Internal distribution code:

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

Datasheet for the decision of 20 September 2017

Case Number: T 1452/16 - 3.3.01

Application Number: 06819802.7

Publication Number: 1954808

IPC: A23C9/12, C12N9/38

Language of the proceedings: EN

Title of invention:
Enzyme preparation yielding a clean taste

Patent Proprietor:
DSM IP Assets B.V.

Opponents:
DuPont Nutrition Biosciences ApS
NOVOZYMES A/S

Headword:
Lactase preparation/DSM

Relevant legal provisions:
EPC Art. 54(2), 56

Keyword:
Novelty - public prior use - burden of proof
Inventive step - (no)

Decisions cited:
G 0001/92, T 0952/92, T 0472/92, T 0782/92, T 0946/04, T 1457/09, T 2048/12, T 2068/15, T 0609/02, T 0301/94, G 0002/88, G 0001/12

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1452/16 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 20 September 2017

Appellant I: (Patent Proprietor)	DSM IP Assets B.V. Het Overloon 1 6411 TE Heerlen (NL)
Representative:	van Grieken-Plooster, Izabella Johanna DSM Intellectual Property P.O. Box 4 6100 AA Echt (NL)
Appellant II: (Opponent 1)	DuPont Nutrition Biosciences ApS Langebrogade 1 1411 Copenhagen K (DK)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Appellant III: (Opponent 2)	NOVOZYMES A/S Krogshoejvej 36 2880 Bagsvaerd (DK)
Representative:	Wichmann, Hendrik Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstraße 2 81541 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 April 2016 concerning maintenance of European patent No. 1954808 in amended form**

Composition of the Board:

Chairman	A. Lindner
Members:	T. Sommerfeld
	M. Blasi

Summary of Facts and Submissions

I. European patent No. 1954808, based on European patent application No. 06819802.7, which was filed as an international patent application published as WO 2007/060247, was granted with 20 claims.

Claim 1 as granted read as follows:

"1. Process to produce a dairy product which comprises using a preparation of a neutral lactase from *Kluyveromyces* which comprises less than 30 units arylsulfatase activity per Neutral Lactase Unit (NLU) of lactase activity."

Independent claim 17 as granted read as follows:

"17. Use of a preparation of a neutral lactase from *Kluyveromyces* which comprises less than 30 units arylsulfatase activity per Neutral Lactase Unit (NLU) of lactase activity, for producing a dairy product."

II. Two oppositions were filed against the granted patent, both opponents requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC), lack of sufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

III. By an interlocutory decision announced at oral proceedings, the opposition division decided that the third auxiliary request filed as sixth auxiliary request with letter of 25 February 2016 met the requirements of the EPC (Articles 101(3)(a) and 106(2) EPC).

The opposition division considered that the claim sets according to the main request fulfilled the requirements of Articles 123(2) and 83 EPC but not those of Article 54 EPC. It also concluded that the first and second auxiliary requests did not comply with Article 54 EPC.

IV. All parties lodged an appeal against that decision.

V. With its statement of grounds of appeal, appellant I (patent proprietor) requested that the decision be set aside and that the patent be maintained on the basis of the main request or, alternatively, on the basis of the auxiliary requests on file, all filed on 25 February 2016.

VI. With its statement of grounds of appeal, appellant II (opponent 1) requested that the decision be set aside and the patent revoked in its entirety.

VII. With its statement of grounds of appeal, appellant III (opponent 2) requested that the decision be set aside and the patent revoked in its entirety. It also requested acceleration of proceedings in view of pending national proceedings, requested hearing of a technical expert and offered two witnesses in support of the allegations of a public prior use.

VIII. Replies to the grounds of appeal were submitted along with a number of further submissions and documents.

IX. The board issued summons to oral proceedings, which were scheduled for 19 to 21 September 2017. It also sent a communication summarising the main issues of the file.

X. Further letters were sent from all parties, and new documents were submitted.

XI. Oral proceedings before the board took place on 19 and 20 September 2017. During the oral proceedings, appellant I withdrew the pending auxiliary requests 1 and 2. At the end of the oral proceedings, the chairman announced the board's decision.

XII. The **main request** comprises 12 claims, of which independent claims 1 and 9 are identical, respectively, to granted claims 1 and 17 (granted claims 6 and 10 to 16 having been deleted).

In **auxiliary request 3**, the independent claims of the main request were amended by insertion of the features "... wherein said dairy product is UHT milk and said lactase is an intracellular produced lactase". This request corresponds to the sixth auxiliary request filed on 25 February 2016, which the opposition division found to meet the requirements of the EPC.

In **auxiliary request 2'**, the independent claims of the main request were amended by restriction to "UHT milk".

In **auxiliary request 3'**, the independent claims of the main request were amended by replacing the feature "less than 30 units arysulfatase activity" by "less than 20 units arylsulfatase activity".

In **auxiliary request 4**, the independent claims of the main request were amended by insertion of the feature "... wherein said lactase is an intracellular produced lactase".

In **auxiliary request 7**, the independent claims of the main request were amended by replacing the feature "less than 30 units arysulfatase activity" by "less than 20 units arylsulfatase activity" and by the insertion of the feature "wherein said lactase is an intracellular produced lactase".

In **auxiliary request 8**, the independent claims of the main request were amended by insertion of the features "wherein said lactase is an intracellular produced lactase and wherein said lactase is a *K. lactis* lactase".

XIII. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D1 Kim C.S. et al. 2003, Biotech. Lett. 25, 1769-74
D19 Mittal S.B. et al. 1991, Australian Journal of Dairy Technology 46, 46-48
D32 US 2006/0003051
D34 WO 02/060268
D47 English version of Food Chemicals 2003, 221, 96
D48 Declaration of Mr T. Obata 2009 (English translation), with annexed experimental data
D49 Declaration of Mr T. Obata 2013
D50 Declaration of Mr S. Shiotsu 2014, with exhibits 1 to 6
D51 Amano product specification sheet for "Lactase Y Amano L", 16 January 2003 (English version)
D52 Declaration of Mr T. Saito 2013, with exhibits 1 to 12 including further declarations
D65 Mahoney R.R. 2002, in Encyclopedia of Dairy Sciences, ed. Rogisnki H. et al., 907-914
D68 Brewington C.R. et al. 1973, J. Agr. Food Chem. 21(1), 38-39

D73 Kim J.H. et al. 2004, Appl. Microbiol. Biotechnol. 63, 553-559
D79 Memo DSM rework of D11, dated 19 December 2011
D80 Memo DSM rework of D11, dated 19 March 2015
D90 Urbach G. 1997, Intern. J. Dairy Technol. 50, 79-89
D108 Declaration of Dr Dekker, dated 8 February 2016
D115 Memo DSM rework of D5, dated 7 February 2016
D120 Gürsoy and Kinik 2002, J. Engineer. Sci. 9, 79-88
D160 US 4853246
D169 Declaration of Dr Skov, dated 31 August 2016, with exhibits 1 to 4
D170 Declaration of Dr Skov, dated 1 September 2016, with exhibits 1 to 5
D171 Declaration of Ms S. Yoshida, dated 19 August 2016, with annexes 1 and 2
D172 Declaration of Mr T. Katagiri, dated 10 August 2016, with annexes 1 and 2
D174 Declaration of Professor Hankemeier, dated 8 September 2016, with annexes 1 to 3
D178 Email exchange between Amano and customers
D179 Amano's website (captures Aug. 2003 - Oct. 2004)
D180 Declaration of Mr Tamagawa, dated 18 January 2017, with exhibits 1 to 4
D181 Takao T. 2001, in Practical knowledge on milk and dairy products, chapter 3, 83-105 (English translation D181A and D181B)
D187 Information with respect to milk in Japan
D191 Declaration of Professor de Jong, dated 21 April 2017, with annexes 1 to 7
D195 Email Hoyng Rokh Monegier to Brinkof, dated 30 March 2017
D198 Declaration III of Mr Tamagawa, dated 10 August 2017, with exhibit 1

XIV. Appellant I's submissions, in so far as they are relevant to the present decision, may be summarised as follows:

Novelty (all requests)

It was not contested that Lactase Y Amano L, i.e. the Amano lactase, was publicly available, but commercial availability as such was not sufficient to establish lack of novelty: analysability and reproducibility, as required in G 1/92, were not given. As shown in D108 and not contested by the opponents, it was not possible to identify arylsulfatase in the Amano lactase preparation using structural analysis methods. Testing of arylsulfatase activity, while possible at the priority date, required that the assay be specifically chosen, with deliberate choice of outside conditions, and would only be performed with hindsight: moreover, arylsulfatase activity was an extrinsic property. The claimed ASU/NLU ratio, if at all fulfilled by the Amano lactase, was a hidden property which was not available to the skilled person. Even if an impurity might be considered intrinsic to the composition, it was not available to the skilled person if it could not be identified, i.e. was not analysable: T 2048/12 taught that G 1/92 should not be read in such a way that impurities too were considered part of state of the art. In view of the many possible impurities of enzyme preparations, the skilled person would have to use thousands of assays to render the product reproducible, which would be an undue burden: therefore compositional analysis rather than activity assays should be used. A prior use also had to be reproducible, and the teaching of the patent could not be used to enable the prior art (T 1457/09). The Amano lactase was however not reproducible, without the patent's knowledge, in

respect of the claimed ratio. There was hence a clear link between analysability and reproducibility. This view was in line with inter alia T 946/04 and T 2068/15, while T 301/94 related to a different case, where analysability (which was structural) was considered to be given. The property was not available and the product could not be made: the Kluveromyces strain was not publicly available and the process to produce the lactase was unknown ("unique fermentation process"). The ratio was not an unusual parameter, because it merely required common assays, once it was known what was present in the composition; it was not a newly defined parameter. Whether different assays could produce different results was not a problem, because the skilled person would always rely on the assay of the patent (not on the one of D73) and rule out interpretations that did not make technical sense. The assays of the prior art to test ASU were used for preparations that mainly consisted of arylsulfatase, e.g. D32. As to the experimental data provided by the opponents, the results of D48 were not verifiable, because the raw data was not available and appellant I had had no access to it (D195); it was also not apparent that they were statistically significant (D174), and there were inconsistencies between the ratios measured in D48 and in D170. The stability experiments were not conclusive because they used a starting material with a ratio already falling within the claim. As to the use of the Amano lactase for the production of a dairy product, it had not been proven that the preparation used and sold had the claimed ratio; none of the prior-art documents relating to the Amano lactase disclosed the ASU/NLU ratio. The conversion of lactose mentioned in D51 could not be considered as a process for production of a dairy product. As regards the production of the Pokka coffee-

milk drink, it was not clear that the process had been publicly disclosed, and it was also not known which lactase batch had been used.

As to auxiliary request 3, there was no disclosure in the prior art for the use of the Amano lactase in the production of UHT milk. UHT milk did not encompass UHT pasteurised milk, which needed to be refrigerated and had a shelf life of a few weeks, while UHT milk could be kept at room temperature with a shelf life of months (D191 and Annexes; patent, paragraphs [0011] and [0029]). Disclosure of the genus "milk" in D52 did not take away the novelty of the species "UHT milk". UHT milk constituted at the most 5% of the milk consumed in Japan (D187). As to the alleged public prior use by Pokka, there was no production of UHT milk in the process, nor did the process make use of UHT milk: the long shelf life of the Pokka product (as referred to in D171, paragraph 10) was simply due to UHT treatment at the end of the procedure. The designation "UHT milk" was clear in the art, having a well-defined meaning which ruled out UHT pasteurised milk; it was not identical to "UHT processed milk". While UHT milk implied sterile packaging, this did not have to be stated in the claim, as it was implicit. The Pokka's process was not public, as confirmed by the fact that the process sheet had been redacted. Between Pokka and Amano there was a tacit agreement of confidentiality, as usual in supplier-producer business relationships.

As to auxiliary request 3', a ratio of less than 20 further contributed to novelty. As apparent from D198, exhibit 1, right column, at least two tested products had a ratio above 20, so that not all Amano lactase samples fell within the claim. There was thus no

unambiguous disclosure that a batch with a ratio of less than 20 was used in a process as claimed.

Inventive step (auxiliary requests 3 and 2')

Starting from D19, the technical problem would be the production of lactose-free UHT milk with less off-flavour despite long storage time. The skilled person would have no motivation to remove arylsulfatase from the lactase preparations, because D19 clearly stated that proteases were the contaminants of interest. Many other contaminants would be present and there was no pointer, without hindsight, to arylsulfatase. In fact, D120 disclosed a whole myriad of potential off-flavour causes, and the presence of arylsulfatase could not be detected in the lactase preparations; moreover, p-cresol was not associated with one type of off-flavour but rather caused different types of off-flavour. While D19 emphasised the need for highly purified lactase preparations, it did not require 100% purification and did not aim at arylsultafase. The purification protocols of the prior art aimed at removing proteases and would not lead to a lactase preparation with the characteristics as defined in the claim, because arylsulfatase was not readily separated from lactase (as apparent from the examples of the patent): e.g. Maxilact®, which was described as "highly purified" (D160, column 4), still had a high ASU/NLU ratio. D79, D80, D108 and D115 all demonstrated that the purification protocols of the prior art would not lead to an ASU/NLU ratio of less than 30. D108 showed that even the most purified lactase still contained about ten contaminant proteins and that arylsulfatase could not be detected. None of the documents mentioning arylsulfatase and/or p-cresol as cause of off-flavour (D120, D68, D90) was related to lactase preparations,

so they did not provide any incentive to reduce arylsulfatase in lactase preparations. Combination of D19 with D34, which did not relate at all to lactase preparations but rather to a food additive which was not even an enzyme, required hindsight. As to the Amano lactase, this was just one among several possible enzymes, and there was no teaching that it was pure or even highly purified or that it did not cause off-flavour.

XV. Appellants II and III's arguments, in so far as they are relevant to the present decision, may be summarised as follows:

Novelty (all requests)

The Amano lactase was publicly available before the priority date, and all samples tested had been shown to have an ASU/NLU ratio below 30 (D52, D48). Although tested only months later, the stability studies reported in D180 and D198 showed that the ratio remained constant, below 30. This was also confirmed in D50 (table 1 at section 11). These results were obtained not only with the patent's assay but also with the prior-art assay of D73 (D170, section 21). Since the ASU/NLU ratio was an unusual parameter, it was incumbent on the patentee to establish that it distinguished the claimed subject-matter from the prior art; an unusual parameter should not serve to render a prior-art product novel, as was stated in G 1/92, Reasons 2.1. Otherwise, since analytical techniques continuously improved, it would always be possible to render known products novel by simply defining new parameters, through the use of new assays. Referring to extrinsic characteristics, G 1/92 gave examples falling within the scope of application of G 2/88, which was

not the case here, since there was no effect mentioned in the claim other than production of a dairy product, which was the same as that of the prior art (D47, D52) and comprised all reaction substrates (including those for arylsulfatase) without requiring new outside conditions. Purity was an intrinsic characteristic of the composition, and part of its definition. There was no need for a motivation for analysing (G 1/92, paragraphs 2, 2.1), and it was not necessary to have a complete analysis of the product; rather, it was enough to identify an embodiment that fell within the scope of the claim (T 952/92). Since the claimed product was not defined structurally but rather functionally, it was this functional parameter that had to be analysed; therefore the findings of D108 were irrelevant. It also made more technical sense to look for the enzyme activity rather than for the presence of the enzyme as a contaminant, since an enzyme could be present but inactive. The question of undue burden was relevant only to reproducibility, not to analysability, which only required the skilled person to be able to analyse with techniques available at the time (D73, described as "standard assay" in D32, paragraph [0024]); hence it would not be an undue burden to have to look through all possible activities, which in any case were only two enzyme activities. As to reproducibility as required by T 952/92, it was not necessary to reproduce the enzyme of the prior art, but only to recreate an enzyme preparation that fulfilled the terms of the claim. For this, conventional methods had to be used (as acknowledged in the patent, paragraph [0045], and demonstrated in D169, section 11). The burden of proof did not lie on the opponents, because the enzyme was publicly available. There was evidence for Pokka's use in dairy processing, as confirmed by D171 (paragraphs 9 and 10), and such use was not bound to confidentiality.

That at least one of the tested samples in D48 was sold to Pokka was shown by D52, exhibit 12; one embodiment falling within the claim was all that was required for lack of novelty; even if the ratio was not known at the time, this was an inherent property. Product specification sheet D51, which indicated the use of the Amano lactase, was made available to the public on Amano's website before the priority date and distributed by Amano to its customers and potential customers (D52, section 6).

Regarding auxiliary request 3, either the term "UHT milk" was unclear or else the reference to milk in D51 also included UHT milk. This document was mostly directed to the Japanese market, and UHT milk was the most consumed milk in Japan, as evidenced by D181. The term "UHT milk" merely encompassed milk that was submitted to UHT treatment, either UHT sterilised milk or UHT pasteurised milk: hence it encompassed both items 3 and 4 mentioned in D181, page 86, and was not restricted to shelf-stable milk, which required not only UHT treatment but also aseptic packaging (which was not in the claim). The patent did not provide any definition of UHT milk, and from the different Annexes of D191 it was apparent that there were many different definitions of UHT, which varied from country to country. Since the term was inherently unclear, it could not serve to distinguish over the prior art. Moreover, Pokka's preparation was a UHT milk product. Exhibit 7 of D52 taught in section 9 that UHT milk from cows was used in the Pokka product; this was confirmed in D172. Also, D171 stated that the lactase was for use in UHT milk and that such use was publicly known, with no secrecy obligation, as usual in the context of a commercial collaboration between supplier and producer.

The final coffee-milk product was not UHT milk, but UHT milk was produced as an intermediate product.

As to auxiliary request 3', the ratio of at most 20 did not impart novelty, because all tested lactase samples in D48 fulfilled this parameter (Table). Even if multiplication by a factor of 5 was arguably needed as alleged by the patent proprietor, still only two values would be above 20. Moreover, the lots which were delivered to Pokka corresponded to samples having a ratio of less than 20, even upon multiplication by 5.

Inventive step (auxiliary requests 3 and 2')

The closest prior art was the Amano enzyme, which was disclosed for use in milk in general (D51). To use the same enzyme for treatment of UHT milk would be an obvious extension of the use of the product. Even starting from D19 as closest prior art, this document taught to prepare a very pure preparation in order to avoid off-flavours. Prompted by D19 (and by D65) to use very pure preparations, the skilled person would turn to the Amano lactase, which is disclosed in D51 as having a regulatory position GRAS, i.e. safe for food, and would thus also arrive at an enzyme preparation fulfilling the claim requirements. A further alternative would be to combine it with document D34, which also related to the same problem of reducing off-flavour arising from milk additives of microbial source and taught formation of p-cresol as a cause of off-flavour. D34's teaching to use denaturation of the gellan gum preparation would of course be unsuitable in the context of an enzyme preparation, so the skilled person would immediately be aware that the suitable alternative would be further purification, with conventional purification methods, with the purpose of

removing arylsulfatase, which could be assessed by measuring arylsulfatase activity or using an odour or flavour test.

XVI. Appellant I requested that the decision under appeal be set aside and the patent maintained on the basis of the claims of the main request filed on 25 February 2016, or alternatively that the other appellants' appeal be dismissed (i.e. that the patent be maintained on the basis of auxiliary request 3 filed as auxiliary request 6 on 25 February 2016), or further alternatively that the patent be maintained on the basis of the claims of auxiliary request 2' or 3' filed as auxiliary requests 2 and 3 on 25 February 2016, respectively, or further alternatively on the basis of the claims of auxiliary request 4, 7 or 8 filed on 25 February 2016.

Appellants II and III requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

Reasons for the Decision

1. The appeals are admissible.

2. With its notice of appeal and statement of grounds of appeal, appellant III requested acceleration of the appeal proceedings, in view of pending national proceedings. On the basis of the documentary evidence subsequently submitted by appellant III and in the absence of any objections to this request by any of the other parties, the board decided to accelerate the present proceedings.

3. Appellant III had requested, in its written submissions and again at the oral proceedings, that the board should first deal with the ground for opposition under Article 100(b) EPC before turning to the grounds under Article 100(a) EPC because the board's decision on insufficiency would have an impact on the discussion of novelty and inventive step.

The board notes that there is no right of a party to have oral proceedings conducted by the board in a particular manner. It is up to the board to decide what points are to be addressed during the oral proceedings, and in which order. In this respect the board is guided by Article 15(6) RPBA, which stipulates that the board must ensure that, as a general rule, each case is ready for decision at the conclusion of the oral proceedings. Self-evidently, the board is, pursuant to Article 113(1) EPC, under the obligation to give the parties the opportunity to present their comments on all the grounds or evidence on which it will base its final decision. The various grounds for opposition under Article 100(a) to (c) EPC which might be prejudicial to the maintenance of a granted patent are separate ones, and the board considered it most appropriate to start the discussion at the oral proceedings with the topic of the alleged public prior use concerning the product Amano lactase.

4. Main request

Novelty over the alleged public prior use of "Lactase Y Amano L"

4.1 Several lactase preparations from Kluyveromyces, and in particular from K. lactis, were known and available at the priority date (patent, paragraphs [0008] and

[0023]; D1), K. lactis being the major commercial source of lactase, according to D1 (page 1769, left column, lines 1 to 3: β-galactosidase is lactase; see patent, paragraph [0003]). These lactases were known to be neutral and intracellularly produced (patent, paragraph [0008]), but there was no information at the priority date as to the presence of arylsulfatase in these preparations, let alone concerning the ratio of arylsulfatase activity (ASU) and lactase activity (NLU).

4.2 One such lactase preparation was "Lactase Y Amano L" (in the following also referred to as "the Amano lactase"), which was accepted by all parties to have been on the market prior to the priority date of the patent in suit (cf. minutes of the oral proceedings before the board, page 3). Evidence for the commercial availability of this product is present on file in the form of:

- D47, which is page 96 of the Japanese journal Food Chemicals 221, September 2003 (English translation), listing available enzymes, including distributors, manufacturers and applications; among the listed enzymes is "Lactase Y Amano L", obtained from Kluyveromyces lactis and described as suitable for "degradation of lactose, dairy processing";
- D51, the Amano product specification sheet in English for "Lactase Y Amano L", dated 16 January 2003, confirming that it is a neutral lactase from K. lactis (first paragraph), able to hydrolyse lactose in milk (second paragraph);
- D52, and accompanying documentary evidence in the form of exhibits, which consists of a declaration of Mr Saito, employee of Amano Enzyme Inc. since 2006 (Exhibit 1), wherein it is stated that the enzyme, which was developed by Amano with Nagase

ChemteX Corporation, has been sold since at least 2003 (section 4); exhibit 2 is D51; exhibit 3 is also a product specification sheet, originally in Japanese, dated 25 June 2003; exhibit 5 is the Japanese publication corresponding to D47.

4.3 There is no documentary evidence published before the priority date that the Amano lactase preparation had an ASU/NLU ratio below 30, as required by claim 1. There is however post-published evidence, in the form of declarations accompanied by experimental results, that Amano lactase batches offered for sale before the priority date had such a ratio: D48 and D49 (both declarations by Mr Obata, employee of Nagase ChemteX Corporation, dated 4 March 2009 and 19 December 2013, respectively). D48 shows the results, obtained on 20 December 2007, of experiments determining the ASU/NLU ratio of Lactase Nagase F (which, according to D49, section 3, is the Nagase internal designation for the Amano enzyme; see also D52, section 16 and exhibit 12), using conserved samples from batches which had been manufactured between 22 May 2003 and 11 December 2006 (D48, Table; D49, section 4). D49 further states, in the last two lines of section 8, that the experiments were performed "in full accordance with the assay provided on pages 29-30 of WO 2007/060247", i.e. of the patent application forming the basis for the patent in suit. The results of D48 (Table) show that all nine samples tested, of which six had been manufactured before the priority date, had an ASU/NLU ratio between 0.3 and 6.6, i.e. well below 30, in fact below 10.

4.4 According to Enlarged Board of Appeal opinion G 1/92, OJ EPO 1993, 277, two preconditions have to be fulfilled by a product which is as such available to the public in order to be considered state of the art:

analysability and reproducibility. Where it is possible for the skilled person to discover the composition or the internal structure of the product and to reproduce it without undue burden, then both the product and its composition or internal structure become state of the art (G 1/92, supra, Reasons 1.4). G 1/92 moreover clarifies that there is no additional requirement that "the public should have particular reasons for analysing a product put on the market, in order to identify its composition or internal structure. According to Article 54(2) EPC the state of the art shall be held to comprise everything made available to the public. It is the fact that direct and unambiguous access to some particular information is possible, which makes the latter available, whether or not there is any reason for looking for it" (G 1/92, supra, Reasons 2). Decision T 952/92, OJ EPO 1995, 755, further clarifies that: "Information as to the composition or internal structure of a prior sold product is made available to the public and becomes part of the state of the art in the sense of Article 54(2) EPC if direct and unambiguous access to such information is possible by means of known analytical techniques which were available for use by a skilled person before the relevant filing date" (T 952/92, supra, Headnote II). It also confirms that: "The novelty of a claimed invention is destroyed by the prior disclosure (by any means) of an embodiment which falls within the claim. The possibility of a complete analysis of a prior sold product is not necessary. The novelty of a claim is destroyed if an analysis of a prior sold product is such as to inform the skilled person of an embodiment of the product which falls within the claim" (T 952/92, supra, Headnote IV); and it goes on to explain that this requirement does not imply that "a complete analysis of

a prior used product must be possible, so as to enable an exact reproduction of such product, in order to destroy the novelty of the claimed product" (T 952/92, supra, Reasons 2.3).

4.5 In view of the evidence available on file, the board is satisfied that the preconditions of analysability and reproducibility, as required by Enlarged Board opinion G 1/92 and decision T 952/92 supra, are fulfilled by the Amano lactase. D170 shows that the claimed ASU/NLU ratio could be analysed in a sample of Lactase Nagase F (corresponding to the Amano lactase, see section 4.3 above) by methods available for use by a skilled person before the relevant filing date (D170, sections 19 to 23, using the method of D73). Moreover, reproducing an enzyme with the characteristics as claimed would only require conventional purification methods, as acknowledged by the patent (paragraph [0045]), coupled with available methods for measuring ASU activity (D73), as demonstrated in D169 (section 11).

4.6 Appellant I contested the validity of the results presented in D48 and of the conclusions drawn therefrom by the opponents. The board however is not convinced by appellant I's arguments. The details given in D48 are considered sufficient, being certainly not less than what is given in the patent (compare to patent, Examples 2 and 7). Despite the lack of statistical evaluation (as argued in D174), the board considers that D48's results undoubtedly demonstrate that the tested Amano lactase samples have an ASU/NLU ratio within the claimed range. It is also to be noted that the claim does not impose any further limitations as to the ratio, neither in what concerns the measurement method nor with regard to statistical significance. Moreover, D170 confirms the results of D48 in relation

to a later sample, "Lactase Nagase F (batch 4449363)" (D170, sections 19 to 21; see also D50, section 11, especially Table 1), both using the assay of the patent and using a prior-art assay disclosed in D73 (D170, section 21): the difference in the results obtained for the same sample in D50 and in D170 may be due to the different dilutions used, while any further small degree of variation observed between the measurements is considered acceptable in biological assays. The stability studies displayed in D180 and D198 satisfactorily show that even after 30 months of sample storage at 5°C, i.e. as disclosed in D49, section 4, in relation to the sample of D48, there was no significant change in the measured ASU/NLU ratio (D198, sections 4 and 5). Contrary to appellant I's arguments, the board finds these stability studies conclusive and does not see the need for it to be demonstrated that preparations with a starting ratio higher than claimed would not with time change to a ratio falling within the claim. Hence the board is satisfied that the values for the ASU/NLU ratio reported in D48, which were measured between 12 and 55 months after manufacture of the batches, can be taken as the values of the ASU/NLU ratio of the batches at the date of manufacture. It follows that at least six batches of the Amano lactase with a ratio below 30 were manufactured before the earliest priority date of the patent; at least two of them (batches 2463850 and 2470983) were also sold, upon order placement, to the "End user: Pokka Corporation" and delivered to Pokka's toll-manufacturer Sanwa Canning company before the priority date (see D52, section 10 and D52, exhibit 7, sections 4 and 5 with annex D, and D52, exhibit 12, comprising in particular the packing lists and shipping package documents, confirming that 10 kg Lactase Nagase F lot No. 2463850 (Amano lot No. LAFC1252906YL)

and 10 kg Lactase Nagase F lot No. 2470983 (Amano lot No. LAFD0352846YL) were shipped on 1 April 2005 and 6 May 2005, respectively). In view of the various declarations on file illustrating the relationship between Amano and Nagase on the one hand, and Pokka and Sanwa on the other (in particular D52 with exhibits 6 and 7 and respective annexes), having regard to the documentary evidence relating to various purchases of the Amano lactase by Pokka in substantial amounts exceeding amounts expected for testing purposes, and also relating to purchases by other companies such as Saputo Dairy Products, the board has no doubt that Pokka was, in the context of the purchase of the Amano lactase, a member of the public not bound by any obligation to secrecy.

4.7 As to appellant I's arguments that it had had no access to the Amano lactase samples (D195) and that the standard of "up to the hilt" and "beyond reasonable doubt" had to be applied, the following is noted. In those cases where practically all the evidence in support of an alleged public prior use lies within the power and knowledge of the opponent, while the patentee has barely any or no access to it all, it is incumbent upon the opponent to prove the alleged prior use "up to the hilt" (T 472/92, OJ EPO 1998, 161; Headnote I, Reasons 3.1) or "beyond reasonable doubt" (T 782/92, Reasons 2.2). By contrast, when both the patent proprietor and the opponent have access, the usual standard of the balance of probabilities is applicable (T 472/92 supra). In this context, it has to be pointed out, however, that even though these different concepts as to the level of proof have developed in the case law of the boards, they have in common that a judgement is to be made on the basis of application of the principle of free evaluation of evidence (cf. in particular

decision G 1/12, OJ EPO 2014, A114, Reasons 31). The board therefore takes the view that what matters is whether or not the deciding body, here the board, is - having regard to all evidence and arguments put forward by the parties - convinced that the alleged facts, e.g. a public prior use, had indeed occurred. Hence, even if the present case falls into the category of "balance of probabilities", the board did not merely form its opinion on the basis of whether the alleged facts were just slightly more likely to have occurred than not, but on the basis of whether it was convinced that they had occurred.

4.7.1 In the present case, the alleged public prior use concerning the Amano lactase is one falling into the sphere not of the opponents but in fact of third parties. Moreover, the product which was the subject of the prior use, namely the Amano lactase, was commercially available (as agreed by all parties: see above, section 4.2), and documents D47 and D51 were in the public domain: it was thus possible for appellant I to simply obtain samples and test them, just like he had tested other lactase preparations in the patent. Hence appellant I would have had the possibility of testing the Amano lactase for the claimed ratio, even before the priority date, and he certainly still had the possibility of testing it throughout the whole opposition and appeal proceedings. Of course, when testing samples manufactured after the priority date the legitimate question could arise of whether the results obtained were representative of the ratios present in the samples of the prior art. However, by using a parameter which had not been used in the prior art, the burden is on the patentee to prove that the prior art does not fall within the terms of the claim. Rather than the patent proprietor, it was the opponents

that were at a disadvantage in the present case, since they were only prompted to test the available enzymes for the claimed ratio once this was used as a characterising parameter in the patent: were it not for the existence of stored samples (the ones used in D48), it would have been virtually impossible for the opponents to test that ratio in samples available before the priority date.

4.8 Appellant I also disputed that the Amano lactase fulfilled the requirements of analysability and reproducibility stipulated by Enlarged Board opinion G 1/92 for a product to be state of the art. According to appellant I, it was not possible to identify arylsulfatase in the Amano lactase preparation (D108), and arylsulfatase activity was an extrinsic property which could not be analysed except with hindsight (cf. T 946/04, reasons 3.24 and 3.29.3), and the assays of the prior art (D73) were designed for preparations that consisted mainly of arylsulfatase (such as those of D32) and would not work for preparations where arylsulfatase was merely a contaminant; moreover, it would not be possible to reproduce the Amano lactase, since the producer strain and the process were not available.

4.9 The board does not agree with this argumentation. In order to assess whether a prior-art product falls within the terms of the claim, one obviously has to assess the claimed parameters, even if these have never been used before: this is not hindsight, as otherwise the purpose of opinion G 1/92 would be contradicted, and patent protection could be obtained for a known product merely by redefining it with parameters that had not been used before. Since the product in the claim is defined in terms of activity, it is activity

rather than structure that is to be analysed. Hence, it is irrelevant whether the enzyme could be detected by structural analysis or not. On the other hand, enzymatic activity is an inherent property of an enzyme, and detection of an enzymatic activity implies that the corresponding enzyme must be present (and active) in the tested product as part of its composition: such an enzymatic assay is thus in fact an analysis, albeit a functional one, of the product composition and is therefore directed to what is considered in opinion G 1/92 (Reasons 3) and decision T 952/92 (Headnote II, supra) to be implicitly disclosed by an available product, namely composition or internal structure. In this context it is noted that, contrary to appellant I's arguments, decision T 952/92 does not stipulate that structural assays have to be used but rather only refers to "compositional analysis", which does not have to be complete: all that is required is an analysis to the extent needed to determine whether the product falls within the claim (cf. T 952/92, Reasons 2.3). There is also no undue burden, since only two enzymatic activities have to be analysed, for which assays were available in the prior art. D170 provides evidence that arylsulfatase activity could be measured in the Amano lactase samples using the prior-art assay of D73. Contrary to appellant I's arguments, the skilled person does not have to test for all possible impurities. As to reproducibility, decision T 952/92 supra also clarifies that no complete reproducibility is needed (i.e. the skilled person does not have to reproduce a completely identical product of the prior art), but rather only a product which falls within the terms of the claims of the patent (i.e. a product with the characteristics as claimed). Hence, knowledge of the specific strain and fermentation

method used to produce the Amano lactase is not required.

4.10 The present case thus differs from the cases underlying decisions T 946/04 (supra), T 1457/09, T 2048/12 and T 2068/15, all cited by appellant I as support for its argumentation concerning analysability and reproducibility of the prior-art product.

4.10.1 In decision T 946/04, Technical Board 3.3.03 concluded that the case was different to that underlying decision T 952/92 because the compositions according to the patent in suit were reactive products comprising two kinds of polymers which had to exhibit very specific respective curing patterns in order to allow the formation of a non-IPN structure; whether such specific curing patterns were present or not could only be established provided that the exact composition of the prior sold product could be determined, i.e. provided a complete analysis was carried out (T 946/04, Reasons 3.8.1 to 3.8.3). In the present case however, the prior sold product, a lactase preparation, is not a composition with reactive chemical products that undergo chemical reaction to allow formation of a given structure. Rather, the two relevant components of the preparation (among other possible components) exist separately in the preparation and exert their inherent action (the enzymatic activity) independently of each other's presence.

4.10.2 As to decision T 1457/09, Technical Board 3.3.04 confirmed the established view that the principles developed in decision T 609/02 (Reasons 9), as regards enablement of second medical use claims, also had to be fulfilled by the disclosure of prior-art documents in order to make credible that the therapeutic effect on

which the disclosed treatment relied could be achieved (T 1457/09, Reasons 36). While the present board agrees with these conclusions, it notes that they have no bearing on the present case, where the disputed issue is enablement of a product rather than of a medical use.

4.10.3 In decision T 2048/12, Technical Board 3.3.06 came to the conclusion that the commercial availability of a chemical product did not necessarily disclose all impurities contained therein (Reasons 2.4.3). Appellant I interpreted this conclusion as supporting the argument that the commercial availability of the Amano lactase did not disclose the impurity arylsulfatase contained therein. The board however notes that the situation underlying decision T 2048/12, where the claimed compound consisted of a composition comprising two catalytic compounds while the product of the prior use was sold as a highly pure preparation of the first catalytic compound, is essentially different to the present case. Present claim 1 does not require both lactase and arylsulfatase to be present in the composition, but rather limits the amount of (active) arylsulfatase in relation to that of (active) lactase that can be present in the composition, and in fact encompasses compositions in which arylsulfatase is not present at all. Clearly, arylsulfatase can be considered an impurity (since it is a contaminating compound of the preparation) which, following decision T 2048/12, would not be part of the implicit disclosure of the lactase preparations of the prior art which were considered to be highly pure (e.g. Amano lactase). A priori, such highly pure lactase concentrations would be considered to contain no contaminants, let alone the specific contaminant arylsulfatase, and the burden would be on appellant I to demonstrate that they did

contain it (or not) in a ratio falling outside the scope of the claim.

4.10.4 Finally, decision T 2068/15 of Technical Board 3.3.09 was cited by appellant I as supporting the argument that analysability as required by G 1/92 is not allowed using the teaching of the patent (Reasons 2.6). The board notes that the mentioned passages, while discussing whether the analysis has been made with previous knowledge of the product composition or not, do not conclude that such knowledge would be impermissible. Moreover, as argued by appellant II and III, what is discussed is not the allowability of using the knowledge of the claim but that of the structure of the product for its analysis. The board maintains that, without knowledge of the claim, it is not possible to analyse whether a product of the prior art falls within the claim scope or not.

4.11 For the sake of completeness, the board also notes that the dispute among the parties over whether the arylsulfatase activity should be considered an extrinsic characteristic of the composition (as argued by appellant I) or not (as argued by appellants II and III) is not considered relevant in the context of the present discussion on whether the product as defined by the claims is novel or not. While opinion G 1/92, Reasons 3, refers to extrinsic characteristics as not being part of what is implicitly disclosed by a commercially available product, it nevertheless does not state that such extrinsic characteristics could render a commercially available product novel: rather, it explains that they may underlie a new use of the known product, as is apparent from the examples given in the mentioned section of G 1/92: "the application as a pharmaceutical product of a known substance or

composition (...) and the use of a known compound for a particular purpose, based on a new technical effect" [emphasis added by the board]. Hence, independently of the arylsulfatase activity being considered an extrinsic characteristic or not, the product per se would still be known. In the present case, the arylsulfatase activity does not underlie a new use of the composition, the claimed use being the usual one for lactase compositions, i.e. hydrolysis of lactose in the production of dairy products.

4.11.1 The same conclusion is also reached in decision T 301/94, Reasons 3.6: "The appellants argued that the sulphide concentration of the glass was a 'hidden' or secret feature in the sense of decisions G 2/88 and G 1/92 (item 3). (...) The board cannot follow this line of argument for the following reasons: Item 3 of opinion G 1/92 refers to the use of a known compound for a particular purpose, based on a new technical effect as defined in G 2/88, and it is stated in this context that such characteristics cannot be regarded as having already been made available to the public when the compound itself is available to the public. (...) It is the new technical effect which constitutes a hidden or secret feature, not the composition itself or one component thereof. Furthermore, when arguing that the chemical composition of the green glass was not made available to the public because the skilled person would not have analysed the sulphide content on the basis of the common general knowledge at the priority date, the appellants in fact introduce an additional requirement for the chemical composition to be available to the public. This additional requirement is that the skilled person should be able to recognise a priori, on the basis of the common general knowledge, which components the commercially available product

might contain and in which amounts. Such an additional requirement would not be in agreement with the essence of opinion G 1/92, where only analysability and reproducibility of the commercially available product are required for its chemical composition to be state of the art. According to opinion G 1/92, it is the fact that direct and unambiguous access to some particular information is possible which makes the latter available, whether or not there is any reason for looking for it. As, in the present case, the skilled person would have been able to both analyse the commercially available green glass using the analytical methods known at the priority date and reproduce it without undue burden, the chemical composition of this glass is state of the art even if it had not been common general knowledge that a green glass with high UV absorption might contain a relatively low, but measurable, amount of sulphides."

4.12 The board hence comes to the conclusion that the evidence on file convincingly demonstrates that a lactase preparation fulfilling the parameters recited in claim 1 of the main request was publicly available for purchase - and had, in fact, been sold to at least one member of the public not bound to secrecy - before the priority date.

4.13 It thus has to be decided whether said product has also been used in a "process to produce a dairy product" (claim 1 of the main request). In this context, it is noted that the claim is directed to a process but does not in fact comprise particular process steps. The only characterising features of the claimed process are thus that it is for production of a dairy product and that it involves the use of a product as defined in the claim.

4.14 D51 discloses that "Approx. 25 ml of Lactase YL "Amano" is able to hydrolyse more than 90% of lactose in 100 litres of milk at 30°C for 7 hours". Hydrolysis of lactose in milk results in lactose-free or nearly lactose-free milk, which is, by definition, a dairy product (e.g. claim 6 of the main request). The board takes this statement as evidence that not only has the Amano lactase enzyme been advertised for use in production of dairy products but also in fact a "process to produce a dairy product" with the Amano lactase has been disclosed in the prior art.

4.15 Appellant I essentially argued that there was no evidence that an Amano lactase with the ratio as claimed was indeed used in a process to produce a dairy product. The board notes that in view of the fact that virtually all batches tested did have a ratio as claimed (in fact, all batches if the results of D48 are not multiplied by 5 as required by appellant I, and all batches except lot No. 2449587 if the results are multiplied by 5), the board is convinced that the enzyme preparation used in the underlying assay reported in product specification sheet D51 also had such a ratio. Moreover, there is satisfactory evidence on file that the batches sold to Pokka (D52, exhibit 12, and D48) had such a ratio and that Pokka, having also received product specification sheet D51, also obtained the information that the Amano lactase was for use in the production of a dairy product. Accordingly, Pokka (a member of the public) received a lactase preparation falling within the definition of the claim together with the information of its use for production of dairy products.

4.16 The board is thus convinced that the evidence on file supports the conclusion that an enzyme with the characteristics as claimed was commercially available in the prior art and that its use in a process as claimed had also been made available to a member of the public, and hence is also state of the art. Claim 1 of the main request is therefore not novel (Article 54(2) EPC).

5. Auxiliary request 3

Novelty over the Amano lactase prior use

5.1 Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that the enzyme is further characterised as being "intracellular produced" and the dairy product is further defined as being UHT milk. As regards the first feature, characterising the enzyme, it was accepted by all parties that this was an inherent feature of the Kluyveromyces lactis lactase (patent, paragraph [0027]) and hence did not serve to impart novelty to the claimed subject-matter over the Amano lactase public prior use. As to the "UHT milk" feature, appellants II and III essentially argued that it was an unclear feature, and thus not appropriate to establish novelty; that "UHT milk" was synonymous with or at least included in the term "milk" in the context of D51; and that a process involving production of UHT milk was anticipated by the disclosure of the use of the Amano lactase for production of the coffee-milk product "Coffee First Drip Straight Latte R" by Pokka.

5.2 As argued by appellants II and III, there is no definition of UHT milk in the patent. However, in paragraph [0011] the patent teaches that: "The UHT milk has received a high heat treatment to obtain a shelf

life of several months at room temperature". At least the long shelf life at room temperature clearly distinguishes UHT milk from milk in general and from other forms of heat-treated milk that do not have a shelf life of several months at room temperature. It is true that in the prior art the term "UHT" has been used in connection with different types of milk treatment, not always resulting in long-life, shelf-stable milk: e.g. UHT pasteurised milk, disclosed in D181, page 86 of the annotated and partially translated version of the document (labeled D181A). However, as argued by appellant I, the designation "UHT milk" is consistently used in the art to mean long-life, shelf-stable milk, in accordance with the patent's statement in paragraph [0011]: D191 (paragraphs 10 to 13) and its Annexes, in particular Annex 3 (page 45, third paragraph), Annex 4 (page 2643, left column, first 3 lines), Annex 6 ("Definitions" on page 32) and Annex 7 (paragraph 2.7 on last page). The claim does not refer to "UHT-processed milk", which would also encompass UHT pasteurised milk, but rather to "UHT milk", which, according to the patent and the prior art, is long-life shelf-stable milk. Whether attaining such a long-life shelf-stable milk requires not only UHT treatment but also aseptic packaging, as disclosed in D191 and Annexes, is irrelevant for the concept of "UHT milk".

5.3 There is no explicit disclosure in the prior art for a use of the Amano lactase in a process for the production of UHT milk. In particular, the board does not consider that the use for hydrolysis of lactose in milk disclosed in D51 is an implicit disclosure of a use to produce UHT milk. The concept of UHT milk is of course part of the general concept of milk, but, as discussed above, is distinct therefrom by its long shelf life at room temperature.

5.4 Moreover, the board is not convinced by appellant II and III's argument that "milk" implicitly meant UHT milk at least in Japan, which was the main target public of product specification sheet D51.

5.4.1 First of all, product specification sheet D51, distributed to customers and potential customers (as confirmed by Mr Saito, D52, section 6), was not restricted to the Japanese market but in fact publicly available in English even on the internet, as argued by the opponents relying on D178 (a print-out of an email exchange between Amano and a potential customer in France, including two emails, dated 21 December 2004 and 8 September 2003, respectively) and D179 (print-out of Amano webpage captures of 2003 and 2004). There is also evidence on file for sale of the enzyme preparation to Saputo, a company in Canada (D52, exhibits 8 and 9).

5.4.2 Secondly, the board is not persuaded that most milk consumed in Japan at the priority date was in fact UHT milk corresponding to the above definition, i.e. long-life shelf-stable milk. In document D171, Ms Yoshida (of Amano Enzyme Inc.) declared that "at that time when referring to milk in Japan, generally UHT milk was meant as this was technical common sense in the Japanese market. UHT milk was (and is) the most common type of milk (as opposed to fresh or pasteurized milk) in Japan" (paragraph 7). In document D172, Mr Katagiri (of Pokka Sapporo Food & Beverage) declared that "The usage of UHT milk is very common in the Japanese market" (paragraph 5). Document D181 (English translation: D181B) on page 86 lists different milk types available in Japan; the 6 types of milk listed in items 1 to 6 are: 1. low-temperature pasteurised milk,

2. high-temperature short-time pasteurised milk, 3. ultra-high-temperature pasteurised milk, 4. ultra-high-temperature sterilised milk (long-life milk), 5. other types of pasteurised milk, and 6. unpasteurised milk. In item 3, referring to ultra-high-temperature pasteurised milk, it is stated that "Most of drinking milk in our country is this type". The board does not agree with the appellant-opponents' interpretation of this statement as meaning that UHT milk constitutes most of the drinking milk in Japan. According to the normal use of the term "UHT milk" in the prior art and in the patent, UHT milk corresponds to the "ultra-high-temperature sterilised milk (long-life milk)" of item 4 and not to the "ultra-high-temperature pasteurised milk" of item 3. This is hence not in disagreement with D187, an information print-out in respect of the milk market in Japan covering the years 2001 to 2006, according to which the yearly revenues for "shelf-stable milk" in Japan are much lower than those for "fresh milk", a designation which, according to appellant I, relying on D191, section 10, corresponds to the UHT pasteurised milk of D181.

5.5 Finally, the board also concludes that the prior use of the Amano lactase for the production of the coffee-milk product "Coffee First Drip Straight Latte R" by Pokka does not anticipate the subject-matter of claim 1 either, because this prior use is not a use in a process for production of a dairy product, wherein the dairy product is UHT milk. While the process may indeed have used UHT milk (Exhibit 7 of D52: declaration of Mr Katagiri, section 9; D172: second declaration of Mr Katagiri, section 5), it does not result in the production of UHT milk because the coffee-milk product (the final product) is not UHT milk.

5.6 The board disagrees with appellant II and III's argument that, despite the fact that Pokka's coffee-milk product was not UHT milk, UHT milk was nevertheless produced as an intermediary product in the manufacturing process. The manufacturing process of Pokka's coffee-milk product is disclosed in D52's Exhibit 7, Annex H (English version). On the fifth page of this document, entitled "Mixture operation Process drawing", the production flow as well as the production requirements and conditions are displayed in the form of a table (which is redacted). The following ingredients are listed in the second column of the table: "Lactase Y (Amano) L" at the top, followed by "Emulsifier" (twice), "Nonfat powdered milk", "Fresh cream", "Milk" and "Baking soda (sodium hydrogen carbonate)". The board fails to see a step where lactase is used to treat UHT milk; rather, in the step when milk (not further characterised) is added to the process, not only lactase is present but also other ingredients such as emulsifiers, nonfat powdered milk and fresh cream. The resulting product of this first step is thus not UHT milk, independently of whether or not UHT milk is used as one of the ingredients.

5.7 In view of the fact that the process of production of Pokka's coffee-milk product is not a "process to produce a dairy product, wherein said dairy product is UHT milk", a decision on whether or not said process was available to the public before the priority date - disputed among the parties - is not necessary.

5.8 The board thus comes to the conclusion that the subject-matter of the claims of auxiliary request 3 is novel over the prior use of the Amano lactase (Article 54(2) EPC).

Inventive step (Article 56 EPC)

5.9 The present patent is directed to the use of lactase in the production of dairy products. The problem that the patent aims to solve is identified in paragraph [0011]: "It is found that even lactase preparations with low protease activity can still give rise to off-flavour formation. This is especially the case for the neutral lactases, derived from the cytoplasm of yeast. The off-flavour formation that is associated with the use of lactase preparations is especially critical for lactose hydrolysed UHT-milk. (...) The UHT milk has received a high heat treatment to obtain a shelf life of several months at room temperature. The long storage times outside the refrigerator make these products especially prone to off-flavour formation: even a very low off-flavour formation rate can give rise to significant off-flavour formation after several months of storage, making the product unattractive for consumption". Hence the aim of the patent is to reduce off-flavour caused by lactase treatment of milk, in particular UHT milk.

5.10 Document D19, which is also concerned with the development of off-flavour in lactose-hydrolysed milk, including UHT milk, is the closest prior art. D19 teaches that "it is of considerable importance that the lactase preparations used by the dairy industry for hydrolysis be as pure as possible" and that "Contaminants of particular importance are proteases, which if introduced into milk, can result in the development of bitter flavours" (page 46, right column, lines 18 to 23). D19 comes to the conclusion that "Care must be taken by the manufacturers of lactose-hydrolyzed products to ensure that any lactase preparations employed are, as far as possible, free from contaminating proteases. High levels of protease

will result in the rapid development of off-flavours in the product" (page 47, left column, last paragraph, first five lines of "Conclusions" section). The difference over the claimed subject-matter is that D19 does not teach the use of a lactase preparation with a ratio of less than 30 units arylsulfatase activity per Neutral Lactase Unit (NLU) of lactase activity, and the technical problem can be formulated as the provision of an alternative process for producing lactose-free UHT milk with less off-flavour despite long storage time. The solution is a process making use of a lactase preparation as claimed and, in view of the data presented in the patent (Example 7), the board is satisfied that the problem has been plausibly solved.

5.11 It hence has to be examined whether the skilled person would arrive at the claimed solution in an obvious manner.

5.12 Document D120 is a review article, published in 2003, that discusses the causes of off-flavour formation in milk and milk products. On page 82, left column, last paragraph, it discloses that: "Indigenous phenolic compounds have also been linked to flavour defects in Cheddar cheese and milk (...). The development of a phenolic off-flavour in in-bottle sterilized milk is due to the presence of p-cresol (Figure 3), produced by Bacillus circulans (...)". P-cresol is among the compounds which had been identified in cow's milk as conjugates (e.g. glucuronides and sulfates), as disclosed in D68 (abstract and Table I). D68, which is a publication of the year 1973, furthermore states in the abstract (last four lines) that: "It is speculated that the origin of some of the free flavor compounds arises from the action of enzymes normally present in milk on the conjugates". It also teaches β-

glucuronidase and arylsulfatase as the two enzymes used to hydrolyse the conjugates into free compounds (first page, left column, last paragraph). In the right column of the second page, third paragraph, D68 states that: "All of the compounds identified, (...), have been found in milk systems before and contribute to the overall flavor picture". Likewise, D90, which is a review, published in 1997, on "The flavour of milk and dairy products" (Title), discusses on page 82, last paragraph of left column to first paragraph of right column, the role of phenolic compounds in the flavour quality of milk and cheeses, stating that the flavour becomes "unpleasant" as the concentration of these compounds increases. In accordance with the teaching of D68, D90 too teaches on page 82, in the first paragraph of the right column, that: "Phenolic compounds occur in milk as glucuronides or sulphates and can be liberated by the β-glucuronidase or aryl esterase, which also occur in milk". Aryl esterase is another designation for arylsulfatase. In the third paragraph of the same column, D90 lists a number of phenolic compounds, among them p-cresol; albeit in the context of cheese, it is stated in this passage that: "Phenol and cresols (o, m, p) contributed strong phenolic and medicinal flavour notes."

5.13 The board hence concludes that, contrary to the statements of the patent in e.g. paragraphs [0016] and [0017], it was not surprising to find that arylsulfatase was a "crucial enzyme activity, responsible for off-flavor formation" (paragraph [0016]) and that "hydrolysis of metabolic conjugates, in particular alkyl phenols substituted with a sulfate group, by arylsulfatases is a mechanism resulting in the development of off-flavor" (paragraph [0017]). In fact, as discussed in the above section, it was well

known from the prior art, e.g. D120, D68 and D90, that phenolic compounds had an impact on milk flavour and off-flavour and that two enzymes, β-glucuronidase and arylsulfatase, were involved in the process. Moreover, it was also known in the art that contamination of milk additives with arylsulfatase resulted in the development of off-flavours especially in UHT milk: this is disclosed in D34 in relation to sterilised milk compositions comprising gellan gum (page 6, second paragraph). D34 also teaches that: "Analysis of the food product has linked the off-flavor and odor to the development of a chemical called para-cresol, which is detectable in milk-based gellan products that have been treated at ultra high temperatures and further stored at room temperature" (page 4, first paragraph). D34 furthermore states in the above-mentioned second paragraph of page 6 that "para-cresol develops in sterilized milk when the enzymes glucuronidase and aryl sulfatase have been added (J. Agr. Food Chem. Vol. 1, 1973)"; the given reference appears to be D68. Finally, D34 teaches that "para-cresol production can be disrupted by denaturing the residual enzymes that reside in the native gellan gum. In particular, (...) by addition of a denaturing agent" (page 6, third paragraph). The "residual enzymes" mentioned in this passage are "presumably glucuronidase and aryl sulfatase" which "survive the ultra-high-temperature heat processing" and "over time, (...) cleave the naturally occurring para-cresol conjugates in the sterilized native gellan/milk composition to generate free para-cresol" (page 6, second paragraph).

5.14 It follows that, in the search for a solution to the technical problem of providing an alternative process for producing lactose-free UHT milk with less off-flavour despite long storage time, the skilled person

would certainly consider arylsulfatase as one of the candidate enzymes to be investigated.

5.15 The skilled person would thus be motivated to test for the presence of arylsulfatase activity, by using methods known in the prior art (e.g. D73), or to test for the presence of p-cresol (e.g. D68; D34, page 7, last paragraph, to page 8, first paragraph) in known lactase preparations. Kluyveromyces lactis being the major commercial source of lactase at around the priority date (D1, page 1769, left column, lines 1 to 3), the skilled person would certainly consider lactase preparations obtained from this microorganism. Most likely, he would also test the commercially available Amano lactase, which had been certified as a food additive according to the indicated regulatory position of D51, and would in this manner identify a lactase preparation that solved the problem. Alternatively, he would develop methods to reduce arylsulfatase activity in the available lactase preparations. Such an approach was explicitly taught in D34 (page 6, third paragraph), which proposed "denaturing the residual enzymes [glucuronidase and aryl sulfatase] (...) in the native gellan gum". It would be immediately apparent to the skilled person that denaturation would be suitable for gellan gum preparations (gellan gum being a polysaccharide: D34, page 2, first line) but not for lactase preparations, because it would destroy not only arylsulfatase but also lactase (both being enzymes). Nevertheless the skilled person would just have to develop methods of purification, based on routine techniques, to eliminate the arylsulfatase activity. In fact, D19 (page 46, right column, lines 18 to 20) and D65 (page 911, right column, lines 7 to 9) had already stressed the importance of having lactase preparations as pure as possible. The patent itself acknowledges

that conventional purification methods are suitable for the purpose of the claimed subject-matter (paragraph [0045]), and in fact the purification method used in the patent merely uses commercially available Q-sepharose and butyl-sepharose columns (Example 5 and Table 1).

5.16 The board thus comes to the conclusion that the skilled person would arrive at the claimed solution without the need for inventive skill.

5.17 Appellant I essentially argued that, starting from D19, the skilled person would have no motivation to remove arylsulfatase from the lactase preparations, because there was no teaching in the prior art that arylsulfatase was a contaminant of lactase preparations, let alone that its presence was linked to the development of off-flavour in lactase-treated UHT milk. None of the documents mentioning arylsulfatase and/or p-cresol as a cause of off-flavour were related to lactase preparations; therefore they did not provide any incentive to reduce arylsulfatase in lactase preparations. Moreover, combination of D19 with D34 required hindsight, because D34 did not relate to lactase preparations at all, but rather to gellan gum, a food additive which was not even an enzyme.

5.18 The board agrees that D19 is specifically concerned with proteases as contaminants of lactase preparations; however, its general statement that lactase preparations should be as pure as possible cannot be seen as being restricted to protease contamination. While there could in fact be a whole myriad of potential off-flavour causes (reviewed in D120 and discussed in appellant I's reply to the appeal, page 52, middle), there were nevertheless pointers in the

prior art to two particular enzymes, one of them being arylsulfatase (section 5.13). That this enzyme per se could not be identified in lactase preparations would not be an obstacle to the detection of its activity, since the resulting free compounds such as p-cresol were known and could be detected (D34, D68, D90); in this context, it was also irrelevant that p-cresol could cause different types of off-flavour, because more reliable tests than odour or flavour testing were available. The fact that a prior-art enzyme, Maxilact®, which was described as "highly purified" (D160, column 4, line 31), still had a high ASU/NLU ratio as shown in the patent and that known purification protocols would not necessarily lead to a lactase preparation with an ASU/NLU ratio of less than 30 (D79, D80, D115, all disclosing reworks of prior-art purification methods) does not mean that it would not be possible, using routine purification protocols, to remove arylsulfatase from lactase preparations once it was known that this was desirable. In this respect, appellant I's argument that the examples of the patent showed that arylsulfatase was not readily separated from lactase is contradicted by the patent's statement (paragraph [0045]) that arylsulfatase could be removed by conventional purification protocols. As to the combination of D19 with D34, the board notes that the skilled person, motivated to find a solution to the problem of off-flavour occurring in lactase-treated UHT milk, would certainly consider literature disclosing the same problem in the same product (UHT milk) when another food additive was added, in particular a food additive that, while not being an enzyme, was nevertheless also produced by microorganisms and obtained from "biological soups", i.e. from fermentation broths (D34, page 2, second paragraph).

5.19 Auxiliary request 3 is thus not allowable because it contravenes Article 56 EPC.

6. Auxiliary request 2'

6.1 Claim 1 of this request is in fact directed to the same subject-matter as claim 1 of auxiliary request 3, differing therefrom only by deletion of the feature "intracellular produced".

6.2 Hence, for the same reasons as discussed above in relation to auxiliary request 3, the subject-matter of claim 1 of auxiliary request 2' also lacks inventive step (Article 56 EPC).

7. Auxiliary request 3'

7.1 Claim 1 of this request differs from claim 1 of the main request in that it requires an ASU/NLU ratio of less than 20 instead of less than 30.

7.2 All nine Amano lactase samples tested in D48 (Table) display an ASU/NLU ratio which is below 20; even if multiplied by factor 5 to correct for the sample dilution, only for two of the tested samples does the ratio exceed 20 (D198, exhibit 1, right column). Moreover, at least the two samples which had been sold to Pokka prior to the priority date (as evidenced by D52, exhibit 12, see also point 4.15 above) have a ratio of less than 20. Hence the board concludes that claim 1 of auxiliary request 3' lacks novelty over the public prior use of the Amano lactase, for the same reasons as discussed above for the main request.

7.3 The board is not persuaded by appellant I's argument that, since not all tested Amano lactase samples had a

ratio as claimed, there was no unambiguous disclosure that a batch with a ratio of less than 20 had indeed been used in a process as claimed. In fact, the Amano lactase in general was advertised for use - and was used (reasons 4.14 and 4.15 above) - in the production of dairy products, and this use was also made available to Pokka (a member of the public) via product specification sheet D51, as concluded above in relation to the main request. Moreover, at least two batches for which there is evidence of sale to Pokka had a ratio as claimed; in view of the large amount sold to Pokka (D52, exhibit 12), it is apparent that the sale was not done for testing reasons only but rather for production of dairy products, as attested by Ms Yoshida and Mr Katagiri (D171 and D172).

7.4 Auxiliary request 3' is thus not allowable for lack of novelty of the subject-matter of claim 1 (Article 54(2) EPC).

8. Auxiliary requests 4, 7 and 8

8.1 Claim 1 of these requests differs from claim 1 of the main request by the addition of the feature "wherein said lactase is an intracellular produced lactase" (auxiliary requests 4, 7 and 8), by the replacement of the ratio of "less than 30" by "less than 20" (auxiliary request 7) and by the addition of the feature "and wherein said lactase is a K. lactis lactase" (auxiliary request 8).

8.2 As to the features "intracellular produced" and ratio "less than 20", it has already been concluded above, in relation to auxiliary requests 3 and 3', respectively, that they do not contribute to novelty (see points 5.1 and 7.1 to 7.4). Hence claim 1 of auxiliary requests 4

and 7 lacks novelty for the same reasons as given for the main request and for auxiliary requests 3 and 3'.

8.3 As regards the feature that the lactase is from K. lactis, it is noted that the Amano lactase is also from K. lactis (D47, D51). Hence this feature cannot render the claimed subject-matter novel either. Claim 1 of auxiliary request 8 also lacks novelty over the Amano lactase public prior use.

8.4 Auxiliary requests 4, 7 and 8 are thus also not allowable for lack of novelty (Article 54(2) EPC).

Order

For these reasons it is decided that:

1. Appellant I's appeal is dismissed.

2. The decision under appeal is set aside.

3. The patent is revoked.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated