

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 September 2006 (21.09.2006)

PCT

(10) International Publication Number
WO 2006/099013 A3

(51) International Patent Classification:
A23L 1/29 (2006.01)

(21) International Application Number:
PCT/US2006/008354

(22) International Filing Date: 8 March 2006 (08.03.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/660,087 9 March 2005 (09.03.2005) US

(71) Applicant (for all designated States except US): **ABBOTT LABORATORIES** [US/US]; Dept. 377/AP6A-1, 100 Abbott Park Road, Abbott Park, Illinois 60064 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **BARRETT-REIS, Bridget** [US/US]; 9401 Traceyton Drive, Dublin, Ohio 43017 (US). **MAZER, Terry** [US/US]; 7032 Cunningham Drive, New Albany, Ohio 43054 (US). **BLACK, Cynthia** [US/US]; 747 Westray Drive, Westerville, Ohio 43081 (US).

(74) Agents: **WINTER, William, J.** et al.; 108140 DS1, 625 Cleveland Avenue, Columbus, OH 43215 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

(88) Date of publication of the international search report:
23 November 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CONCENTRATED LIQUID HUMAN MILK FORTIFIER (HMF)

(57) Abstract: Disclosed are concentrated, liquid, human milk fortifier compositions comprising from about 15% to about 45% by weight of protein, on a dry weight basis, and having a caloric density of from about 1.25 kcal/ml to about 6.0 kcal/ml, wherein the liquid human milk fortifier composition is added to human milk in a volume-volume ratio of from about 1:3 to about 1:9. These composition include embodiments comprising carbohydrate and fat, that are formulated with improved stability by selecting any one of the following variations: 1) certain whey-casein protein blends, 2) water insoluble calcium-containing materials, 3) protein hydrolysates, and 4) aseptically packaged concentrates. The liquid concentrates are especially useful for providing nutrition to preterm infants in neonatal intensive care units or similar other institutional setting, and to minimize the risk of introducing microbial contaminants such as *Enterobacter sakazakii* to infant feedings during preparation in such institutional settings.



WO 2006/099013 A3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/008354

A. CLASSIFICATION OF SUBJECT MATTER
INV. A23L1/29

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)
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)

EPO-Internal, WPI Data, FSTA, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	WO 2005/051088 A (ABBOTT LABORATORIES; JOHNS, PAUL, W; BARRETT-REIS, BRIDGET; MAZER, TER) 9 June 2005 (2005-06-09)	1-33
P, Y	page 13, paragraph 2; claims; table 2 page 14, last paragraph page 15, paragraph 2 page 17, paragraphs 2,3 page 21, paragraphs 3,4 page 27, last paragraph; table 6	1-33
P, Y	WO 2005/122790 A (N.V. NUTRICIA; VAN TOL, ERIC, A., F; WILLEMSSEN, LINETTE, EUSTACHIA, MA) 29 December 2005 (2005-12-29) page 12, paragraph 3 - page 14, paragraph 4 ----- -/--	1-33

☒ Further documents are listed in the continuation of Box C.

☒ See patent family 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.
- * & * document member of the same patent family

Date of the actual completion of the international search

12 July 2006

Date of mailing of the international search report

01/09/2006

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

Baminger, U

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/008354

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/021868 A1 (BARRETT-REIS BRIDGET ET AL) 30 January 2003 (2003-01-30) paragraphs [0007], [0013], [0014], [0016], [0017], [0019], [0020], [0033], [0063]; claims; table 1	7-29, 31-33
Y	WO 2004/032651 A (WYETH; BURGHER, ANITA, MARIA; KAUP, SUSAN, MARIE; KUHLMAN, CHARLES, FR) 22 April 2004 (2004-04-22) page 1, paragraph 1 page 5, line 2 - line 10	7-29, 31-33
A	US 2001/029267 A1 (KUCHAN MATTHEW A ET AL) 11 October 2001 (2001-10-11) paragraph [0034]; claims 8,15	1-33
A	VAN ACKER JOS ET AL: "Outbreak of necrotizing enterocolitis associated with Enterobacter sakazakii in powdered milk formula" JOURNAL OF CLINICAL MICROBIOLOGY, vol. 39, no. 1, January 2001 (2001-01), pages 293-297, XP002389533 ISSN: 0095-1137 page 297, last paragraph	1-33
A	US 2003/175358 A1 (EUBER JOHN RUSSELL ET AL) 18 September 2003 (2003-09-18) paragraph [0005]	1-33
A	MOYER-MILEUR L ET AL: "EVALUATION OF LIQUID OR POWDERED FORTIFICATION OF HUMAN MILK ON GROWTH AND BONE MINERALIZATION STATUS OF PRETERM INFANTS" JOURNAL OF PEDIATRIC GASTROENTEROLOGY AND NUTRITION, RAVEN PRESS, NEW YORK, NY, US, vol. 15, no. 4, 1992, pages 370-374, XP000933692 ISSN: 0277-2116 page 373, paragraph 2 - page 374, paragraph 1 page 371, paragraph 1	
T	ROSS, ABBOTT LABORATORIES: "Similac Natural Care Advance, Low Iron Human Fortifier (HMF)"[Online] XP002389553 Retrieved from the Internet: URL:http://rpdcon40.ross.com/pn/PediatricP roducts.NSF/web_Ross.com_XML_PediatricNutr ition/20CB14E07C70552785256A8000754761?Ope nDocument> [retrieved on 2006-07-04]	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/008354

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005051088 A	09-06-2005	NONE	
WO 2005122790 A	29-12-2005	NONE	
US 2003021868 A1	30-01-2003	NONE	
WO 2004032651 A	22-04-2004	AU 2003279193 A1 BR 0315152 A CA 2500564 A1 CN 1703152 A EP 1549158 A1 MX PA05003596 A NZ 539849 A	04-05-2004 16-08-2005 22-04-2004 30-11-2005 06-07-2005 03-06-2005 28-04-2006
US 2001029267 A1	11-10-2001	NONE	
US 2003175358 A1	18-09-2003	NONE	