(19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 21 June 2007 (21.06.2007)

(10) International Publication Number WO 2007/070611 A3

(51) International Patent Classification:

A23L 1/29 (2006.01) A23L 1/30 (2006.01)

A61K 31/202 (2006.01)

(21) International Application Number:

PCT/US2006/047642

(22) International Filing Date:

14 December 2006 (14.12.2006)

(25) Filing Language: English

(26) Publication Language: **English**

(30) Priority Data:

US 11/303,374 16 December 2005 (16.12.2005)

(71) Applicant (for all designated States except US): BRISTOL-MYERS SQUIBB COMPANY [US/US]; Lawrenceville-princeton Road, Princeton, NJ 08543-4000 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): ANTHONY, Joshua C. [US/US]; 3301 Cobblefield Drive, Evansville, IN 47711 (US). PETERSON, Catherine A. [US/US]; 2201 Misty Glen, Columbia, MO 65203 (US). SIMS, Kevin A. [US/US]; 601 Hwy 62 West, P.o. Box 328, Mt. Vernon, IN 47620-0328 (US). DIERSEN-SCHADE, Deborah [US/US]; 8100 Upper Mt. Vernon Road. Evansville, IN 47712 (US). HOSSEN, Monjur [BD/US]; 2729 Sugar Cane Lane, Evansville, IN 47715 (US). SAMUEL, Priscilla [IN/US]; 2011 Willow Lake Dr., Newburgh, IN 47630 (US).

- (74) Agent: NELSON MULLINS RILEY & SCARBOR-OUGH LLP; 1320 Main Street/17th Floor, Columbia, SC 29201 (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, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report: 13 September 2007

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: NUTRITIONAL SUPPLEMENT CONTAINING LONG-CHAIN POLYUNSATURATED FATTY ACIDS

(57) Abstract: The present invention relates to a nutritional supplement for administration to children. The supplement comprises a protein component, a carbohydrate component, and a fat or lipid component which further comprises a source of DHA. The supplement has an ω-6:ω- 3 fatty acid ratio of about 6:1 or less. The present invention also relates to a method of providing nutrition to a pediatric subject comprising administering to the subject a nutritional supplement comprising a protein component; a carbohydrate component; and a fat or lipid component, which further comprises a source of DHA, wherein the composition has an ω-6:ω-3 fatty acid ratio of about 6:1 or less.

WO 2007/070611 A3



International application No PCT/US2006/047642

A. CLASSIFICATION OF SUBJECT MATTER INV. A23L1/29 A23L1 Ä23L1/30 A61K31/202 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 A61K 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 C. DOCUMENTS CONSIDERED TO BE RELEVANT Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X JENSEN R G: "LIPIDS IN HUMAN MILK" 1-21 LIPIDS, CHAMPAIGN, IL, US, vol. 34, no. 12, 1999, pages 1243-1271, XP008040614 ISSN: 0024-4201 table 10 WO 2005/084129 A2 (HTL HIGH TECH LIPIDS 1 - 30X LTD [IL]; ROZEN GEILA [IL]; SHOCHAT IRIT [IL]) 15 September 2005 (2005-09-15) page 6, lines 21-33; claims 1-29,62,63 US 2005/054724 A1 (MUSTAD VIKKIE A [US] ET AL) 10 March 2005 (2005-03-10) 1 - 30X claims 1-45; examples A-D See patent family annex. Further documents are listed in the continuation of Box C. * Special categories of cited documents: "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 "A" document defining the general state of the art which is not considered to be of particular relevance invention "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to 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) 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 continuous step. "O" document referring to an oral disclosure, use, exhibition or other means in the art. *P* document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 24/07/2007 13 July 2007 Authorized officer 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 De Jong, Ellen

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT						
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.				
X	US 2004/219188 A1 (COMER GAIL M [US] ET AL) 4 November 2004 (2004-11-04) paragraph [0055]; claims 1-23; tables 1-4,9	1-30				
X	DE 43 04 394 A1 (FRESENIUS AG [DE]) 2 September 1993 (1993-09-02) claims 1-17; examples 1-17	1–30				
X	WO 2004/105516 A (NUTRINOVA [DE]; RUESING MATTHIAS [DE]; HAUSMANNS STEPHAN [DE]) 9 December 2004 (2004-12-09) page 11, lines 14-16; claims 1-21; examples 1-4 page 15, lines 11-20	1-30				
Y	SIMOPOULOS A P: "The importance of the ratio of omega-6/omega-3 essential fatty acids" BIOMEDICINE AND PHARMACOTHERAPY, ELSEVIER, PARIS, FR, vol. 56, no. 8, October 2002 (2002-10), pages 365-379, XP002438414 ISSN: 0753-3322 pages 374-376	1-30				
Y	KOLETZKO B ET AL: "EFFECTS OF DIETARY LONG-CHAIN POLYUNSATURATED FATTY ACIDS ON THE ESSENTIAL FATTY ACID STATUS OF PREMATURE INFANTS" EUROPEAN JOURNAL OF PEDIATRICS, SPRINGER VERLAG, vol. 148, no. 7, 1989, pages 669-675, XP009046783 ISSN: 0340-6199 pages 674-675; table 1	1-30				
Υ	MORLION B J ET AL: "P.98 What is the optimum omega-3 to omega-6 fatty acid (FA) ratioof parenteral lipid emulsions in postoperative trauma?" CLINICAL NUTRITION, CHURCHILL LIVINGSTONE, LONDON, GB, vol. 16, August 1997 (1997-08), page 49, XP004683442 ISSN: 0261-5614 the whole document	1-30				
Y	WO 02/15720 A (NESTLE SA [CH]; AGRONOMIQUE INST NAT RECH [FR]) 28 February 2002 (2002-02-28) cited in the application the whole document	1-30				

	PCT/US2006/047642
Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
WO 03/043445 A (GERBER PROD [US]; NOVARTIS NUTRITION AG [CH]; CARY JULIE [US]; COLETTA) 30 May 2003 (2003-05-30) cited in the application page 5, paragraph 3; examples 1-12	1-30
US 5 902 797 A (BELL STACEY J [US] ET AL) 11 May 1999 (1999-05-11) cited in the application the whole document	1-30
US 2004/013787 A1 (THEUER RICHARD C [US]) 22 January 2004 (2004-01-22) the whole document	1-30
EP 1 557 096 A (NUTRICIA NV [NL]) 27 July 2005 (2005-07-27) the whole document	1-30
WO 2004/112508 A (NESTEC SA [CH]; SECRETIN MARIE-CHRISTINE [CH]) 29 December 2004 (2004-12-29) the whole document	1-30
KOCH T ET AL: "Benefits of omega-3 fatty acids in parenteral nutrition" CLINICAL NUTRITION SUPPLEMENTS, ELSEVIER, vol. 1, no. 3, 2005, pages 17-24, XP004988204 ISSN: 1744-1161 the whole document	1-30
US 5 374 657 A (KYLE DAVID J [US]) 20 December 1994 (1994-12-20) claims 1-22; tables 2-6	1-30
	Citation of document, with indication, where appropriate, of the relevant passages WO 03/043445 A (GERBER PROD [US]; NOVARTIS NUTRITION AG [CH]; CARY JULIE [US]; COLETTA) 30 May 2003 (2003-05-30) cited in the application page 5, paragraph 3; examples 1-12 US 5 902 797 A (BELL STACEY J [US] ET AL) 11 May 1999 (1999-05-11) cited in the application the whole document US 2004/013787 A1 (THEUER RICHARD C [US]) 22 January 2004 (2004-01-22) the whole document EP 1 557 096 A (NUTRICIA NV [NL]) 27 July 2005 (2005-07-27) the whole document WO 2004/112508 A (NESTEC SA [CH]; SECRETIN MARIE-CHRISTINE [CH]) 29 December 2004 (2004-12-29) the whole document KOCH T ET AL: "Benefits of omega-3 fatty acids in parenteral nutrition" CLINICAL NUTRITION SUPPLEMENTS, ELSEVIER, vol. 1, no. 3, 2005, pages 17-24, XP004988204 ISSN: 1744-1161 the whole document US 5 374 657 A (KYLE DAVID J [US]) 20 December 1994 (1994-12-20)

International application No. PCT/US2006/047642

INTERNATIONAL SEARCH REPORT

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 26-30(partly) because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 26-30 are directed to a method of treatment of the human body, the search has been carried out and based on the alleged effects of the compound/composition.
Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

information on patent family members

					<u></u>		
	ent document n search report	-	Publication date		Patent family member(s)		Publication date
WO 2	2005084129	A2	15-09-2005	CA EP	2557927 1723096		15-09-2005 22-11-2006
US 2	2005054724	A1	10-03-2005	AU BR CA CN EP JP KR 2 MX WO	2004271928 PI0414096 2536692 1874692 1662905 2007504225 20060076766 PA06002481 2005025334	A A1 A A1 T A	24-03-2005 31-10-2006 24-03-2005 06-12-2006 07-06-2006 01-03-2007 04-07-2006 20-06-2006 24-03-2005
US 2	2004219188	A1	04-11-2004	NONE			والمر يستم مست المتن المتن والمن المتن والمن المتن والمن المتن المتن المتن المتن المتن المتن المتن المتن المتن
DE 4	4304394	A1	02-09-1993	EP FI NO	0611568 940629 940236	Α	24-08-1994 14-08-1994 15-08-1994
WO 2	2004105516	A	09-12-2004	DE EP JP US	10324548 1633207 2007501852 2007010480	A1 T	16-12-2004 15-03-2006 01-02-2007 11-01-2007
WO	0215720	A	28-02-2002	AT AU BR CA CN DE CN DE EP EP HU JP MX PL RU RU	313273 9177701 9548801 0113367 0113390 2418285 2419026 1469712 1471363 60116112 0215719 1313378 1313376 2254496 0301475 0301586 2004506436 2004506437 PA03001598 PA03001600 365934 365936 2277354 2277355	A A A A A A A A A A A A A A A A A A A	15-01-2006 04-03-2002 04-03-2002 29-07-2003 29-07-2002 28-02-2002 21-01-2004 28-01-2004 03-08-2006 28-02-2002 28-05-2003 28-05-2003 28-05-2003 16-06-2006 28-08-2003 04-03-2004 04-03-2004 01-11-2004 04-06-2003 10-01-2005 24-01-2005
WO (03043445	Α	30-05-2003	AU BR CA MX	2002366229 0214320 2465813 PA04006244	A A1	10-06-2003 03-11-2004 30-05-2003 17-05-2005
US!	5902797	Α	11-05-1999	NONE			
US :	2004013787	A1	22-01-2004	NONE			

Information on patent familiy members

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 1557096	Α	27-07-2005	DK EP EP	1237419 T3 1237419 A1 1535520 A1	27-06-2005 11-09-2002 01-06-2005
WO 2004112508	Α	29-12-2004	AU CA CN US	2004248912 A1 2532472 A1 1829452 A 2007110849 A1	29-12-2004 29-12-2004 06-09-2006 17-05-2007
US 5374657	A .	20-12-1994	AT AU BR CA DE DE DK EP ES GR IL JP MX NZ OA RU	200619 T 661297 B2 1239292 A 9205526 A 2101274 A1 69231793 D1 69231793 T2 568606 T1 568606 T3 0568606 A1 2157898 T3 3036139 T3 100733 A 2731035 B2 6505153 T 9200320 A1 241359 A 10348 A 2093996 C1	15-05-2001 20-07-1995 27-08-1992 19-04-1994 25-07-1992 23-05-2001 08-11-2001 25-02-1999 23-07-2001 10-11-1993 01-09-2001 28-09-2001 31-12-1995 25-03-1998 16-06-1994 01-10-1992 26-08-1994 19-10-2001 27-10-1997
نا بعد جلدا الهو بعدة الله بعدة الله بعد الله بعدا الله بعد سند مند مند			SG WO ZA	49307 A1 9212711 A1 9200452 A	18-05-1998 06-08-1992 28-10-1992