

JOSE LLOREDA CAMACHO & CO.

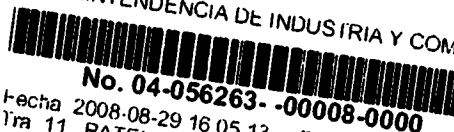
Calle 72 No. 5-83 Piso 5, Bogotá, D.C. Tel: 6069700 Fax 6069701

Señor

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

E. _____ S. _____

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 04-056263-00008-0000

Fecha 2008-08-29 16 05 13 Dep 2020 NUECREACIONE
Tra 11 PATENTEIYII Eve 379 FASENACIONALII
Act 444 RESPUESTAREQUE Folios 24

Re: P1.-WYETH.-Solicitud de Patente de Invención en Fase Nacional PCT para
"COMPOSICIONES DE FORMULA INFANTIL QUE COMPRENDEN
CANTIDADES AUMENTADAS DE ALFA-LACTALBUMINA".-Clase A23C
9/15.-Expediente número 04-056.263.-

1. Me refiero al auto dictado por ese Despacho notificado mediante fijación en lista de 6 de Junio de 2008.

2. De acuerdo con el Concepto Técnico No. 1419 se tiene que:

"A efectos del examen de patentabilidad y como requerimiento de esta oficina, se solicita proporcionar, en un plazo que no exceda de 3 meses, los siguientes documentos relativos a la solicitud extranjera correspondiente a la misma invención que se examina:

a) Copia de todos los resultados de exámenes de patentabilidad efectuados respecto a la solicitud extranjera, junto con los siguientes documentos que afectan dicha patentabilidad reportados en el correspondiente informe de búsqueda:

1- J. TIMMER: "Whey protein concentrates with non-traditional compositions".
EUROPEAN DIARY MAGAZINE, vol. 189, no.8, 1997, pages 47-49,
XP008016321.

3. Para responder a los requerimientos del señor Examinador de conformidad con el Artículo 46 de la Decisión 486, anexo me permito presentar a ese Despacho copia de los siguientes documentos solicitados:

- J. TIMMER: "Whey protein concentrates with non-traditional compositions".
EUROPEAN DIARY MAGAZINE, vol 189 no.8, 1997, pages 47-49,
XP008016321;

JOSE LLOREDA CAMACHO & CO.

Calle 72 No. 5-83 Piso 5, Bogotá, D.C. Tel: 6069700 Fax 6069701

120
128

Así mismo, me permito presentar los siguientes resultados de Exámenes de Patentabilidad, suministrados por el solicitante:

- Resultados del Examen de Patentabilidad adelantado por la Oficina de Patentes de Estados Unidos de América correspondiente a la solicitud No. US 10/318,977.
 - Resultados del Examen de Patentabilidad adelantado por la Oficina de Patentes Europea correspondiente a la solicitud No. EP 02 805 966.5-2114.
 - Resultados del examen de patentabilidad adelantado por Autoridad de Examen Preliminar correspondiente a la solicitud No. PCT/US02/40811.
4. En vista de lo anterior, ruego a usted tomar atenta nota y proceder de conformidad.

Señor Superintendente,


ALICIA LLOREDA RICAURTE
T.P. 53.215

Whey protein concentrates with non-traditional compositions?

Dr. J. M. K. Timmer, NL-Edo

A new challenge for product developers

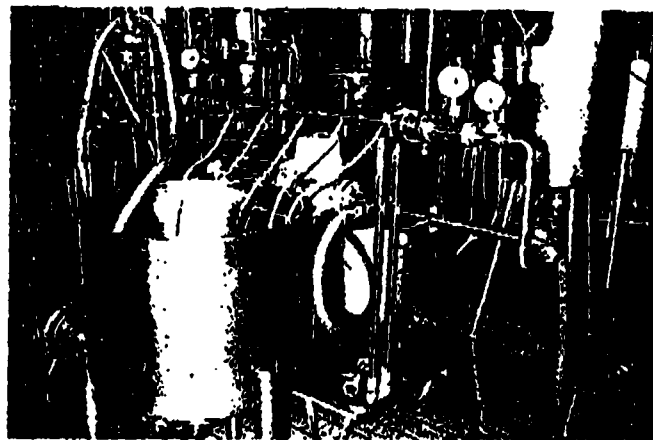
In 1993 an EU-AIR (A/R2- CT93-1207) project was started aimed at the development of a membrane-based process to obtain the individual whey proteins in a purified form, starting from whey or whey-derived products. The process would be based on ultrafiltration and micro-filtration, using (modified) membranes.

Now, after three years, processes have been developed for the preparation of α -lactalbumin and β -lactoglobulin enriched fractions, starting from Gouda cheese whey and from acid casein whey-derived whey protein concentrates.

Total process performance, expressed in potential product yield and composition, was determined on a pilot-plant scale. Key parameters in the protein separation process were identified and recommendations for further improvement of the processes were given. In addition, strategies for cleaning of membranes were developed to restore original membrane properties and reduce the costs for cleaning.

The findings of this project were discussed at a public meeting last October at Nizo, Ede, The Netherlands.

Small pilot-plant membrane system for quick determination of optimal process conditions (photo NIZO)



Aims of the project

To study the possibilities and all aspects of the fractionation of whey proteins by membrane processes, eight laboratories and institutes from France, Spain and the Netherlands collaborated (table 1) and the AIR-programme provided part of the funding. The main

objectives of the project were to develop membrane-based processes for the fractionation of whey proteins in whey or pretreated whey and to develop efficient cleaning procedures. The major products aimed at were a β -lactoglobulin (β -lg) enriched fraction with more than 90 per cent of β -lg in the protein fraction and an α -lactalbumin (α -lac) enriched fraction with more than 70 per cent of α -lac in the protein fraction. The selection of these two products was based on interviews made with nine dairy companies in Spain, France and the Netherlands.

New processes and products

Different membrane separation steps were developed on a laboratory scale for the fractionation of three typical whey sources: Gouda cheese whey (GCW), a liquid acid casein whey protein concentrate (75 per cent protein on dry matter, ACW-WPC75), and an acid casein whey protein concentrate solution (90 per cent protein on dry matter, ACW-WPC90) prepared from a powder. The processes based on GCW (figure 1) and ACW-WPC75 (figure 2) were tested on a pilot-plant scale. The major difference in the processes

Fig. 1: Flow sheet of ACW-WPC75-based process

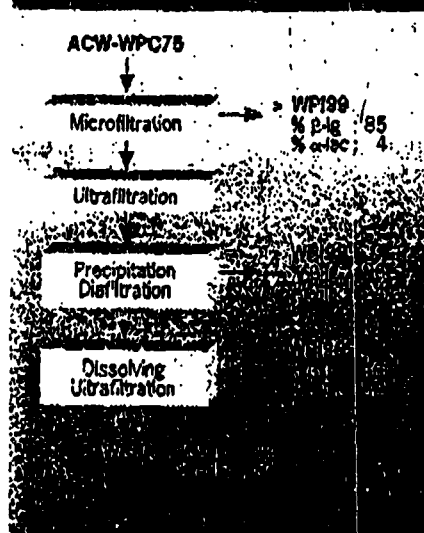
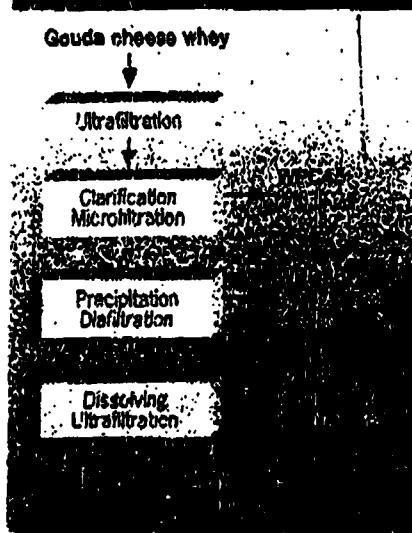


Fig. 2: Flow sheet of Gouda cheese whey-based process



Tab. 2: Comparison of purity and overall yield α -lac and β -lg (reference de Wit - 1992)

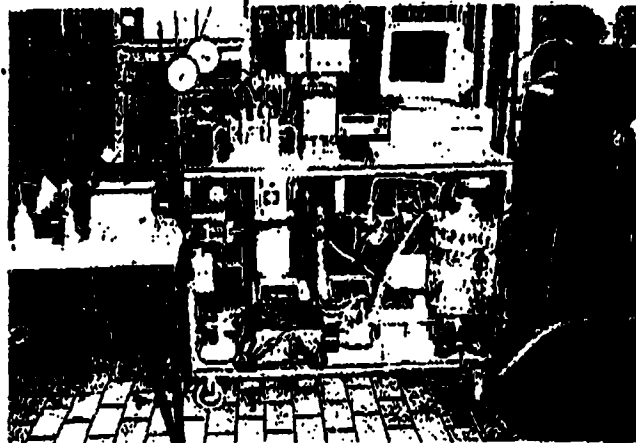
	purity (%)		yield (%)	
	α -lac	β -lg	α -lac	β -lg
reference	62	80	80	1
pilot GCW	76	90	47	86
lab ACW-WPC75	77-83	96-99	60-70	60
pilot ACW-WPC75	77	96	47	62

developed is the first membrane separation.

In the ACW-WPC75 process two goals had to be achieved. The first goal was to remove the "large" proteins as serum albumin and immunoglobulins from the "small" proteins β -lg and α -lac. The second goal was to increase the ratio of the concentrations of α -lac and β -lg in the permeate in order to improve the feed conditions for the second processing step, which is α -lac precipitation. These goals were not set for the GCW process. To obtain the β -lg enriched fraction, diafiltration is applied to the solution containing α -lac precipitate. The washed precipitate is dissolved, making use of the property that α -lac can be precipitated reversibly. The dissolved α -lac is further purified by ultrafiltration.

In each of the processes four major product streams are distinguished. For the process based on GCW the β -lg enriched fraction and the α -lac enriched fraction have the quality of a WPC75 and WPC90, respectively, and the desired level of purity.

The two other products in this process have the quality of a WPC45



left: Laboratory-scale membrane system for making feeding studies (photo NIZO)

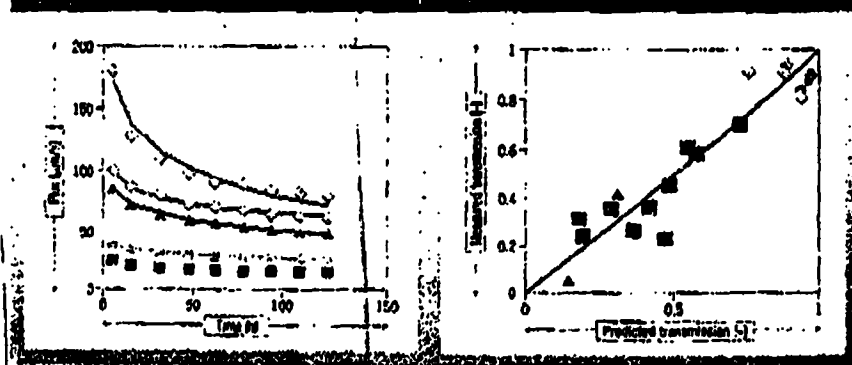
right: Pilot plant membrane system facility (photo NIZO)

and WPC99. The WPC45 has a traditional whey protein composition, while the WPC99 contains equal amounts of α -lac and β -lg. Almost all the protein originally present in the feed is recovered in the four products. The β -lg enriched fraction contains about 40 per cent of the protein while the α -lac enriched fraction contains ten per cent. For the process based on ACW-WPC75 all the products have a WPC99 quality and the β -lg enriched fraction and the α -lac enriched fraction have the desired levels of purity.

enriched fraction contains about 10 %. Also in this process a WPC99 was obtained with equal amounts of α -lac and β -lg.

Compared to traditional processes for making α -lac and β -lg enriched fractions the purity of these fractions in the two newly developed processes is higher (table 2). Comparing the GCW process to the ACW-WPC75 process showed that the purities of the two fractions in the latter process were higher.

Fig. 3: A two adjustable parameter model was developed that allows the simultaneous prediction of flux and protein transmission for various membrane module geometries, feed conditions and process conditions



All the protein originally present in the feed is recovered in the products. The β -lg enriched fraction contains more than 50 % of the protein while the α -lac

More efficient cleaning procedures

A second important topic dealt with in the project was cleaning of membrane systems. In the dairy industry the use of cleaning-in-place (CIP) systems is common practice. The CIP cleaning solutions are re-used and cleaning procedures are optimized with respect to cleaning time and volumes of cleaning solution. However, for membrane processes hardly any attention has previously been paid to this. Rinsing with water, enzymatic and chemical cleaning were studied. The outcome was that the major part of the original membrane capacity can be restored by a water-rinse, and enzymatic and chemical cleaners can be re-used. Also industrial

Tab. 1: Contacts of laboratories and institutes involved in the AIR-project

Contact	laboratory/institute
H. C. van der Horst	NIZO, Ede, The Netherlands
G. Daufin	INRA, LRTL, Rennes, France
A. Quemener	IUT Rennes, LSS, Rennes, France
P. Labbe	ENSC, Paris, France
R. Alvarez	University of Oviedo, Oviedo, Spain



UNITED STATES PATENT AND TRADEMARK OFFICE

132
132

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22301-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/318,977	12/13/2002	Charles F. Kuhlman	AM100926	8497
25291	7590	09/27/2004	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			PRATT, HELEN F	
			ART UNIT	PAPER NUMBER
			1761	
DATE MAILED: 09/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

138
(3)

Office Action Summary	Application No.	Applicant(s)	
	10/318,977	KUHLMAN ET AL.	
	Examiner	Art Unit	
	Helen F. Pratt	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on ____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) ☐ Claim(s) ____ is/are allowed.

6) ☒ Claim(s) 1-11 is/are rejected.

7) ☐ Claim(s) ____ is/are objected to.

8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____.
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) ☐ Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date ____.	6) ☐ Other: ____.

134
134

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakai (Canadian patent 1243887) and Uchida et al. (5,503,864) and Kuwata et al. (5,436,020).

Nakai disclose an formula containing a whey fraction which has less than 40% of the total protein as alpha-lactalbumin (AL) and less than 8 % beta-lactoglobulin (BL). Claim 1 differs from the reference in the particular amount of BL. However, no criticality is seen at this time in the use of a whey fraction which has more than 8% BL because generally the goal of formulas is to make the milk more like human milk which does not have any BL (page 10, Table 3). Also, it is known that cows milk has 9% BL of the total protein of cow's milk. (Table 3). Uchida et al. disclose that it is known to make an AL enriched fraction from whey in which the AK to BK ratio is greater than 3:1 to make a breast-milk substitute using this composition in which the AL to BK is greater than 6:1. (col. 4, lines 65-70 and col. 7, lines 30-34, col. 8, lines 10-14). Applicants' ratio of AL to BL is about 5:1. Kuwata discloses that it is known to use whey fractions in the claimed amounts, therefore, in a ratio of 5:1, AL to BL and that since due to production costs, it is desirable to use a product obtained by decreasing the content of BK of the whey

135
135

protein concentrate to produce these ratios (col. 5, lines 26-35, col. 10, lines 1-14).

Therefore, it would have been obvious to add more AL to a formula to increase the amount of AL as shown by Uchida in the process of Nakai or to use a composition which has the claimed ratio of BL as shown by Kuwata as the whey protein of Nakai.

The limitations of claim 8 have been discussed above and are obvious for those reasons. It is seen that the formula of the references would have been well-tolerated as it is known how to make such a composition. Therefore, it would have been obvious to make the claimed composition as shown by the combined references.

Claim 11 is to the method of feeding an infant the claimed composition. However, as the references shown formulas for feeding infants, it would have been obvious to use the claimed composition in feeding infants.

Claims 2-7, 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above combined references as applied to the above claims, and further in view of Roger et al. (4,485,040).

Claim 2 further requires an amount of bovine milk which has 1.0 to 1.2 grams of protein /100 KC. Roger et al. disclose 1.65 g of protein in milk (col. 12, lines 12-15). No patentable distinction is seen in the difference in grams at this time. Applicants' specification discloses that Standard milk-based infant formula has 15-16 g/L of protein (page 7, Table 1). It is not known how many KC are found in formula. However, as it is well known that infants require protein, it would have been within the skill of the ordinary worker to use enough protein to provide for necessary growth of the infant particularly as disclosed by Roget et al.. The further limitations have been discussed above and

136
136

are obvious for those reasons. Therefore, it would have been obvious to use around the claimed amount of protein in the composition of the combined references.

Claim 3 further requires that the BL is in a higher percentage. However, the above references disclose various amounts of BL and that it is known as shown by Kuwata that it is not practical to totally remove BL from whey, it would have been obvious to leave particular amounts of BK in the composition and to add the AL as shown by the combined references.

Claim 4 further requires a particular amount of non-protein, total protein, fat and ash in the bovine whey material. However, as it is well known how to filter milk to achieve these amounts it would have been within the skill of the ordinary to do so. Kuwata et al. disclose less than 15% non-protein nitrogen, and less than 4.5% ash (table 2, col. 6.). The total protein and fat content depend on the degree of filtration and amount of water in the composition. If there is little water then a 95% amount of protein could have been achieved or lesser amounts as in claims 5 and 6. Applicants table 1 on page 7 disclose 33-55 g/L of protein which is within the claimed amount as in claim 5. Further removal of water would have produced particular amounts as in claim 6. Therefore, it would have been obvious to filter by various means to achieve the claimed amounts.

Claim 7 further requires particular amounts of amino acids. Rogers et al. disclose various amounts of amino acids. Certainly, the amounts depend on the type of proteins from which they come and the types of filtration methods. Nothing critical is

137
137

seen at this time in the particular amounts. Therefore, it would have been obvious to use various amounts of amino acids in the claimed composition.

Claim 8 further requires that the dominant whey protein is alpha lactalbumin. Kuwata discloses a whey product which contains such (col. 7, lines 45-50), as does Nakai (page 10, Table 3). Therefore, it would have been obvious to use AL as the dominant whey protein in the composition of the combined references.

Claim 10 further requires a particular amount of AL in the infant formula. As the combined references disclose that it is known that the AL is 2.2 grams per 670 KC or more. Kuwata discloses that human milk can contain 2.6 grams per liter of AL which surely contains 670 KC (col. 1, lines 50-66). Therefore, it would have been obvious to use the same amount of AL as in human milk, which is known to be good for infants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Application/Control Number: 10/318,977

Page 6

Art Unit: 1761

you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

Hp 9-22-04

H. Pratt
HELEN PRATT
PRIMARY EXAMINER



☐ EPA/EPO/EB
D-80298 München
☎ +49 89 2399-0
TX 523 656 epmu d
FAX +49 89 2399-4465

Europäisches
Patentamt

Generaldirektion 2

European
Patent Office

Directorate General 2

Office européen
des brevets

Direction Générale 2

Connelly, Michael John
John Wyeth & Brother Limited
Huntercombe Lane South
Taplow
Maidenhead
Berkshire, SL6 0PH
ROYAUME-UNI

Telephone numbers:

Primary Examiner
(substantive examination) +49 89 2399-2138

Formalities Officer / Assistant
(Formalities and other matters) +49 89 2399-0



Application No. 02 805 966.5 - 2114	Ref. AM-100926	Date 14.08.2006
Applicant Wyeth		

Communication pursuant to Article 96(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 36(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).



Merkel, B
Primary Examiner
for the Examining Division

Enclosure(s): 2 page/s reasons (Form 2906)



The examination is being carried out on the following application documents:

Description, Pages

1-24 as published

Claims, Numbers

1-12 as published

1. An International Preliminary Report on Patentability / International Preliminary Examination Report has already been drawn up for the present application in accordance with the PCT. The deficiencies mentioned in that report give rise to objections under the corresponding provisions of the EPC.
2. To meet the requirements of Rule 27(1)(b) EPC, the documents D1-D5 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.

The last paragraph on page 24 is superfluous and contributes to ambiguity and therefore should be deleted (Guidelines C-III, 4.3a).

The attention of the applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC).

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern



Bescheid/Protokoll (Anlage)		Communication/Minutes (Annex)	Notification/Procès-verbal (Annexe)
Datum Date Date	14.08.2006	Blatt Sheet Feuille	Anmelde-Nr.: Application No.: Demande n°:
		2	02 805 966.5

141
141

amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based.

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/40811

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A23C9/15 A23C11/04 A23L1/305

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A23C A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, FSTA

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	J. TIMMER: "Whey protein concentrates with non-traditional compositions" EUROPEAN DAIRY MAGAZINE , vol. 189, no. 8, 1997, pages 47-49, XP008016321 page 48 -page 49; figure 2 ---	1,8-11
X,P	WO 02 28194 A (ELGAR DAVID FRANCIS ;NEW ZEALAND DAIRY BOARD (NZ); UNIV MASSEY (NZ) 11 April 2002 (2002-04-11) page 37; table 9 ---	1,8,11
X	US 6 312 755 B1 (WU CHAO) 6 November 2001 (2001-11-06) example 6 ----- -/--	1,9

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

A document member of the same patent family

Date of the actual completion of the international search

17 April 2003

Date of mailing of the international search report

29/04/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Desmedt, G

INTERNATIONAL SEARCH REPORT

Intern al Application No

PCT/US 02/40811

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 311 283 A (EXPRESS FOODS GROUP LTD) 12 Apr11 1989 (1989-04-12) example 2 ---	1,8
A	CA 1 243 887 A (CANADIAN DAIRY COMMISSION COMM) 1 November 1988 (1988-11-01) page 10; table 3 ---	1,2,8-11
A	US 5 436 020 A (KOBAYASHI TOSHITAKA ET AL) 25 July 1995 (1995-07-25) cited in the application examples 1,5; table 2 ---	1,2
A	US 5 503 864 A (UCHIDA YUKIO ET AL) 2 Apr11 1996 (1996-04-02) example 1; table III ---	1,2
A	US 4 485 040 A (ROGER LOIC ET AL) 27 November 1984 (1984-11-27) column 10; example 1 ---	1,2
A	EP 0 604 684 A (CAMPINA MELKUNIE BV) 6 July 1994 (1994-07-06) cited in the application & US 5 420 249 A 30 May 1995 (1995-05-30) -----	1,2

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern al Application No

PCT/US 02/40811

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0228194	A	11-04-2002	AU 1111502 A	15-04-2002
			WO 0228194 A1	11-04-2002
US 6312755	B1	06-11-2001	AU 5933900 A	05-02-2001
			EP 1196045 A1	17-04-2002
			WO 0105243 A1	25-01-2001
			US 2002044998 A1	18-04-2002
EP 0311283	A	12-04-1989	AT 73298 T	15-03-1992
			AU 2290988 A	13-04-1989
			CA 1307075 A1	01-09-1992
			DE 3869037 D1	16-04-1992
			DK 543688 A	09-04-1989
			EP 0311283 A2	12-04-1989
			ES 2032565 T3	16-02-1993
			IE 60312 B1	29-06-1994
			JP 1165343 A	29-06-1989
			NZ 226344 A	27-08-1991
			US 5008376 A	16-04-1991
CA 1243887	A	01-11-1988	CA 1243887 A1	01-11-1988
US 5436020	A	25-07-1995	JP 3240437 A	25-10-1991
			JP 3261429 B2	04-03-2002
			AU 622066 B2	26-03-1992
			AU 7097491 A	22-08-1991
			DE 69110151 D1	13-07-1995
			DE 69110151 T2	09-05-1996
			EP 0443763 A2	28-08-1991
			IE 910475 A1	28-08-1991
			NZ 237077 A	27-06-1994
US 5503864	A	02-04-1996	JP 2622789 B2	18-06-1997
			JP 5236883 A	17-09-1993
			AU 666512 B2	15-02-1996
			AU 3307493 A	19-08-1993
			FR 2687901 A1	03-09-1993
			NZ 245929 A	22-12-1994
US 4485040	A	27-11-1984	FR 2459619 A1	16-01-1981
			AR 222560 A1	29-05-1981
			AU 538288 B2	09-08-1984
			AU 5966680 A	08-01-1981
			BR 8003973 A	13-01-1981
			CA 1136919 A1	07-12-1982
			DE 3063675 D1	14-07-1983
			DK 273380 A ,B,	27-12-1980
			EP 0022696 A1	21-01-1981
			ES 8201006 A1	01-03-1982
			FI 802010 A ,B,	27-12-1980
			JP 1701735 C	14-10-1992
			JP 3062720 B	26-09-1991
			JP 56036494 A	09-04-1981
			NO 801903 A ,B,	29-12-1980
			US 4711953 A	08-12-1987
			ZA 8003748 A	24-06-1981
EP 0604684	A	06-07-1994	EP 0604684 A1	06-07-1994

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No
PCT/US 02/40811

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0604684	A	AT 154200 T	15-06-1997
		AU 664934 B2	07-12-1995
		AU 5267493 A	07-07-1994
		CA 2111668 A1	24-06-1994
		DE 69220374 D1	17-07-1997
		DK 604684 T3	26-01-1998
		JP 7123927 A	16-05-1995
		NZ 250400 A	27-04-1995
		US 5420249 A	30-05-1995

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

RECEIVED

05 MAR 2004

Applicant's or agent's file reference AM100926	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/US 02/40811	International filing date (day/month/year) 18.12.2002	Priority date (day/month/year) 21.12.2001
International Patent Classification (IPC) or both national classification and IPC A23C9/15		
Applicant WYETH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

EPO - DG 1

09. 04. 2004

103

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(II) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 30.06.2003	Date of completion of this report 04.03.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Merkl, B Telephone No. +49 89 2399-2138 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/US 02/40811**

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-24 as originally filed

Claims, Numbers

1-12 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

148
148

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/US 02/40811**

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	10-12
	No: Claims	1-9
Inventive step (IS)	Yes: Claims	
	No: Claims	1-12
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US02/40811

149
149

Item V:

1. D1: J. TIMMER: 'Whey protein concentrates with non-traditional compositions' EUROPEAN DAIRY MAGAZINE, vol. 189, no. 8, 1997, pages 47-49, XP008016321
D2: WO 02 28194 A (ELGAR DAVID FRANCIS ;NEW ZEALAND DAIRY BOARD (NZ); UNIV MASSEY (NZ) 11 April 2002 (2002-04-11)
D3: US-B1-6 312 755 (WU CHAO) 6 November 2001 (2001-11-06)
D4: EP-A-0 311 283 (EXPRESS FOODS GROUP LTD) 12 April 1989 (1989-04-12)
D5: CA-A-1 243 887 (CANADIAN DAIRY COMMISSION COMM) 1 November 1988 (1988-11-01)
D6: US-A-5 436 020 (KOBAYASHI TOSHITAKA ET AL) 25 July 1995 (1995-07-25) cited in the application
D7: US-A-5 503 864 (UCHIDA YUKIO ET AL) 2 April 1996 (1996-04-02)
D8: US-A-4 485 040 (ROGER LOIC ET AL) 27 November 1984 (1984-11-27)
D9: EP-A-0 604 684 (CAMPINA MELKUNIE BV) 6 July 1994 (1994-07-06) cited in the application & US 5 420 249 A 30 May 1995 (1995-05-30)
D10: US-A-5420249

2. D1 discloses whey protein concentrates comprising 36% α -lactalbumin and 32% [SPEC0803]-lactoglobulin (see Fig. 2). Although infant formulas are not mentioned there the product WPI99 is regarded to be suitable also as infant formula. Therefore the subject-matter of claims 1 and 2 is regarded not to be novel.

D2 discloses a protein composition comprising 34% α -lactalbumin and 18% [SPEC0803]-lactoglobulin (page 37, Table 9) as being a useful ingredient for an infant formula. Therefore the subject-matter of claims 1-3 is regarded not to be novel. The features additionally defined in claims 4-9 are not disclosed literally in D2 but can be present inherently.

D3 discloses an α -lactalbumin enriched whey protein product wherein the α -lactalbumin level is 37,3% (Example 6) which can also be used for infant formula (col. 1, lines 23, 35-42). The amount of [SPEC0803]-lactoglobulin is not disclosed but could possibly be within the range claimed in the claims of the pending application.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US02/40811

D4 discloses in Example 2 a whey protein product wherein the ratio of α -lactalbumin to [SPEC0803]-lactoglobulin is 7:4. The amounts are not disclosed but could fall within the percentages defined in the claims of the pending application.

From D5 is known to reduce the [SPEC0803]-lactoglobulin content for infant formula (Table 3).

It appears that the problem of the pending application, namely to provide an infant formula with improved tolerance by infants has already been solved by the cited prior art. The claims on file do not appear to comprise any additional features which might be the basis for an inventive step

Additionally the following remarks are made:

Claim 8 is an independent claim which differs from claim 1 only in that the desired result is stated. However, as the result is not a technical feature said claim does not differ from claim 1 and is regarded as being superfluous.

Claim 9 comprises the expression "dominant whey protein" and therefore is unclear as the meaning of said expression is not well-defined in the art (dominant in which respect?).