effects induced by the tested compositions comprising *Prevotella copri* could be generalised to the *Prevotella ruminicola* strain.

1.5 It found, however, that the subject-matter of claim 1 was not sufficiently disclosed for the treatment of metabolic syndrome, cardiovascular diseases, dementia, Alzheimer's disease and inflammatory bowel disease. In its opinion, the patent did not make it plausible that the claimed composition was suitable for treating these diseases.

1.6 The board comes to a different conclusion. It considers that the experiments described in the opposed patent make it credible that the product of claim 1 is suitable for treating all the diseases mentioned in claim 1.

1.7 The experiments described in Example 1 of the patent show that the administration of barley kernel bread (BB) instead of white wheat bread to healthy human responders induces:

- a decrease of postprandial blood glucose, insulin release and appetite

- an increase of perceived satiety, breath H_2 excretion associated with gut fermentation and an increase of the plasma concentration of GLP-1, GLP-2 and PYY, *i.e.* factors enhancing insulin sensitivity and reducing food intake and gastric mobility

1.8 The experiments described in Example 2 of the patent show that the administration of BB to the aforementioned group of human responders:

- increases the level of *Prevotella* species

- increases the level of succinate, which is a major metabolite of fermentation by *Prevotella* species

1.9 The experiments in Example 2 of the patent show, in addition, that the inoculation and consequent colonisation of mice intestines with *Prevotella copri* improves glucose tolerance. They also show that *Prevotella copri* prevents the impairment of glucose tolerance induced by *Bacteroidetes thetaiotaomicron*.

1.10 These results are confirmed by D8, which shows that the integration of *Prevotella* strains in mice microbiota decreases postprandial blood glucose and improves glucose tolerance (see abstract and Figure 5b). Furthermore, D50 indicates that a high *Prevotella* to *Bacteroides* ratio correlates with a decrease in body weight and fat loss in humans.

1.11 As submitted by the appellant, these results make it credible that the beneficial physiological effects observed in the aforementioned experiments are due to the increased abundance of *Prevotella* strains in the gut microbiome.

1.12 These results, together, also make it credible that the administration of a composition comprising *Prevotella* strains is not only suitable for treating obesity and type 2 diabetes - as correctly decided by the opposition division - but also the other diseases mentioned in claim 1. This is especially the case when

also taking into account, as submitted by the appellant, that:

- metabolic syndrome is caused and diagnosed by the clustering of metabolic complications, including obesity, raised fasting glucose levels and type 2 diabetes (see D21, D22 and D39)

- the risk of cardiovascular diseases increases in patients affected by metabolic syndrome and decreases by reducing obesity and postprandial glycemia and improving glucose tolerance (see D21, D40, D41 and D42)

- dementia and Alzheimer's disease can be treated using GLP-1 analogues (see D26 and D51) and improving glucose tolerance (see D29, D43 and D45), and a decrease in the amount of *Prevotella copri* in the gut microbiome contributes to the onset of Parkinson's disease

- inflammatory bowel disease (IBD) is associated with endothelial dysfunctions occurring in type 2 diabetes (see D43 and D49) and with decreases in the amount of *Prevotella* in the gut microbiome; furthermore, IBD can be improved by GLPs (D33)

1.13 Taking into account the effects observed in the experiments described in the patent, and their relevance, which was set out by the appellant and was not disputed, it is credible that the claimed composition is suitable for inducing the therapeutic benefits mentioned in claim 1 of the patent as granted.

Thus, the claimed invention is sufficiently disclosed, and the ground for opposition under Article 100(b) EPC does not prejudice the maintenance of the patent.

2. *Further issues*

2.1 The opposition division decided that the claims of the patent as granted do not contain added subject-matter.

2.2 It also decided that the subject-matter of then auxiliary request 9 fulfilled the requirements of novelty and inventive step over the cited prior-art documents. The opponent has not provided any reason why the opposition division's conclusions on these issues should not apply to the subject-matter of the claims as granted, and the board does not see any reason either.

2.3 The opposition division's finding that the subject-matter of then auxiliary request 9 is novel because D3 to D6 do not directly and unambiguously disclose *Prevotella ruminicola* apply equally to the claims of the main request. The fact that more diseases are mentioned in claim 1 as granted is irrelevant for the aforementioned novelty finding.

2.4 The opposition division's finding that the subject-matter of then auxiliary request 9 involves an inventive step over D7 because D7 does not provide any suggestion to select *Prevotella* strains for treating type 2 diabetes and obesity applies *mutatis mutandis* to the claims of the main request. D7 relates, like claim 1 of then auxiliary request 9, to the treatment of type 2 diabetes and obesity. The fact that claim 1 of the main request mentions other diseases in addition to type 2 diabetes and obesity does not render the teaching of D7 closer to the claimed subject-matter.

Consequently, even if more diseases are claimed, the opposition division's finding that the claimed subject-matter involves an inventive step remains applicable.

3. In view of the above, the main request is allowable.

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:

M. Schalow M. Ansorge

Decision electronically authenticated