INFORMATION DISCLOSURE STATEMENT BY APPLICANT
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Application Number	
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	
Examiner Name	
Attorney Docket Number	AKBM-14409/US-13/CON

	11	2524217	JP		1996-08-14	TAIYO FISHERY CO LTD		
	12	2963152	JP		1992-02-25	CHLORINE ENG CORP LTD		
	13	3081692	JP		1994-07-19	CHLORINE ENG CORP LTD		
	14	3344887	JP		1997-07-08	IKEDA SHOKKEN KK		
	15	3467794	JP		2003-09-05	NIPPON OIL & FATS CO LTD		
	16	3486778	JP		2003-10-31	GREEN CROSS CORP		
	17	3611222	JP		1997-08-05	CHLORINE ENG CORP LTD		
	18	3678317	JP		2005-05-20	CHLORINE ENG CORP LTD		
	19	4012665	JP		1992-01-17	MATSUSHITA ELECTRIC IND CO LTD		
	20	61281159	JP		1986-12-11	SHISEIDO CO LTD; NIPPON SUISAN KAISHA LTD.		
	21	2001-158736	JP		2001-06-12	SNOW BRAND MILK PROD CO LTD		

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	22	2003-003192	JP		2003-01-08	UNITIKA LTD		
	23	2003-048831	JP		2003-02-21	SUNTORY LTD		
	24	2003-146883	JP		2003-05-21	SNOW BRAND MILK PROD CO LTD		
	25	2005-245379	JP		2005-09-15	NIPPON SUISAN KAISHA LTD		
	26	2006-069948	JP		2006-03-16	HIROSE YUKIHIRO		
	27	2006-083136	JP		2006-03-30	SUNTORY LTD		
	28	2006-290784	JP		2006-10-26	HIROSE YUKIHIRO		
	29	2006-316073	JP		2006-11-24	IBR ISRAELI BIOTECHNOLOGY RESEARCH LTD		
	30	2006-328014	JP		2006-12-07	HIROSE YUKIHIRO		
	31	2007-126455	JP		2007-05-24	FUJI CHEM IND CO LTD		
	32	2007-246404	JP		2007-09-27	SNOW BRAND MILK PROD CO LTD		

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	33	220741	SU		1971-01-06	KRGUCHKOV		
	34	1986/06082	WO		1986-10-23	MAT-CON RADGIVENDE INGENIØRFIRMA A/S		
	35	1990/05765	WO		1990-05-31	MIKALSEN		
	36	1993/24142	WO		1993-12-09	PHAIRSON MEDICAL AB		
	37	1997/38585	WO		1997-10-23	THE UNIVERSITY OF BRITISH COLUMBIA		
	38	1997/39759	WO		1997-10-30	BRIGHAM AND WOMEN'S HOSPITAL		
	39	1998/34498	WO		1998-08-13	BIOZYME SYSTEMS INC.		
	40	1999/39589	WO		1999-08-12	ALOISE		
	41	2000/23546	WO		2000-04-27	UNIV SHERBROOKE		
	42	2000/25608	WO		2000-05-11	NIPPON SUISAN KAISHA, LTD		
	43	2000/38708	WO		2000-07-06	PHAIRSON MEDICAL INC.		

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	44	2002/102394	WO		2002-12-27	NEPTUNE TECHNOLOGIES & BIORESS		
	45	2003/011873	WO		2003-02-13	NEPTUNE TECHNOLOGIES & BIORESSOURCES INC.		
	46	2005/037848	WO		2005-04-28	ENZYMOTEC LTD.		
	47	2005/038037	WO		2005-04-28	ENZYMOTEC INC.		
	48	2007/080514	WO		2007-07-19	KRILL A/S		
	49	2007/080515	WO		2007-07-19	AKER BIOMARINE ASA		
	50	2007/108702	WO		2007-09-27	AKER SEAFOODS HOLDING AS		

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	1	ANDO and HATANO, 1988, "Isolation of apolipoproteins from carotenoid-carrying lipoprotein in the serum of chum salmon, Oncorhynchus keta", J. Lipid Research, 29: 1264-1271	
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	3	BRITTON, 1985, "General Carotenoid Methods", Methods in Enzymology, Vol 111, pp. 113-149
	4	CALDER, 2006, "n-3 polyunsaturated fatty acids, inflammation, and inflammatory diseases", Am. J. Clin. Nutr., 83: 1505S
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	6	CHEN and MEYERS, 1982, "Extraction of Astaxanthin Pigment from Crawfish Waste Using a Soy Oil Process", J. Food Sci., 47: 892-896
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	27	KOLAKOWSKA, 1989, "Krill lipids after frozen storage of about one year in relation to storage time before freezing", Die Nahrung Food, 33(3): 241-244	
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	45	SACHINDRA, 2006, "Recovery of carotenoids from shrimp waste in organic solvents", Waste Management, 26: 1092-1098	
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	48	SIDEHU et al., 1970, "Biochmical Composition and Nutritive Value of Krill (Euphausia superb dana)", J. Sci Food Agr., Vol 21, 293-296	
	49	SIMOPOULOS, 1991, "Omega-3 fatty acids in health and disease and in growth and development", Am. Clin. Nutr. 54:438-63	
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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/J. Mitchell Jones/	Date (YYYY-MM-DD)	2016-06-13
Name/Print	J. Mitchell Jones	Registration Number	44174

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SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
15/180,439	06/13/2016	424	1651	AKBM-14409/US-13/CON

APPLICANTS

AKER BIOMARINE ANTARCTIC AS, Stamsund, NORWAY;

INVENTORS

Inge Bruheim, Volda, NORWAY;
Snorre Tilseth, Bergen, NORWAY;
Daniele Mancinelli, Orsta, NORWAY;

**** CONTINUING DATA ***************************

This application is a CON of 14/020,162 09/06/2013 PAT 9375453
which is a CON of 12/057,775 03/28/2008 PAT 9034388
which claims benefit of 60/920,483 03/28/2007
and claims benefit of 60/975,058 09/25/2007
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          0*  FILE BIOTECHNO
          2   FILE CAPLUS
          0*  FILE CEABA-VTB
          0*  FILE CIN
          0*  FILE FOMAD
          0*  FILE FROSTI
          2   FILE IFIALL
  30 FILES SEARCHED...
          0*  FILE KOSMET
          0*  FILE NTIS
          0*  FILE PASCAL
         15   FILE USPATFULL
          4   FILE USPAT2

   4 FILES HAVE ONE OR MORE ANSWERS,   46 FILES SEARCHED IN STNINDEX
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L2   QUE KRILL(P) OIL AND PHOSPHOLIPID? AND TRIMETHYL(P) AMINE AND ASTAXANTHIN

=> file uspat2 usptfull ifiall caplus
'USPTFULL' IS NOT A VALID FILE NAME
Enter "HELP FILE NAMES" at an arrow prompt (=>) for a list of files
that are available.  If you have requested multiple files, you can
specify a corrected file name or you can enter "IGNORE" to continue
accessing the remaining file names entered.
ENTER A FILE NAME OR (IGNORE):.
COST IN U.S. DOLLARS                                SINCE FILE      TOTAL
                                                         ENTRY    SESSION
FULL ESTIMATED COST                                       2.91       3.18

FILE 'USPAT2' ENTERED AT 21:08:51 ON 09 JUL 2016
CA INDEXING COPYRIGHT (C) 2016 AMERICAN CHEMICAL SOCIETY (ACS)

FILE 'IFIALL' ENTERED AT 21:08:51 ON 09 JUL 2016
COPYRIGHT (C) 2016 IFI CLAIMS(R) Patent Services (IFI)

FILE 'CAPLUS' ENTERED AT 21:08:51 ON 09 JUL 2016
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COPYRIGHT (C) 2016 AMERICAN CHEMICAL SOCIETY (ACS)

=> s L2
L3           8 L2

=> dup rem L3
PROCESSING COMPLETED FOR L3
L4            8 DUP REM L3 (0 DUPLICATES REMOVED)

=> d L4 1-8

L4   ANSWER 1 OF 8  USPAT2 on STN
AN     2014:304518  USPAT2
TI     Formulations of water-soluble derivatives of vitamin E and compositions
       containing same
IN     Bromley, Philip J., Fullerton, CA, UNITED STATES
PA     Virun, Inc., Walnut, CA, UNITED STATES (U.S. corporation)
PI     US 9351517          B2  20160531
AI     US 2014-14207310        20140312 (14)
PRAI   US 2013-61852243        20130315 (61)
DT     Utility
FS     GRANTED
LN.CNT 12112
NCL    NCLM:  424/094.100
       NCLS:  426/072.000; 514/458.000; 514/690.000
CPC    CPCI   A23L0002-52 [I]; A61K0031-355 [I]; A61K0031-122 [I]; A61K0031-202
              [I]; A61K0031-355 [I], A61K2300-00; A61K0031-202 [I],
              A61K2300-00; A61K0031-201 [I], A61K2300-00; A61K0031-122 [I],
              A61K2300-00; A61K0031-05 [I], A61K2300-00; A61K0031-59 [I],
              A61K2300-00
       CPCI-2 A23L0002-52 [I]; A23L0001-30 [I]; A23L0001-3002 [I]; A23L0001-302
              [I]; A23L0001-304 [I]; A23L0001-3006 [I]; A23L0001-3008 [I];
              A23L0002-02 [I]; A23L0002-60 [I]; A61K0009-0095 [I];
              A61K0009-1075 [I]; A61K0031-05 [I]; A61K0031-122 [I];
              A61K0031-201 [I]; A61K0031-202 [I]; A61K0031-355 [I]; A61K0031-59
              [I]; A61K0047-36 [I]; A61K0047-44 [I]; A61K0031-355 [I],
              A61K2300-00; A61K0031-202 [I], A61K2300-00; A61K0031-201 [I],
              A61K2300-00; A61K0031-122 [I], A61K2300-00; A61K0031-05 [I],
              A61K2300-00; A61K0031-59 [I], A61K2300-00
IPC    IPCI   A23L0002-52 [I]; A61K0031-122 [I]; A61K0031-202 [I]; A61K0031-355
              [I]
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IPCI-2 A61K0038-43 [I]; A23L0002-52 [I]; A61K0031-355 [I]; A61K0031-122 [I]; A61K0031-202 [I]; A23L0001-30 [I]; A23L0001-302 [I]; A23L0001-304 [I]; A23L0002-02 [I]; A23L0002-60 [I]; A61K0031-05 [I]; A61K0031-201 [I]; A61K0031-59 [I]; A61K0009-00 [I]; A61K0047-36 [I]; A61K0009-107 [I]; A61K0047-44 [I]
IPCR A23L0002-52 [I]; A61K0031-122 [I]; A61K0031-202 [I]; A61K0031-355 [I]

L4 ANSWER 2 OF 8 USPAT2 on STN
AN 2013:254433 USPAT2
TI Reduced fluoride crustacean oil compositions
IN Bruheim, Inge, Volda, NORWAY
Griinari, Mikko, Espoo, FINLAND
Remoy, Stig Rune, Fosnavaag, NORWAY
PA OLYMPIC SEAFOOD AS, NORWAY (non-U.S. corporation)
PI US 9068142 B2 20150630
AI US 2013-13856642 20130404 (13)
RLI Division of Ser. No. US 2012-13342664, filed on 3 Jan 2012, Pat. No. US 8557297 Continuation of Ser. No. US 1900-63488, PENDING A 371 of International Ser. No. WO 2009-NO322, filed on 14 Sep 2009
PRAI NO 2008-3906 20080912
DT Utility
FS GRANTED
LN.CNT 1416
NCL NCLM: 001/001.000; 530/359.000
NCLS: 530/350.000; 554/078.000
CPC CPCI C11B0003-006 [I]; C07K0019-00 [I]; C07K0014-43509 [I]
CPCI-2 C11B0003-006 [I]; A23L0001-0153 [I]; A23L0001-3053 [I]; A23L0001-33 [I]; A23L0001-3006 [I]; A23L0001-3252 [I]; A23D0009-013 [I]; A23J0001-04 [I]; A23L0001-0152 [I]; C07K0014-43509 [I]; C07K0019-00 [I]; A23J0003-34 [I]; A23D0009-007 [I]; A23D0009-02 [I]; C11B0001-10 [I]; C11B0001-104 [I]; C11B0001-025 [I]
IPC IPCI C11B0003-00 [I]; C07K0014-435 [I]; C07K0019-00 [I]
IPCI-2 C07K0001-00 [I]; C11B0003-00 [I]; A23L0001-015 [I]; A23L0001-305 [I]; A23L0001-33 [I]; A23L0001-30 [I]; A23L0001-325 [I]; A23D0009-013 [I]; A23J0001-04 [I]; C07K0014-435 [I]; C07K0019-00 [I]; A23J0003-34 [I]; A23D0009-007 [I]; A23D0009-02 [I]; C11B0001-10 [I]; C11B0001-02 [I]
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CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L4 ANSWER 3 OF 8 IFIALL COPYRIGHT 2016 IFI on STN
AN 14080750 IFIALL
TI METHOD FOR PROCESSING CRUSTACEANS TO PRODUCE LOW FLUORIDE/LOW TRIMETHYL AMINE PRODUCTS THEREOF
IN Bruheim Inge (NO); Griinari Mikko (FI); Ervik Jon Reidar (NO); Remoy Stig Rune (NO); Remoy Even (NO); Cameron John (NO)
PA Unassigned or assigned to individual (68000)
PPA Olympic Seafood As; Rimfrost As (Probable)
PI US 20150030751 A1 20150129
AI US 2012-370324 20121221 (14)
WO 2012-IB3004 20121221
20140702 PCT 371 date
20140702 PCT 102(e) date
RLI US 2012-342664 20120103 CONTINUATION-IN-PART 8557297
FI US 20150030751 20150129
US 8557297

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DT    Utility; Patent Application - First Publication
FS    CHEMICAL
      APPLICATION
ED    Entered STN: 30 Jan 2015
      Last Updated on STN: 20 Nov 2015
CLMN  25

L4   ANSWER 4 OF 8  USPAT2 on STN
AN     2012:168278  USPAT2
TI     Method for processing crustaceans and products thereof
IN     Bruheim, Inge, Volda, NORWAY
       Griinari, Mikko, Espoo, FINLAND
       Ervik, Jon Reidar, Aalesund, NORWAY
       Remoy, Stig Rune, Fosnavag, NORWAY
PA     Olympic Seafood, AS, Fosnavaag, GERMANY, FEDERAL REPUBLIC OF (non-U.S.
       corporation)
PI     US 8557297          B2  20131015
AI     US 2012-13342664        20120103 (13)
RLI    Continuation of Ser. No. US 1900-63488, PENDING A 371 of International
       Ser. No. WO 2009-NO322, filed on 14 Sep 2009
DT     Utility
FS     GRANTED
LN.CNT 1435
INCL   INCLM: 424/538.000
       INCLS: 435/068.100; 435/325.000; 435/381.000; 500/300.000; 500/359.000;
              426/665.000; 426/417.000
NCL    NCLM:  424/538.000; 530/300.000
       NCLS:  426/417.000; 426/665.000; 435/068.100; 435/325.000; 435/381.000;
              530/300.000; 530/359.000; 554/008.000; 554/021.000; 554/084.000
CPC    CPCI   A23J0003-04 [I]; A23D0009-007 [I]; A23D0009-013 [I]; A23D0009-02
              [I]; A23J0001-04 [I]; A23J0003-34 [I]; A23L0001-0152 [I];
              A23L0001-0153 [I]; A23L0001-3006 [I]; A23L0001-3053 [I];
              A23L0001-3252 [I]; A23L0001-33 [I]; C07K0014-43509 [I];
              C07K0019-00 [I]; C11B0001-025 [I]; C11B0001-10 [I]; C11B0001-104
              [I]; C11B0003-006 [I]; Y02P0020-544
       CPCI-2 A23J0003-04 [I]; A23D0009-007 [I]; A23D0009-013 [I]; A23D0009-02
              [I]; A23J0001-04 [I]; A23J0003-34 [I]; A23L0001-0152 [I];
              A23L0001-0153 [I]; A23L0001-3006 [I]; A23L0001-3053 [I];
              A23L0001-3252 [I]; A23L0001-33 [I]; C07K0014-43509 [I];
              C07K0019-00 [I]; C11B0001-025 [I]; C11B0001-10 [I]; C11B0001-104
              [I]; C11B0003-006 [I]; Y02P0020-544
IPC    IPCI   C11B0001-10 [I]; C07F0009-02 [I]; C07K0014-00 [I]; C07K0002-00
              [I]
       IPCI-2 A61K0035-64 [I]
       IPCR   A61K0035-64 [I]
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L4   ANSWER 5 OF 8  USPAT2 on STN
AN     2010:256169  USPAT2
TI     Phospholipid and protein tablets
IN     Tilseth, Snorre, Bergen, NORWAY
       Hoem, Nils, Oslo, NORWAY
PA     Aker Biomarine ASA, Oslo, NORWAY (non-U.S. corporation)
PI     US 8372812          B2  20130212
AI     US 2010-711822          20100224 (12)
PRAI   US 2009-61155758        20090226 (61)
DT     Utility
FS     GRANTED
LN.CNT 3399
INCL   INCLM: 514/021.920
       INCLS: 514/762.000; 424/464.000; 424/476.000; 424/477.000
NCL    NCLM:  514/021.920; 514/005.500
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NCLS: 424/464.000; 424/476.000; 424/477.000; 514/762.000; 514/691.000
CPC CPCI A23L0001-0026 [I]; A23L0001-3006 [I]; A23L0001-305 [I]; A23L0001-33 [I]; A61K0009-2009 [I]; A61K0009-2054 [I]; A61K0009-2866 [I]; A61K0031-122 [I]; A61K0031-685 [I]; A61K0035-612 [I]; A61K0031-122 [I], A61K2300-00; A61K0035-612 [I], A61K2300-00; A61K0031-685 [I], A61K2300-00
CPCI-2 A23L0001-0026 [I]; A23L0001-3006 [I]; A23L0001-305 [I]; A23L0001-33 [I]; A61K0009-2009 [I]; A61K0009-2054 [I]; A61K0009-2866 [I]; A61K0031-122 [I]; A61K0031-685 [I]; A61K0035-612 [I]; A61K0031-122 [I], A61K2300-00; A61K0035-612 [I], A61K2300-00; A61K0031-685 [I], A61K2300-00
IPC IPCI A61K0038-02 [I]
IPCI-2 A61K0038-17 [I]; A61K0031-01 [I]; A61K0009-20 [I]; A61K0009-38 [I]; A61K0009-42 [I]
IPCR A61K0038-17 [I]; A61K0009-20 [I]; A61K0009-38 [I]; A61K0009-42 [I]; A61K0031-01 [I]
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L4 ANSWER 6 OF 8 CAPLUS COPYRIGHT 2016 ACS on STN
AN 2013:1076636 CAPLUS
DN 159:212682
TI Phospholipid-protein complex from crustaceans with low fluoride and low trimethyl amine
IN Bruheim, Inge; Griinari, Mikko; Ervik, Jon Reidar; Remoy, Stig Rune; Remoy, Even; Cameron, John
PA Olympic Seafood AS, Norway
SO PCT Int. Appl., 60pp.
CODEN: PIXXD2
DT Patent
LA English
FAN.CNT 4
PI

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2013102792	A2	20130711	WO 2012-IB3004	20121221
WO 2013102792	A3	20131227		
W: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, 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, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW				
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US 20120149867	A1	20120614	US 2012-13342664	20120103
US 8557297	B2	20131015		
CA 2862261	A1	20130711	CA 2012-2862261	20121221
AU 2012364278	A1	20140724	AU 2012-364278	20121221
KR 2014107663	A	20140904	KR 2014-7021397	20121221
EP 2800481	A2	20141112	EP 2012-837639	20121221
R: AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LI, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR				
CN 104159456	A	20141119	CN 2012-80071115	20121221
JP 2015504947	T	20150216	JP 2014-550767	20121221
NZ 626764	A	20160429	NZ 2012-626764	20121221
US 20150030751	A1	20150129	US 2014-14370324	20140702

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     AU 2015100022        A4   20150212    AU 2015-100022          20150109
     AU 2015100022        B4   20160107
PRAI US 2012-13342664     A    20120103
     WO 2009-NO322        A    20090914
     US 2011-13063488     A1   20110524
     AU 2012-364278       A3   20121221
     WO 2012-IB3004       W    20121221
ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT

L4   ANSWER 7 OF 8  CAPLUS  COPYRIGHT 2016 ACS on STN
AN   2010:1135144  CAPLUS
DN   153:392038
TI   Low viscosity phospholipid compositions
IN   Tilseth, Snorre
PA   Aker Biomarine ASA, Norway
SO   U.S. Pat. Appl. Publ., 37 pp., Cont.-in-part of U.S. Ser. No. 201,325.
     CODEN: USXXCO
DT   Patent
LA   English
FAN.CNT 3
PI
     PATENT NO.          KIND  DATE        APPLICATION NO.          DATE
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     US 20100226977       A1   20100909    US 2010-711553           20100224
     CA 2839075           A1   20090305    CA 2008-2839075          20080829
     US 20090061067       A1   20090305    US 2008-201325           20080829
     NZ 598062            A    20131129    NZ 2008-598062           20080829
     EP 2732709           A1   20140521    EP 2014-154671           20080829
         R:  AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU,
             IE, IS, IT, LI, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI,
             SK, TR
     CN 103815114         A    20140528    CN 2014-10024848         20080829
     JP 2012087132        A    20120510    JP 2011-253673           20111121
     JP 5639990           B2   20141210
     AU 2013202260        A1   20130502    AU 2013-202260           20121030
     AU 2012244229        B2   20131121    AU 2012-244229           20121030
     US 20140107072       A1   20140417    US 2013-14136848         20131220
     AU 2014100741        A4   20140724    AU 2014-100741           20140627
     AU 2014100741        B4   20140911
     US 20150050403       A1   20150219    US 2014-14490204         20140918
     JP 2015038141        A    20150226    JP 2014-217988           20141027
     AU 2014256341        A1   20141120    AU 2014-256341           20141029
     AU 2014256341        B2   20160414
PRAI US 2007-60968765     P    20070829
     US 2008-201325       A2   20080829
     US 2009-61155767     P    20090226
     AU 2008-291978       A    20080829
     CA 2008-2697730      A3   20080829
     CN 2008-80112125     A3   20080829
     EP 2008-788481       A3   20080829
     JP 2010-522444       A3   20080829
     NZ 2008-583520       A3   20080829
     JP 2011-253673       A3   20111121
     AU 2012-244229       A3   20121030
     AU 2013-202260       A3   20121030
ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT
OSC.G   2     THERE ARE 2 CAPLUS RECORDS THAT CITE THIS RECORD (2 CITINGS)

L4   ANSWER 8 OF 8  IFIALL  COPYRIGHT 2016 IFI on STN
AN    12061067  IFIALL
TI    METHOD FOR MAKING KRILL MEAL
IN    Hostmark Oistein (NO); Tilseth Snorre (NO)
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PA    Aker BioMarine ASA NO (79725)
PI    US 20090061067  A1  20090305
AI    US 2008-201325      20080829  (12)
PRAI  US 2007-968765P      20070829 (Provisional)
FI    US 20090061067      20090305
DT    Utility; Patent Application - First Publication
FS    CHEMICAL
      APPLICATION
ED    Entered STN: 10 Mar 2009
      Last Updated on STN: 9 Apr 2009
CLMN  51


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     ESBIOBASE, FOMAD, FROSTI, FSTA, GENBANK, IFIALL, ...' ENTERED AT 21:06:59
     ON 09 JUL 2016
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               0*  FILE KOSMET
               0*  FILE NTIS
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                SEA KRILL(P)OIL AND PHOSPHOLIPID? AND TRIMETHYL(P)AMINE AND AST
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               2   FILE IFIALL
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               0*  FILE NTIS
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              15   FILE USPATFULL
               4   FILE USPAT2
L2              QUE KRILL(P) OIL AND PHOSPHOLIPID? AND TRIMETHYL(P) AMINE AND A
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     FILE 'USPAT2, IFIALL, CAPLUS' ENTERED AT 21:08:51 ON 09 JUL 2016
L3             8 S L2
L4             8 DUP REM L3 (0 DUPLICATES REMOVED)

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ALL L# QUERIES AND ANSWER SETS ARE DELETED AT LOGOFF
LOGOFF? (Y)/N/HOLD:y

COST IN U.S. DOLLARS	SINCE FILE ENTRY	TOTAL SESSION
FULL ESTIMATED COST	55.14	58.32

STN INTERNATIONAL LOGOFF AT 21:13:40 ON 09 JUL 2016

WEST Search History for Application 15180439

Creation Date: 2016070921:03

Prior Art Searches

Query	DB	Hits	Op.	Plur.	Thes.	Date
krill.clm. and oil.clm. and superba.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	20	OR	YES		07-09-2016
krill.clm. and oil.clm. and phospholipid.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	140	OR	YES		07-09-2016
krill.clm. and oil.clm. and phospholipids.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	140	OR	YES		07-09-2016
(krill.clm. and oil.clm. and phospholipids.clm.) and trimethyl.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	2	OR	YES		07-09-2016
krill and oil and phospholipid and trimethyl	PGPB, USPT, USOC, EPAB, JPAB, DWPI,	108	OR	YES		07-09-2016

	TDBD, FPRS					
(krill and oil and phospholipid and trimethyl) and astaxanthin	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	57	OR	YES		07-09-2016
(krill and oil and phospholipid and trimethyl and astaxanthin) and ether	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	55	OR	YES		07-09-2016
(krill and oil and phospholipid and trimethyl and astaxanthin and ether) and Euphausia	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	13	OR	YES		07-09-2016
(krill and oil and phospholipid and trimethyl and astaxanthin and ether and Euphausia) and ((A61K2300/00 | A61K35/612 | A61K31/122 | A61K31/685 | A61K31/133 | A61K31/198 | A61K31/202 | A61K31/575 | A61K38/1767 | A61K9/2009 | A61K9/2054 | A61K9/2866 | A23L1/3006 | A23L1/33 | A23L1/305 | A23L1/0152 | A23L1/0153 | A23L1/3053 | A23L1/3252 | A23L1/0026 | A23L1/30 | A23L1/3008 | A23L1/326 | A23D9/013 | A23D9/007 | A23D9/02 | A23D7/011 | C11B1/10 | C11B1/025 | C11B1/104 | C11B3/006 | C11B1/06 | A23J1/04 | A23J3/34 | A23J3/04 | A23J7/00 | Y02P20/544 | A23K20/158 | A23K10/22 | A23K20/179 | A23K50/80 | C07K14/43509 | C07K19/00 | C07F9/103 | A23V2002/00).CPC.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	13	OR	YES		07-09-2016
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A23L1/3006 | A23L1/33 | A23L1/305 | A23L1/0152 | A23L1/0153 | A23L1/3053 | A23L1/3252 | A23L1/0026 | A23L1/30 | A23L1/3008 | A23L1/326 | A23D9/013 | A23D9/007 | A23D9/02 | A23D7/011 | C11B1/10 | C11B1/025 | C11B1/104 | C11B3/006 | C11B1/06 | A23J1/04 | A23J3/34 | A23J3/04 | A23J7/00 | Y02P20/544 | A23K20/158 | A23K10/22 | A23K20/179 | A23K50/80 | C07K14/43509 | C07K19/00 | C07F9/103 | A23V2002/00).CPC.)	JPAB, DWPI, TDBD, FPRS					
(((A61K2300/00 | A61K35/612 | A61K31/122 | A61K31/685 | A61K31/133 | A61K31/198 | A61K31/202 | A61K31/575 | A61K38/1767 | A61K9/2009 | A61K9/2054 | A61K9/2866 | A23L1/3006 | A23L1/33 | A23L1/305 | A23L1/0152 | A23L1/0153 | A23L1/3053 | A23L1/3252 | A23L1/0026 | A23L1/30 | A23L1/3008 | A23L1/326 | A23D9/013 | A23D9/007 | A23D9/02 | A23D7/011 | C11B1/10 | C11B1/025 | C11B1/104 | C11B3/006 | C11B1/06 | A23J1/04 | A23J3/34 | A23J3/04 | A23J7/00 | Y02P20/544 | A23K20/158 | A23K10/22 | A23K20/179 | A23K50/80 | C07K14/43509 | C07K19/00 | C07F9/103 | A23V2002/00).CPC.)) and krill and oil and phospholipid	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	804	OR	YES		07-09-2016
(((A61K2300/00 | A61K35/612 | A61K31/122 | A61K31/685 | A61K31/133 | A61K31/198 | A61K31/202 | A61K31/575 | A61K38/1767 | A61K9/2009 | A61K9/2054 | A61K9/2866 | A23L1/3006 | A23L1/33 | A23L1/305 | A23L1/0152 | A23L1/0153 | A23L1/3053 | A23L1/3252 | A23L1/0026 | A23L1/30 | A23L1/3008 | A23L1/326 | A23D9/013 | A23D9/007 | A23D9/02 | A23D7/011 | C11B1/10 | C11B1/025 | C11B1/104 | C11B3/006 | C11B1/06 | A23J1/04 | A23J3/34 | A23J3/04 | A23J7/00 | Y02P20/544 | A23K20/158 | A23K10/22 | A23K20/179 | A23K50/80 | C07K14/43509 | C07K19/00 | C07F9/103 | A23V2002/00).CPC.) and krill and oil and phospholipid) and trimethyl	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	40	OR	YES		07-09-2016
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A23L1/3252 | A23L1/0026 | A23L1/30 | A23L1/3008 | A23L1/326 | A23D9/013 | A23D9/007 | A23D9/02 | A23D7/011 | C11B1/10 | C11B1/025 | C11B1/104 | C11B3/006 | C11B1/06 | A23J1/04 | A23J3/34 | A23J3/04 | A23J7/00 | Y02P20/544 | A23K20/158 | A23K10/22 | A23K20/179 | A23K50/80 | C07K14/43509 | C07K19/00 | C07F9/103 | A23V2002/00).CPC.) and krill and oil and phospholipid and trimethyl) and astaxanthin	TDBD, FPRS					
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(krill.clm. and oil.clm. and superba.clm.) and trimethyl.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	OR	YES		07-09-2016
Inge.in. and Bruheim.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	116	OR	YES		07-09-2016
(Inge.in. and Bruheim.in.) and krill.clm. and phospholipid.clm. and trimethyl.clm.	PGPB, USPT, USOC, EPAB, JPAB,	1	OR	YES		07-09-2016

	DWPI, TDBD, FPRS					
trimethyl.clm. and astaxanthin.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	19	OR	YES		07-09-2016
(trimethyl.clm. and astaxanthin.clm.) and krill.clm. and oil.clm. and phospholipid.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	2	OR	YES		07-09-2016
20040241249	PGPB	1	OR	YES		07-09-2016
(20040241249) and trimethyl	PGPB	0	OR	YES		07-09-2016
(20040241249) and phospholipid	PGPB	1	OR	YES		07-09-2016
(20040241249 and phospholipid) and methyl	PGPB	0	OR	YES		07-09-2016
Krill and oil and (encapsulated or capsule)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	1182	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule)) and methyl and amine	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	328	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule)) and trimethyl and amine	PGPB, USPT, USOC, EPAB, JPAB,	86	OR	YES		07-09-2016

	DWPI, TDBD, FPRS					
(Krill and oil and (encapsulated or capsule) and trimethyl and amine) and krill and oil	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	86	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule) and trimethyl and amine and krill and oil) and Euphausia	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	12	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule) and methyl and amine) and oil	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	328	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule) and trimethyl and amine and krill and oil) and capsule	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	63	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule) and trimethyl and amine and krill and oil and capsule) and encapsulated and krill and oil	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	6	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule) and trimethyl and amine and krill and oil and capsule and encapsulated and krill and oil)	PGPB, USPT, USOC,	6	OR	YES		07-09-2016

	EPAB, JPAB, DWPI, TDBD, FPRS					
trimethylamine and krill	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	133	OR	YES		07-09-2016
(trimethylamine and krill) and oil	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	122	OR	YES		07-09-2016
(trimethylamine and krill and oil) and astaxanthin	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	64	OR	YES		07-09-2016
(trimethylamine and krill and oil and astaxanthin) and phospholipid	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	54	OR	YES		07-09-2016
9375453.pn.	USPT	1	OR	YES		07-09-2016
9034388.pn.	USPT	1	OR	YES		07-09-2016
(9034388.pn.) and amine.clm.	USPT	0	OR	YES		07-09-2016
(9034388.pn.) and trimethyl.clm.	USPT	0	OR	YES		07-09-2016
(9375453.pn.) and amine.clm.	USPT	0	OR	YES		07-09-2016
(9375453.pn.) and trimethyl.clm.	USPT	0	OR	YES		07-09-2016

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	
Examiner Name	
Attorney Docket Number	AKBM-14409/US-13/CON

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	9119864		2015-09-01	AKER BIOMARINE ANTARCTIC AS	
	2	9072752		2015-07-07	AKER BIOMARINE ANTARCTIC AS	
	3	9034388		2015-05-19	Inge Bruheim et al.	
	4	9028877		2015-05-12	AKER BIOMARINE ANTARCTIC AS	
	5	9078905		2015-07-14	AKER BIOMARINE ANTARCTIC AS	
	6	8372812		2013-02-12	Snorre Tilseth et al.	
	7	8697138		2014-04-15	Inge Bruheim et al.	

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Application Number	
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	
Examiner Name	
Attorney Docket Number	AKBM-14409/US-13/CON

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140274968		2014-09-18	AKER BIOMARINE ANTARCTIC AS	
	2	20150030718		2015-01-29	AKER BIOMARINE ANTARCTIC AS	
	3	20140088043		2014-03-27	AKER BIOMARINE ANTARCTIC AS	
	4	20140088047		2014-03-27	AKER BIOMARINE ANTARCTIC AS	
	5	20140080791		2014-03-20	AKER BIOMARINE ANTARCTIC AS	
	6	20150164841		2015-06-18	AKER BIOMARINE ANTARCTIC AS	
	7	20140363517		2014-12-11	AKER BIOMARINE ANTARCTIC AS	
	8	20100226977		2010-09-09	Snorre Tilseth et al.	
	9	20150050403		2015-02-19	AKER BIOMARINE ANTARCTIC AS	
	10	20140005421		2014-01-02	AKER BIOMARINE ANTARCTIC AS	

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Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	
Examiner Name	
Attorney Docket Number	AKBM-14409/US-13/CON

	11	20140107072		2014-04-17	Snorre Tilseth et al.	
	12	20090061067		2009-03-05	Snorre Tilseth et al.	
	13	20140010888		2014-01-09	AKER BIOMARINE ANTARCTIC AS	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Takahashi et al., Prediction of Relative Retention Value of the Individual Molecular Species of Diacyl Glycerolipid on High Performance Liquid Chromatography, Bull. Fac. Fish. Hokkaido Univ. 38(4), 398-404. 1987	
	2	Tanaka, Biosynthesis of 1,2-dieicosapentaenoyl-sn-glycero-3-phosphocholine in Caenorhabditis elegans, Eur. J. Biochem. 263, 189±194 (1999)	
	3	Tocher, Chapter 6, Glycerophospholipid metabolism, Biochemistry and molecular biology of fishes, vol. 4, Hochachka and Mommsen (eds.)(1995)	

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Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
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Attorney Docket Number	AKBM-14409/US-13/CON

	4	Watanabe et al., Effective Components in Cuttlefish Meal and Raw Krill for Improvement of Quality of Red Seabream Pagrus major Eggs, Nippon Suisan Gakkaishi 57(4):681-694 (1991)("Watanabe")	
	5	WHO News and Activities, Bulletin of the World Health Organization, 73(4), pp. 547-51 (1995) ("WHO Bulletin")	
	6	VALERI, D., et al., "Visocities of Fatty acids, triglycerides and their binary mixtures," JAOCS 74 (1997) pp. 1221-1226	
	7	CRC 2013-2014, 94th ed., pp. 6-231-6-235	
	8	EP Opposition filed February 13, 2014 by Olympic Seafood AS, EP Patent Application No. EP08718910l6	
	9	BRZUSTOWICZ, Michael R., et al., "Controlling Membrane Cholesterol Content. A Role for Polyunsaturated (Docosahexaenoate) Phospholipids," Biochemistry (2002), 41, pp. 12509-12519	
	10	JONG-HO LEE, "A Review: Antioxygenic and Peroxide-decomposing Activities of Antarctic Krill Lipids," J. Korean Soc. Food Mutr. 13(3) pp. 326-333 (1984)	
	11	KI WOONG CHO, et al., "Lipid and Fatty Acid Composition of the Antarctic Krill Euphausia superba," Ocean Research 21(2): 109-116 (1999)	
	12	HVATTUM, Erlend, et al., "Effect of soybean oil and fish oil on individual molecular species of Atlantic salmon...", Journal of Chromatography B, 748 (2000) 137-149	
	13	IGARASHI, Daisuke, et al., "Positional Distribution of DHA and EPA in Phosphatidylcholine and Phosphatidylethanolamine from Different Tissues of Squids," J. Oleo Sci. Vol. 50, No. 9 (2001)	
	14	TOCHIZAWA, Kaoru, et al., "Effects of Phospholipds Containing Docosahexaenoic Acid on Differentiation and Growth of HL-60 Human Promyelocytic Leukemia Cells," J. Jpn. Oil Chem. Soc. Vol. 46, No. 4 (1997)	

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Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
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Examiner Name	
Attorney Docket Number	AKBM-14409/US-13/CON

	15	ZEROUGA, Mustapha, et al., "Comparison of phosphatidylcholines containing one or two docosahexaenoic acyl chains on properties of phospholipid monolayers and bilayers," Biochimica et Biophysica Acta 1236 (1995) 266-272
	16	EUNG-HO LEE, et al., "Studies on the Processing of Krill Sauce," J. Korean Soc. Food Nutr. 13(1) 97-106 (1984)
	17	HYUN-KU KIM, et al., "Effects of Cooking and Drying Methods on the Polar Lipds Composition of Shrimp," Korean J. Food Sci. Technol. Vol. 21, No. 1, pp. 25-30 (1989)
	18	SHON, Mi-Yae, et al., "Effects of Krill and Cadmium on Lipid Composition of Plasma in Cholesterol-Fed Rats," J. Korean Soc. Food Nutr. 23(1), 38-43 (1994)
	19	Summons Materials downloaded from ESPACE on December 16, 2014 for EP Patent Application No. 08 718 910.6
	20	YANASE, M., "Innovations on the russian method for separating heat coagulated protein from antarctic krill, through autolysis," Bulletin of Tokai Regional Fisheries Research Laboratory, 1974, No. 78, p. 79-84
	21	KOLAKOWSKI and GAJOWIECKI, "Optimization of autoproteolysis to obtain and edible product 'precipitate' from Antarctic krill," Seafood Science and Technology, pp. 331-336
	22	EP Opposition filed May 8, 2015 by Olympic Seafood AS, EP Patent No. 2144618, 150 pages
	23	ALLAHPICHAY et al., "Extraction of Growth Promoting Fractions from Non-muscle Krill Meal of Euphausia superba and its Effect on Fish Growth," Bulletin of the Japanese Society of Scientific Fisheries, 1984, 50(5): 821-826

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EXAMINER SIGNATURE

Examiner Signature	/Deborah Ware/	Date Considered	07/11/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	
Examiner Name	
Attorney Docket Number	AKBM-14409/US-13/CON

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.W./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	
Examiner Name	
Attorney Docket Number	AKBM-14409/US-13/CON

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/J. Mitchell Jones/	Date (YYYY-MM-DD)	2016-06-13
Name/Print	J. Mitchell Jones	Registration Number	44174

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/180,439	06/13/2016	Inge Bruheim	AKBM-14409/US-13/CON

CONFIRMATION NO. 4687

72960
Casimir Jones, S.C.
2275 DEMING WAY, SUITE 310
MIDDLETON, WI 53562

PUBLICATION NOTICE

Title:BIOEFFECTIVE KRILL OIL COMPOSITIONS

Publication No.US-2016-0279173-A1
Publication Date:09/29/2016

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Bruheim et al.	Art Unit:	1651
Serial No.:	15/180,439	Examiner:	Ware
Filed:	06/13/2016	Confirmation:	4687
Entitled:	BIOEFFECTIVE KRILL OIL COMPOSITIONS		

RESPONSE TO OFFICE ACTION MAILED JULY 14, 2016

EFS WEB FILED
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Examiner Ware:

This communication is responsive to the Office Action mailed July 14, 2016. The Commissioner is hereby authorized to charge any fees during the entire pendency of this application, including fees due under 37 C.F.R. §§ 1.16 and 1.17 that may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-4302, referencing Attorney Docket No. **AKBM-14409/US-13/CON**. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

CLAIM AMENDMENTS:

1. (Currently amended) A krill oil composition comprising a capsule containing ~~encapsulated~~ *Euphausia superba* krill oil suitable for oral administration, said krill oil comprising from 3% to 15% ether phospholipids w/w of said krill oil[[,]] and astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil~~, and trimethyl amine in an amount of less than 1 mg/kg of said krill oil~~.

2. (Original) The krill oil composition of claim 1, wherein said krill oil composition is substantially odorless.

3. (Original) The krill oil composition of claim 1, wherein said krill oil contains astaxanthin esters in an amount of greater than about 200 mg/kg of said krill oil.

4. (Original) The krill oil composition of claim 1, wherein said krill oil comprises at least 30% total phospholipids w/w of said krill oil.

5. (Original) The krill oil composition of claim 1, wherein said krill oil comprises at least 30% phosphatidylcholine w/w of said krill oil.

6. (Original) The krill oil composition of claim 1, wherein said capsule contains a phytonutrient derived from a source other than krill.

7. (Original) The krill oil composition of claim 1, wherein said krill oil further comprises from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and from about 20% to 50% w/w triglycerides.

8. (Original) The krill oil composition of claim 7, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.

9. (Currently amended) The krill oil composition of claim 1, wherein said ~~krill oil is encapsulated in~~ capsule is a soft gel capsule.

10. (Original) The krill oil composition of claim 1, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.

11. (Currently amended) A composition comprising a soft gel capsule containing Euphausia superba krill oil suitable for oral administration, said krill oil comprising from 3% to 15% ether phospholipids w/w of said krill oil[[,]] and astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil~~, and trimethyl amine in an amount of less than 1 mg/kg of said krill oil~~.

12. (Original) The composition of claim 11, wherein said krill oil composition is substantially odorless.

13. (Original) The composition of claim 11, wherein said krill oil contains astaxanthin esters in an amount of greater than about 200 mg/kg of said krill oil.

14. (Original) The composition of claim 11, wherein said krill oil comprises at least 30% total phospholipids w/w of said krill oil.

15. (Original) The composition of claim 11, wherein said krill oil comprises at least 30% phosphatidylcholine w/w of said krill oil.

16. (Original) The composition of claim 11, wherein said krill oil comprises at least 40% phosphatidylcholine w/w of said krill oil.

17. (Original) The composition of claim 11, wherein said capsule contains a phytonutrient derived from a source other than krill.

18. (Original) The composition of claim 11, wherein said krill oil further comprises from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and from about 20% to 50% w/w triglycerides.

19. (Original) The composition of claim 18, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.

20. (Original) The composition of claim 11, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.

REMARKS

Claims 1-20 are pending and under examination following entry of this amendment. Claims 1, 9 and 11 have been amended. Support for the amendments may be found in the claims as originally filed. No new matter has been added. All amendments and cancellation of claims are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

Applicant thanks the Examiner for the telephonic interview on October 11, 2016.

The pending rejections are addressed in order below.

Indefiniteness. In order to clarify the claims, claim 1 has been amended to recite a capsule, thus providing antecedent basis for use the "capsule" in claim 6. Applicant respectfully submits that this amendment traverses the rejection.

Obviousness. The claims are rejected as allegedly being obvious over Sampalis et al. (US 2004/0241249) in view of Joensen et al. (US 86/06082). Applicant respectfully disagrees. As discussed during the interview, the combined references do not teach each element of the claims and thus there is no prima facie of obviousness.

In particular, the combined referenced do not teach an encapsulated krill oil with from 3% to 15% ether phospholipids. As detailed in the specification, typical phospholipids have two fatty acids attached to a glycerol backbone with ester bonds at positions 1 and 2 along with a polar head group attached at the third position on the glycerol backbone. As indicated at p. 12, lines 6-10 of the specification, an ether phospholipid is a phospholipid having an ether bond at position 1 the glycerol backbone as opposed to the more normal ester bond. Examples of ether phospholipids include, but are not limited to, alkylacylphosphatidylcholine (AAPC), lyso-alkylacylphosphatidylcholine (LAAPC), and alkylacylphosphatidylethanolamine (AAPE). A "non-ether phospholipid" is a phospholipid that does not have an ether bond at position 1 of the glycerol backbone. In the commonly used nomenclature, the ether bond is designated by the "alkyl" in, for example, **alkyl**acylphosphatidylcholine (AAPC).

The Examiner states that Sampalis teaches a krill oil containing 3-15% ether phospholipids, citing paragraphs 0048-0053, which are inserted here for convenience:

[0048] Phospholipids

[0049] Phosphatidylcholine: >4.5 g/100 g

[0050] Phosphatidylinositol: >107 mg/100 g

[0051] Phosphatidylserine: >75 mg/100 g

[0052] Phosphatidylethanolamine: >0.5 g/100 g

[0053] Sphingomyelin: >107 mg/100 g

As can be seen, Sampalis refers to phosphatidylcholine, etc., which is commonly understood to contain two ester bonds as opposed to the claimed ether phospholipids which have an ether bond and would be referred to as the alkylacyl-phospholipids, for example, alkylacylphosphatidylcholine (AAPC). Thus, the concentrations reported in Sampalis do not refer to ether phospholipids as claimed.

Furthermore, Applicant submits that Sampalis (US 2004/0241249) is yet another application directed to the use of Neptune Krill Oil™, which Applicant has tested and shown to contain less than the claimed amounts of ether phospholipids as discussed in more detail below.

The method used to make the krill oil identified in Sampalis (US 2004/0241249) is virtually identical to the method disclosed in Beaudoin (US 6800299; PCT 00/23546) which was cited by the Examiner as the lead reference during the prosecution of Applicant's related patent US 9,078,905 and in Sampalis (US 8,030,348) as discussed during the prosecution of related patent 9,078,905. This can be readily ascertained by comparing the disclosure of the method used in Sampalis (US 2004/0241249) with Sampalis (US 8,030,348).

Sampalis (US 2004/0241249) describes the method used to make the krill oil disclosed as follows at paragraphs 0027-0033:

[0027] The extraction process can be described as the following:

[0028] (a) Placing marine and/or aquatic krill and/or marine in a ketone solvent, preferably acetone, to achieve the extraction of grease from the krill and/or marine;

[0029] (b) Separating the liquid and the solid phases;

[0030] (c) Recovering a lipid rich fraction from the liquid phase obtained at step (b) by evaporation of the solvent present in the liquid phase;

[0031] (d) Placing the solid phase in an organic solvent, which can be alcohol, preferably ethanol, isopropanol or t-butanol, or esters of acetic acid, preferably ethyl acetate. This in order to extract the remaining soluble lipid fraction from the solid phase;

[0032] (e) Separating the liquid and the solid phases; and

[0033] (f) Recovering a lipid rich fraction from the liquid phase obtained at step (e) by evaporation of the solvent present in the liquid phase.

In turn, Sampalis (8,030,348) discloses that the Beaudoin method is used to make Neptune Krill Oil™. See, e.g., column 19, lines 35-40:

iv. Neptune Krill Oil™ (the present invention) phospholipids contain high quantities of eicosapentanoic acid -EPA (20:5) and docosahexanoic acid -DHA (22:6). Their fatty acid profile closely resembles that of human brain phospholipids.

The Beaudoin process used to make the Neptune Krill Oil™ is described at column 18, lines 23-67:

Extraction of the phospholipid composition from the biomass is generally carried out by a method similar to the one described in commonly owned PCT publication number WO 00/23546, published on Apr. 27, 2000, the disclosure of which is incorporated herein by reference. The extraction is generally carried out by successive acetone and alcohol treatments. For the extraction of the instant application, the preferred treatment involves the use of >60% acetone in the first extraction followed by extraction with a mixture of organic solvents at 65-95%/45-50% preferably acetone, ethyl acetate/ethanol mixture. The most preferred extraction solvent system is 100% acetone in the first extraction followed with a 95%/5% ethyl acetate/ethanol mixture. However, other ketones can also be used in combination with or in place of acetone. The alcohol can be other than ethanol, e.g., isopropanol or t-butanol. The acetate may also vary. Further, the ratio of alcohol to acetate may vary widely from 100:0 to 0:100. The procedure produces two successive lipid fractions and a dry residue enriched in protein, including active enzymes.

Preferably, freshly harvested and finely divided marine and aquatic animal material is subjected to acetone extraction, for at least about two hours and preferably overnight. However, extraction time is not critical to the yield of lipid extracted. Particle sizes of comminuted crustacean less than 5 mm are preferred. The extraction is preferably conducted under an inert atmosphere and at a temperature of about 5 degrees Celsius or less. The mixture may be agitated during extraction and a volume ratio of about 6:1 of acetone to biomass is generally most preferred.

The solubilized lipid fraction is separated from the solid starting material by known techniques, for example, by filtration, centrifugation or sedimentation. Filtration is preferred. The residue is optionally washed with acetone to recover more lipid and the acetone removed by flash evaporation or spray drying. Water residue is allowed to separate from the lipid extract at low temperature.

The solid residue left on the filter from the initial extraction is suspended and extracted with 95/5 ethyl acetate/ethanol, preferably two volumes (original volume of material). The filtrate is evaporated yielding a second fraction of lipids. Extraction period is not critical although it is preferred to extract for about 30 minutes at a temperature below about 5 degrees Celsius.

Comparison of the process disclosed in the '348 patent for making Neptune Krill Oil™ with the process disclosed at pages 5 and 6 of Beaudoin (US 6800299; PCT 00/23546) demonstrates that the methods are virtually identical.

The present Applicant analyzed Neptune Krill Oil™ for the presence of ether phospholipids. This data is disclosed in Example 8 and Table 22. The data for NKO (Neptune Krill Oil) shows that the phospholipid fraction of the Neptune Krill Oil contained 8.2% ether phospholipids (7.0% AAPC + 1.2% LAAPC). The Neptune Krill Oil analyzed contained 30% total phospholipids. To give the percent ether phospholipids in the Neptune Krill Oil as a whole, this 8.2% value for the ether phospholipids present in the phospholipid fraction of the krill oil is thus multiplied by 30.0% to give a percent total of 2.46% ether phospholipids w/w of the Neptune Krill Oil™. Applicant respectfully submits that this demonstrates that krill oil made by the Beaudoin method used in Sampalis (US 2004/0241249) and Sampalis (US 8,030,348) does not contain the claimed range of 3% to 15% ether phospholipids as a percentage of the total krill oil composition. Thus, the combined references do not teach each element of the claims.

Joensen does not cure the defects noted for Sampalis (US 2004/0241249) with respect to teaching the claimed concentrations of ether phospholipids.

Applicant respectfully requests that this rejection be withdrawn and the claims passed to allowance.

Double Patenting. The claims are rejected are rejected under provisional double patenting over applications 14/136,848 and 14/370,324. As discussed during the interview, Applicant will file a terminal disclaimer over commonly owned application 14/136,848 and commonly owned related patents 9,320,765; 9,078,905 and 9,072,752.

Application 14/370,324 is not a commonly owned application. Applicant notes that the '324 application claims priority to PCT/IB2012/003004, filed 12/21/2012 which is a CIP of 13/342,664, now US Pat. No. 8,557,297. The '297 patent in turn claims priority to PCT/NO2009/000322 filed on Sep. 14, 2009, which has priority to NO 20083906 filed on Sep. 12, 2008.

The present application claims priority to a parent regular US Application 12/057,775 filed March 28, 2008, which in turns claims priority to a series of US provisional applications with the earliest priority date being March 28, 2007.

Thus the current application has a much earlier priority date than the non-commonly owned '324 application cited by the Examiner. Due to this earlier priority date as compared to the -324 application, Applicant respectfully submits that the double patenting rejection should be withdrawn. See, MPEP §804.

CONCLUSION

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (608) 662-1277.

Dated: October 12, 2016

/J. Mitchell Jones/

John Mitchell Jones
Registration No. 44,174

Casimir Jones, S.C.
2275 Deming Way, Suite 310
Middleton, WI, 53562
(608) 662-1277

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15180439
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	1651
Examiner Name	WARE, DEBORAH K.
Attorney Docket Number	AKBM-14409/US-13/CON

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	1	2011/050474	WO		2011-05-05	ACASTI PHARMA INC.		

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15180439
	Filing Date	2016-06-13
	First Named Inventor	Inge Bruheim
	Art Unit	1651
	Examiner Name	WARE, DEBORAH K.
	Attorney Docket Number	AKBM-14409/US-13/CON

	1	Third Party Observation against corresponding AU Patent Application No. 2014256345, filed May 23, 2016, 50 pages	
	2	Third Party Observation against corresponding AU Patent Application NO. 2013227998, filed July 15, 2016, 6 pages	
	3	Evidence in Support of Opposition, AU Patent Application No. 2013227998, filed September 22, 2016, 22 pages	
	4	Notice of Acceptance of Application, AU Patent Application No. 2013227998, mailed October 5, 2016, 2 pages	

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15180439
	Filing Date	2016-06-13
	First Named Inventor	Inge Bruheim
	Art Unit	1651
	Examiner Name	WARE, DEBORAH K.
	Attorney Docket Number	AKBM-14409/US-13/CON

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/J. Mitchell Jones/	Date (YYYY-MM-DD)	2016-10-12
Name/Print	J. Mitchell Jones	Registration Number	44174

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Australian Government
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Int +61 2 6283 2999
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23 May 2016

Pizzeys Patent and Trade Mark Attorneys Pty Ltd
PO Box 291
WODEN ACT 2606
Australia

44183AKE/TBS

Notification of Further Material Filed Under Section 27

Application Number: 2014256345

Applicant Name: Aker BioMarine Antarctic AS

Your Ref:

Further material has been filed under the provisions of Section 27(1) of the Patents Act 1990 in relation to the above patent application. This further material was received on 23 May 2016.

A copy of this further material has been enclosed for your information and will be considered by the examiner during examination of the application.

If you need any further information please contact 1300 65 1010. Alternatively, please visit us at www.ipaustralia.gov.au

Yours Faithfully

Patents and Plant Breeder's Rights Administration

Shelston IP

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The Commissioner of Patents
IP Australia
PO Box 200
Woden ACT 2606

23 May 2016

Our Ref: 89656AUM00

Contact:
Michael Zammit, PhD

Dear Commissioner

Title: Third Party Observation against AU 2014256345

Urgent

We refer to the above patent application, and in particular the examination report dated 18 November 2015, and the recent response by the Applicant dated 5 May 2016 including a second statement of proposed amendments.

We hereby notify the Commissioner under Section 27 of the *Patents Act 1990* that the alleged invention described and claimed in the above patent application is not a patentable invention because it does not comply with paragraph 18(1)(b) in that it is not novel or does not involve an inventive step when compared with the documents listed in the Annexure. Copies of the prior art are provided with this letter. In support of this notification, we also attach observations on the validity of the claims in the Annexure.

We ask that the Examiner review the prior art and the enclosed observations and take this information into account during further examination.

Yours respectfully
Shelston IP

Michael Zammit, PhD
Registered Patent Attorney
Email: *MichaelZammit@ShelstonIP.com*

THIRD PARTY OBSERVATION AGAINST AU 2014256345

23 May 2016

TABLE OF CONTENTS

BACKGROUND

AU 2014256345 (the **AU '345 application**) is one of the divisional standard applications from AU 2013227998 which has branched out from AU 2011213836, which again is a divisional from AU 2008231570 (WO 2008/117062; Bioeffective krill oil compositions).

The applicant (Aker Biomarine ASA) filed voluntary amendments on 27 August 2015. A first set of third party observations were filed on 12 October 2015, and the first Examination Report subsequently issued on 18 November 2015. A second set of third party observations were filed on 22 December 2015. The Applicant responded to the first examination report on 5 May 2016 and filed a second set of amendments.

The following comprises the third set of third party observations in relation to the amended claims filed by the Applicant on 5 May 2016.

In addition to the first and second set of third party observations (filed on 12 October and 22 December 2015, respectively) the Opponent requests that the Examiner take these third party observations into account when examining the claims submitted by the Applicant on 5 May 2016. This (third) third party submission should be read in conjunction with, and in light of, the first and second set of third party observations.

DISCUSSION OF THE PENDING CLAIMS AND PRELIMINARY COMMENTS

The claims as proposed to be amended in the Applicant's statement of proposed amendments of 5 May 2016 are reproduced in the table below (**the claims** of the AU '345 application). It appears that the Applicant has merely substantially conformed the claims to those of the co-pending US patent, US 9,078,905 (**the '905 Patent**). In the table below, we indicate where the claims are equivalent to those of the '905 Patent. In overview:

- AU claim 1 is equivalent to the combination of claims 1 and claim 6 in US'905 plus the limitation that the astaxanthin ester concentration is greater than 100 mg/kg.
- The subject matter of claims 5, 6, 7, 8, 9, 10 and 11 of the AU claims is identical to the subject matter of claims 4, 5, 7, 8, 9, 10, and 11, respectively, of US'905.
- AU claims 12 to 20 are identical to claims 12 to 20, respectively, of US'905.

	Claims of AU 2014256345	Equivalence to the '905 Patent
1	Encapsulated krill oil comprising: a capsule containing an effective amount of krill oil, said krill oil comprising from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; from about	Claim 1 + Claim 6 + astaxanthin esters concentration greater than 100 mg/kg.

	20% to 50% w/w triglycerides; and greater than about 100 mg/kg astaxanthin esters.	
2	The encapsulated krill oil of claim 1, said krill oil comprising greater than 200 mg/kg astaxanthin esters.	n/a
3	The encapsulated krill oil of claim 1, said krill oil comprising greater than 300 mg/kg astaxanthin esters.	n/a
4	The encapsulated krill oil of claim 1, said krill oil comprising greater than 400 mg/kg astaxanthin esters.	n/a
5	The encapsulated krill oil of claim 1, wherein said krill oil is a polar solvent extract of krill.	Subject matter of claim 4 of the '905 Patent
6	The encapsulated krill oil of claim 1, wherein said capsule contains a phytonutrient derived from a source other than krill.	Subject matter of claim 5 of the '905 Patent
7	The encapsulated krill oil of claim 6, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.	Subject matter of claim 7 of the '905 Patent
8	The encapsulated krill oil of claim 7, wherein from about 70% to 95% of said omega- 3 fatty acids are attached to said phospholipids.	Subject matter of claim 8 of the '905 Patent
9	The encapsulated krill oil of claim 1, wherein said krill is Euphausia superba.	Subject matter of claim 9 of the '905 Patent
10	The encapsulated krill oil of claim 1, wherein said capsule is a soft gel capsule.	Subject matter of claim 10 of the '905 Patent
11	The encapsulated krill oil of claim 1, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.	Subject matter of claim 11 of the '905 Patent
12	Encapsulated krill oil comprising: a capsule containing an effective amount of krill oil, said krill oil comprising from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and from about 20% to 50% w/w triglycerides.	Identical to claim 12 in US'905
13	The encapsulated krill oil of claim 12, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.	Identical to claim 13 in US'905
14	The encapsulated krill oil of claim 13, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said phospholipids.	Identical to claim 14 in US'905

15	The encapsulated krill oil of claim 12, wherein said krill is Euphausia superba.	Identical to claim 15 in US'905
16	The encapsulated krill oil of claim 12, wherein said capsule is a soft gel capsule.	Identical to claim 16 in US'905
17	The encapsulated krill oil of claim 12, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.	Identical to claim 17 in US'905
18	Encapsulated Antarctic krill oil comprising: a soft gel capsule containing an effective amount of krill oil, said krill oil comprising from about 3% to about 10% w/w ether phospholipids, from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and from about 20% to 50% w/w triglycerides.	Identical to claim 18 in US'905
19	The encapsulated krill oil of claim 18, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.	Identical to claim 19 in US'905
20	The encapsulated krill oil of claim 19, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said phospholipids.	Identical to claim 20 in US'905

The Opponent submits that the claims are obvious in view of certain prior art discussed below, and should not be allowed to proceed to acceptance.

Additionally, the Opponent wishes to point out that the claims of US '905 were allowed only after an allegation was made in the prosecution of the '905 Patent of 'unexpected results'. As will be explained below, the allegation in the US prosecution history that 'ether phospholipid' levels in the krill oil were allegedly responsible for superior activity is not tenable. The numbers associated with the bar graphs in Figures 2, 4-6 and 8 of the '905 Patent (which constitute the majority of the data alleged to show unexpected results) reveal that the results with fish oil (which was used as a control) were as good as (or better than) those from krill oil (Superba). Commercial fish oil has no appreciable phospholipids (the omega-3 fatty acids are attached to the triglycerides) due to the way the fish oil is produced (as explained herein). Therefore it is not possible to attribute the results to the presence of phospholipids, let alone to 'ether phospholipids'. Putting this in a legal context, it is impossible for there to be a nexus between the data and the 'ether phospholipid' feature of the claims of the '905 Patent. Without a nexus, the allegation of unexpected results is meaningless. We submit that the Examiner should proceed with great caution in considering the claims of the granted US patent.

Given the issues with the US claims summarised above, and given the submissions made herewith, and given the admissions made on the face of the specification of AU '345, we submit that the claims are obvious and should not be allowed to proceed to acceptance

LIST OF PRIOR ART DOCUMENTS

The following prior art will be relied upon in this submission.

Exhibit	Title / Reference
Exhibit 1001	Bruheim et al., "Bioeffective Krill Oil Compositions" US Patent No. 9,078,905 filed Sept. 18, 2014.
Exhibit 1002	Bruheim et al., "Bioeffective Krill Oil Compositions" US Provisional Application No. 60/920483 filed March 28, 2007.
Exhibit 1003	Bruheim et al., "Bioeffective Krill Oil Compositions" US Provisional Application No. 60/975058 filed Sept. 25, 2007.
Exhibit 1004	Bruheim et al., "Bioeffective Krill Oil Compositions" US Provisional Application No. 60/983446 filed October 29, 2007.
Exhibit 1005	Bruheim et al., "Bioeffective Krill Oil Compositions" US Provisional Application No. 61/024072 filed Jan. 28, 2008.
Exhibit 1006	Catchpole et al., "Process For Separating Lipid Materials" WO 2007/123424 A1 published November 1, 2007.
Exhibit 1007	File Wrapper: Office Action Mailed Nov 17, 2014
Exhibit 1008	File Wrapper: Response to Nov 17, 2014 Office Action
Exhibit 1009	File Wrapper: Final Office Action Mailed Feb 17, 2015
Exhibit 1010	File Wrapper: Response to Feb 17, 2015 Office Action
Exhibit 1011	Bunea et al., "Evaluation of the Effects of Neptune Krill Oil on the Clinical Course of Hyperlipidemia" Altern Med Rev 9(4):420-428 (2004)
Exhibit 1012	Grantham et al., "The Southern Ocean: The Utilization Of Krill" Southern Oceans Fisheries Survey Programme, Food And Agriculture Organization Of The United Nations GLO/SO/77/3 (1977)
Exhibit 1013	Beaudoin et al., "Method Of Extracting Lipids From Marine And Aquatic Animal Tissues" United States Patent No. 6,800,299 B1 filed July 25, 2001.
Exhibit 1014	Beaudoin et al., "Method of Exracting Lipids From Marine And Aquatic Animal Tissues" PCT/CA99/00987 published April 27, 2000 (publication number WO/2000/023546).
Exhibit 1015	Beaudoin et al., "Method Of Extracting Lipids From Marine And Aquatic Animal Tissues" CA 2251265 filed October 21, 1998.
Exhibit 1016	Porzio et al., "Encapsulation Compositions And Processes For Preparing The Same" US Patent No. 7,488,503 B1 filed: March 31, 2004.
Exhibit 1017	Tou et al., "Krill for Human Consumption: Nutritional Value and Potential Health Benefits" Nutritional Reviews 65(2):63-77 (Feb. 2007)

Exhibit 1018	Sampalis et al., "Evaluation of the Effects of Neptune Krill Oil™ on the Management of Premenstrual Syndrome and Dysmenorreha" Altern. Med. Rev. 8(2):171-179 (2003) (referred herein as **Sampalis I**)
Exhibit 1019	Sampalis et al., "Natural Marine Source Phospholipids Comprising Flavonoids, Polyunsaturated Fatty Acids And Their Applications" WO 03/1011873 A2 published February 13, 2003 (referred herein as **Sampalis II**)
Exhibit 1020	Bresson et al., "Safety of 'Lipid extract from Euphausia superba' as a novel food ingredient - Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies" The European Food Safety Authority Journal 938:1-17 (2009)
Exhibit 1022	Wang et al. "Leptin- and Leptin Receptor-Deficient Rodent Models: Relevance for Human Type 2 Diabetes: Curr Diabetes Rev. 10(2):131-145 (2014).
Exhibit 1023	Tanaka et al., "Extraction of Phospholipids from Salmon Roe with Supercritical Carbon Dioxide and an Entrainer" J. Oleo Sci. 53(9):417-424 (2004)
Exhibit 1024	van Lengerich et al., "Encapsulation of readily oxidizable components" United States Patent Number 7,803,413 (filed Oct. 31, 2005).
Exhibit 1025	Maruyama et al., "Krill Phospholipids Fractioning Method" Japanese Patent No. 2909508 (filed: Feb. 14, 1989)
Exhibit 1026	Tanaka et al., "Platelet-activating Factor (PAF)-like Phospholipids Formed during Peroxidation of Phosphatidylcholines from Different Foodstuffs" Biosci. Biotech. Biochem. 59(8): 1389-1393 (1995).
Exhibit 1027	Bork M., "Production Process used in particular for obtaining Lecithin from Dehydrated Egg" New Zealand Patent Number 500824 (priority date: Nov. 18, 1998)
Exhibit 1028	Bork M., "Verfahren zur Gewinnung insbescondere von Lecithin aus Trockenel" European Patent No. 1004245 (priority date: Nov. 18, 1998)
Exhibit 1029	Marathe et al. J. Biol Chem 274:28395-28404 (1999)

Some of these documents have been provided in a previous third party submission. However, for convenience, we enclose all of them with this submission.

OVERVIEW OF ARGUMENTS

We submit that the claims are obvious on the following grounds:

1. An encapsulated krill oil comprising 3-10% ether phospholipids and greater than about 100 mg/kg astaxanthin esters, is obvious in light of Catchpole et al., (Exhibit 1006), in view of Tuo et al. (Exhibit 1017), in view of Antarctica Select™ or that the presence of astaxanthin in krill oil is an inevitable consequence of the solvent extraction process.
2. Claim 12 of the AU'345 application is obvious in light of Catchpole et al. (Exhibit 1006) in view of Tuo et al. (Exhibit 1017).
3. Claim 12 of the AU'345 application is obvious in light of Catchpole et al. (Exhibit 1006) in view of Tuo et al. (Exhibit 1017) and further in view of Beaudoin et al. (Exhibit 1014).

4. Claim 18 of the AU'345 application is obvious in light of Catchpole et al. (Exhibit 1006) in view of Tuo et al. (Exhibit 1017) or Sampalis (Exhibit 1018).
5. Claim 18 of the AU'345 application is obvious in light of Catchpole et al. (Exhibit 1006) in view of Tuo et al. (Exhibit 1017) or Sampalis (Exhibit 1018) and further in view of Beaudoin et al. (Exhibit 1014).
6. An encapsulated krill oil comprising 3-10% ether phospholipids and greater than about 100 mg/kg astaxanthin esters, is obvious in light of Beaudoin et al. (Exhibit 1014) in combination with Tuo et al. (Exhibit 1017), given the admissions in the file wrapper about Beaudoin et al., and in view of Antarctica Select™ or that the presence of astaxanthin in krill oil is an inevitable consequence of the solvent extraction process.
7. Claim 12 of the AU'345 application is obvious in light of Beaudoin et al. (Exhibit 1014) in combination with Tuo et al. (Exhibit 1017), given the admissions in the US file wrapper about Beaudoin et al.
8. Claim 18 of the AU'345 application is obvious in light of Beaudoin et al. (Exhibit 1014) in combination with Tuo et al. (Exhibit 1017) or Sampalis et al. (Exhibit 1018), given the admissions in the file wrapper about Beaudoin et al.
9. The feature a krill oil comprising at least 30% total phospholipids, is obvious in light of Catchpole et al., (Exhibit 1006), in view of Tuo et al. (Exhibit 1017), since Table 16 of Catchpole et al. shows that total phospholipids obtained were approximately 45%.
10. The feature a the krill oil comprising at least 30% phosphatidylcholine, is obvious in light of Catchpole et al., (Exhibit 1006), in view of Tuo et al. (Exhibit 1017), since Table 16 of Catchpole et al. shows a level of phosphatidylcholine of 39.8%.
11. The feature "a polar solvent extract of krill" is obvious in light of Catchpole et al., (Exhibit 1006), in view of Tuo et al. (Exhibit 1017), since Catchpole et al. (Exhibit 1006) discloses ethanol as a polar solvent.
12. The feature "said capsule contains a phytonutrient derived from a source other than krill" is obvious in light of van Lengerich et al. et al. (Exhibit 1024) for disclosing nutraceutical krill oils comprising phytonutrient compounds in combination with Catchpole et al., Tuo et al. and Sampalis et al.
13. Claim 1 of the AU '345 application is obvious in light of Catchpole et al., (Exhibit 1006), in view of Tuo et al. (Exhibit 1017), and in view of Antarctica Select™ or that the presence of astaxanthin in krill oil is an inevitable consequence of the solvent extraction process.
14. Claims 7, 13 and 19 are obvious in light of the admissions made in the Background section of the AU'345 application in combination with Catchpole et al., Tuo et al., and Sampalis et al. as respectively applied to Claims 1, 12 and 18.
15. Claims 8, 14 and 20 are obvious in light of Catchpole et al. (Exhibit 1006) in view of Tuo et al. (Exhibit 1017), since the attachment of omega-3 fatty acids is an inherent property of krill phospholipids.

16. Claims 8, 14 and 20 are obvious in light of Sampalis et al. I (Exhibit 1018) for disclosing that omega-3 fatty acids are naturally attached to phospholipids in combination with Catchpole et al., and Tuo et al.
17. Claims 8, 14 and 20 are obvious in light of Sampalis et al. II (Exhibit 1019) (for disclosing "Free fatty acids are present in the extract in an amount of at least 4% w/w and preferably at least 5% w/w.") in combination with Catchpole et al., and Tuo et al.
18. Claims 8, 14 and 20 are obvious in light of Bunea et al. (Exhibit 1011), for disclosing that omega-3 fatty acids are naturally attached to phospholipids in combination with Catchpole et al., and Tuo et al.
19. Claims 9 and 15 are obvious in light of Grantham et al. (Exhibit 1012) for disclosing that Euphausia superba is a krill species in combination with Catchpole et al., and Tuo et al., as respectively applied to Claims 1 and 12.
20. Claims 10 and 16 are obvious in light of Catchpole et al., (Exhibit 1006), in view of Tuo et al. (Exhibit 1017).
21. Claims 10 and 16 are obvious in light of Catchpole et al., (Exhibit 1006), in view of Sampalis et al. (Exhibit 1018) for disclosing soft gel krill oil capsules.
22. Claims 11 and 17 are obvious in light of Sampalis et al. (Exhibit 1019) ("Arachidonic acid content of the extract is generally very low to non-existent . . .") when taken in combination with Catchpole et al. (Exhibit 1006) and Tuo et al. (Exhibit 1017).
23. Claims 11 and 17 are obvious in light of Grantham et al. (Exhibit 1012) for disclosing krill oil arachidonic levels that are "about" 0.45% (e.g., 0.4%) when taken in combination with Catchpole et al. (Exhibit 1006) and Tuo et al. (Exhibit 1017).
24. Claims 11 and 17 are obvious in view of Bunea et al. (Exhibit 1011) (for disclosing arachidonic acid is associated with inflammation, thereby providing a motivation to reduce arachidonic acid levels in krill oil to improve health-related benefit) in combination with Catchpole et al., and Tuo et al.

THE ADMISSIONS IN AU '345

The Background section of AU '345 makes it clear that extracting krill oil from krill by solvent extraction was known and that "krill oil" is just a lipid extract:

> In order to isolate the krill oil from the krill, solvent extraction methods have been used. See, e.g., WO 00/23546. Krill lipids have been extracted by placing the material in a ketone solvent (e.g. acetone) in order to extract the lipid soluble fraction. This method involves separating the liquid and solid contents and recovering a lipid rich fraction from the liquid fraction by evaporation. Further processing steps include extracting and recovering by evaporation the remaining soluble lipid fraction from the solid contents by using a solvent such as ethanol. See, e.g., WO 00/23546. (page 1, lines 13 to 19 of AU '345)

The Background also makes it clear that krill oil extracts from the prior art contain high amounts of phospholipids and the omega-3 fatty acids EPA and DHA:

> The phospholipid content in the krill lipid extract could be as high as 60% w/w and the EPA/DHA content as high as 35% (w/w). See, e.g., WO 03/011873. (page 1, lines 28 to 30 of AU '345)

The Background section of AU '345 makes it clear that decomposition increases the level of free fatty acids, i.e. fatty acids that are not attached to the phospholipids:

> The methods described above rely on the processing of frozen krill that are transported from the Southern Ocean to the processing site. This transportation is both expensive and can result in degradation of the krill starting material. Data in the literature showing a rapid decomposition of the oil in krill explains why some krill oil currently offered as an omega-3 supplement in the marketplace contains very high amounts of partly decomposed phosphatidylcholine and also partly decomposed glycerides. Saether et al., Comp. Biochem Phys. B 83B(1): 51-55 (1986). The products offered also contain high levels of free fatty acids. (page 2, lines 5 to 12 of AU '345)

These statements in the Background section concerning the work of others and the nature of the krill extracts obtained by others are admissions by the Applicant that can be taken as common general knowledge in the art.

The first sentence of the Detailed Description of AU '345 indicates that the invention enriches the naturally occurring components of krill oil:

> This invention discloses novel krill oil compositions characterized by containing high levels of astaxanthin, phospholipids, included an enriched quantities of ether phospholipids, and omega-3 fatty acids. (emphasis added) (page 12, lines 9 to 11 of AU '345)

Example 8 of AU '345 indicates "*Krill oil was prepared according to the method described in example 7 extracting from the same krill meal.*" (page 43, lines 3 to 4 of AU '345). The analysis of the preparation is found in Table 21 (which shows the amount of total phospholipids, triglycerides and omega-3 fatty acids in the extract) and Table 22; these two tables provide the only ether phospholipid data in the entire specification. Example 8 concludes:

> The main polar ether lipids of the krill meal are alkylacylphosphatidyl-choline (AAPC) at 7-9% of total polar lipids, lysoalkylacylphosphatidyl-choline (LAAPC) at 1% of total polar lipids (TPL) and alkylacylphosphatidyl-ethanolamine (AAPE) at <1% of TPL. (page 43, lines 23 to 26 of AU '345)

The krill oil was tested in Example 9. Fish oil was used as a source of omega-3 fatty acids (i.e. a positive control).

AU '345 does not explain that fish oil has no appreciable phospholipids due to the way the fish oil is produced. The process used does not extract the phospholipids into the oil. The skilled person would understand that commercial fish oils are primarily composed of glycerides of fatty acids. By contrast, the

omega-3 fatty acids in krill oils are attached to phospholipids. This difference comes from the way commercial fish oil is produced, which we explain as follows.

Commercial fish oils used for making omega-3 type supplements are obtained from pelagic species, particularly, sardines, pilchards, tuna, salmon. The fish (or parts thereof) go into a rendering plant in which a neutral oil is obtained as one product, and fish meal as the second product. Any phospholipids originally present in the fish are retained in the fish meal, because the processes used don't extract the phospholipids into the oil. The fish oil that is obtained from the rendering plant then goes through a number of refining steps to get rid of free fatty acids, any residual phospholipids, pigments (carotenoids like astaxanthin), oxidized lipids and odor-causing chemicals. All these types of compounds are regarded as undesirable in the final product as they reduce stability and shelf life, give an unpleasant taste and aroma, and in the case of pigments, give an unacceptable colour.

The Background section of AU '345 makes it clear at page 1, lines 20 to 21, that prior art solvent extraction methods to produce krill oil also produces astaxanthin esters in the extract. For example, prior art solvent extraction method WO 00/23546 produced at least 75 or 90 mg/kg astaxanthin esters along with the extracted krill oil. Another prior art method to produce krill oil extract (see page 1, line 31, to page 2, line 4, of the AU '345 application) also yielded astaxanthin in the extract. It is an inevitable consequence of extraction of krill oil that some astxanthin will also be extracted.

CLAIM CONSTRUCTION

The approach to the construction of claims was discussed by Bennett J in *H Lundbeck A/S v Alphapharm Pty Ltd* [2009] FCAFC 70, 81 IPR 228 at [118] - [120]:

> "the words in a claim should be read through the eyes of the skilled addressee in the context in which they appear ... while the claims define the monopoly claimed in the words of the patentee's choosing, the specification should be read as a whole ... it is not permissible to read into a claim an additional integer or limitation to vary or qualify the claim by reference to the body of the specification ... terms in the claim which are unclear may be defined or clarified by reference to the body of the specification".

The term "effective amount"

The claim limitation of "an *effective amount* of krill oil" is found in all of the independent claims. There is no definition in the specification for "effective amount." Indeed, there is only one passage in the specification that suggests what an effective amount of krill oil might be:

> In some preferred embodiments, the effective amount of a krill oil composition is from 0.2 grams to 10 grams of said krill oil composition. (page 8, lines 13 to 14 of AU '345)

However, since this is characterized as only a range for "preferred embodiments," this cannot be used to limit the term to any particular amount. Moreover, the AU '345 specification does not link the amount to

the time period (e.g. 30 days, 45 days, 90 days etc.) needed to cause a change in a human subject (discussed further below).

Importantly, the "effective amount" language modifies "krill oil" as a whole (and not some particular component of krill oil). This is consistent with the specification:

> In some embodiments, the present invention provides methods of reducing diet-induced hyperinsulinemia, insulin insensitivity, muscle mass hypertrophy, serum adiponectin reduction or hepatic steatosis comprising in a subject consuming a high fat diet or a normal fat diet: administering to said subject consuming a high fat diet or a normal fat diet ***an effective amount of a krill oil composition*** under conditions such that a condition selected from the group consisting of diet-induced hyperinsulinemia, insulin insensitivity, muscle mass hypertrophy, serum adiponectin reduction and hepatic steatosis is reduced. (emphasis added) (page 8, lines 3 to 9 of AU '345)
>
> In some embodiments, the present invention provides methods of inducing diuresis in a subject comprising: administering to said subject ***an effective amount of a krill oil composition*** under conditions such that diuresis is induced. In some embodiments, the present invention provides methods of increasing muscle mass in a subject, comprising: administering to said subject ***an effective amount of a krill oil composition*** under conditions such that muscle mass is increased. In some embodiments, the present invention provides methods of decreasing protein catabolism in a subject, comprising: administering to said subject ***an effective amount of a krill oil composition*** under conditions such that protein catabolism is decreased. In some embodiments, the present invention provides methods of decreasing lipid content in the heart of a subject, comprising: administering to said subject ***an effective amount of a krill oil composition*** under conditions such that lipid content in the heart of the subject is decreased. In some embodiments, the present invention provides methods of decreasing lipid content in the liver of a subject, comprising: administering to said subject ***an effective amount of a krill oil composition*** under conditions such that lipid content in the liver of the subject is decreased. (emphasis added) (page 9, lines 15 to 29 of AU '345)

It should be noted that the claims do <u>not</u> speak of an "effective amount" of ether phospholipids.

Without any definition in the specification (or other source of intrinsic evidence), the extrinsic evidence must be evaluated. Here, the effective amount for humans can be assumed from the capsule sizes sold commercially by vendors of krill oil. The minimum capsule size seems to be 500 mg, i.e. 0.5 grams, and at least one capsule per day is recommended.[1] Thus, the low end of the preferred range given in the AU '345 specification (0.2 g) appears to be too low. Likewise, the upper end of the preferred range given in the AU '345 specification (10 g per day) is too high, since it would involve taking twenty 500 mg

[1] The effective amount for humans can be assumed from the capsule sizes sold commercially by vendors of krill oil. The minimum capsule size seems to be 500 mg, i.e. 0.5 grams, and at least one capsule per day is recommended.

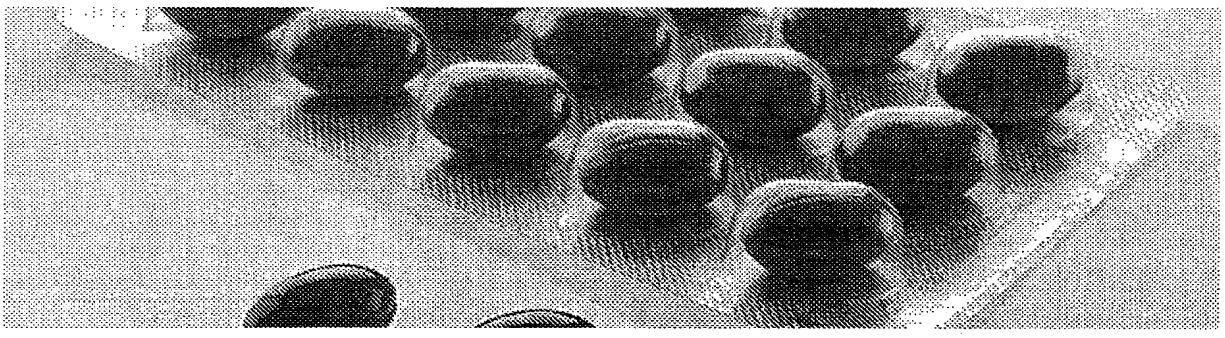
capsules. It is also worth of note that AU '345 specification does not link the amount to the time period (e.g. 30 days, 45 days, 90 days etc.) needed to cause a change in a human subject.

Tuo et al. (Exhibit 1017) reports the administration of 2 grams/day to be effective for some indications, and 3 grams/day to be effective for other indications. One of the studies cited by Tuo et al. (as reference 30) is the paper by Sampalis et al. (Exhibit 1018). Importantly, Tuo et al. reports these studies involved taking these amounts for 45-60 days, and as long as 90 days. Thus, while the AU '345 specification does not link the amount to a time period in which to achieve the therapeutic effect, the extrinsic evidence suggests that between 0.5 grams and 3 grams per day will be effective if taken over a matter of weeks to months. Given the recognized health benefits of omega-3 fatty acids, one skilled in the art would be motivated to encapsulate phospholipid-rich krill extracts, such as extract 2 of Catchpole et al. (Exhibit 1006), in the manner and amounts found by Tuo et al. (Exhibit 1017) to be effective.

The claim terms "encapsulated" and "capsule"

The claims of AU '345 are all composition claims specifying an "encapsulated krill oil." Independent Claims 1 and 12 of AU '345 specify "a capsule containing an effective amount of krill oil" while independent Claim 18 specifies "a soft gel capsule containing an effective amount of krill oil". The specification does not provide any definition for "capsule" or "encapsulated." There is no special meaning offered. Nonetheless, the specification is but one source for claim interpretation. Here, the plain language of the claims suggests that "encapsulated" merely means that the krill oil is in a capsule: "Encapsulated krill oil comprising: a capsule containing an effective amount of krill oil... " (see Claim 1).

We point the Examiner to the Aker Biomarine website shows capsules with liquid krill oil enclosed within (the picture is provided here for convenience of the Examiner):



We submit that one skilled in the art understands, in the context of krill oil, "encapsulate" is meant to indicate that the oil is enclosed in a capsule. This is consistent with the plain language of the claims. This is also consistent with the ordinary meaning of "encapsulate" – which is "to enclose." See Merriam-Webster on-line dictionary. It is well known by the skilled person that krill oil is somewhat unpalatable and encapsulation is necessary to make krill oil more acceptable in the marketplace.

The claim term "krill oil"

The meaning of "krill oil" can be determined from the specification, i.e. it is a lipid extract from krill:

> In order to isolate the krill oil from the krill, solvent extraction methods have been used. See, e.g., WO 00/23546. Krill lipids have been extracted by placing the material in a ketone solvent (e.g. acetone) in order to extract the lipid soluble fraction. (page 1, lines 13 to 15 of AU '345)

In this regard, a lipid extract is equivalent to an oil has also been reported in the art. See, Bresson et al. (Exhibit 1020) (entitled "Safety of 'Lipid Extract of *Euphausia superba*' as a novel food ingredient."). In particular, Bresson et al. reports (on the first page) that the novel food ingredient "is an oil obtained by extraction." We submit that the skilled person would equate lipid extracts with oils, and that these terms are interchangeable.

The term "about 3-10%"

As noted above, AU '345 comprises three independent claims, i.e. Claims 1, 12 and 18. In addition to specifying the terms discussed above (i.e. capsule, krill oil, etc.), Claim 1 of AU '345 specifies ether phospholipids in a range of "about" 3-10%. Claim 12 specifies "krill oil comprising from about 3% to about 10% w/w ether phospholipids" (along with non-ether phospholipids and triglycerides). Claim 18 specifies "krill oil comprising from about 3% to about 10% w/w ether phospholipids" (along with non-ether phospholipids and triglycerides).

While the term "about" appears many times in the specification, there is no definition for the term. As for the term "ether phospholipid" in these claims, it will be shown (later in this submission) that this is a meaningless limitation, since there is no evidence that this feature alone has any impact on how krill oil functions to provide health benefits (let alone an impact throughout the entire range specified in Claims 1, 12 and 18).

The US prosecution history of the '905 Patent reveals that the ether phospholipids range in the claims was specified in order to attempt to distinguish over the prior art. More specifically, a Non-Final Office Action was mailed November 17, 2014 (Exhibit 1007) that rejected all the as-filed claims. In addition to several non-statutory double patenting rejections, the Examiner asserted two United States Patents as prior art references arguing that the disclosures within these patents made the as-filed claims obvious. Beaudoin et al. (Exhibit 1013); and Porzio et al. (Exhibit 1016). Beaudoin et al. was characterized as disclosing krill oil components including phospholipids and triglycerides at similar concentrations as presented in the claims. This was combined with Porzio et al., which teaches how to encapsulate lipid compositions.

A Response to the Non-Final Office Action was filed on December 19, 2014 (Exhibit 1008) with no claim amendments. The cited art was distinguished on the basis that it did not disclose a krill oil comprising "from about 3% - 15% ether phospholipids." It was argued that Beaudoin's '229 patent extraction method was virtually identical to the NKO extraction process. An NKO composition analysis is presented in AU '345 (Example 8 and Table 22), showing that NKO has 7% AAPC and 1.2% LAAPC, i.e. a total ether phospholipid content of 8.2% of total phospholipids. It was argued that this percentage corresponded to

an actual 2.46% value[2] when relative to the krill oil (e.g., based upon a 30% measurement of total NKO phospholipids).[3] It was argued that the Beaudoin et al. method was not capable of generating a krill oil product comprising between 3% - 15% ether phospholipids.

A Final Rejection was mailed on February 17, 2015 (Exhibit 1009) where the non-statutory double patenting and obviousness rejections were maintained. The US Examiner argued that the calculated 2.46% ether phospholipid concentration in Beaudoin et al. was close enough to the claimed range such that it would be obvious for one of ordinary skill in the art to optimize the extraction process through routine means to increase the ether phospholipid content to the claimed 3% concentration because of the known health benefits of ether phospholipids.

A Response to the Final Office Action was filed on April 16, 2015 (Exhibit 1010) with no claim amendments. Instead, a rebuttal was made to the US Examiner's argument that ether phospholipids were well recognized in the art as having health benefits. Marathe et al. (Exhibit 1029) was discussed as demonstrating that ether phospholipids were known as precursor compounds for inflammatory platelet-activating factor-like compounds.[4] It was argued that one of skill in the art would seek to decrease, not increase, the level of ether phospholipids in krill oil.

At this point, an argument concerning alleged unexpected results was also made:

> . . . Applicants obtained unexpected results which demonstrate that the claims krill oil compositions with greater than 3% ether phospholipids have superior activity to the prior art krill oils with lower ether phospholipid levels. The Examiner's attention is respectfully directed to Example 9 in the specification. This example directly compares the claimed krill oils (designated Superba or PL2) to prior art krill oil (designated NKO or PL1). The claimed oil displays unexpected improvements in biological activity in several areas: plasma insulin (Figure 4); HOMA-IR (Figure 5); lipid accumulation in the liver (Figure 7); lipid accumulation in the heart (Figure 8); and DHA partitioning to the brain (Figure 10). The unexpected improvement in these effects is commercially and biologically important. (see Exhibit 1010, pg 6).

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[2] This is an admission that Beaudoin et al. teaches a krill oil with an ether phospholipid level of just below 3%.

[3] Oddly, when these arguments were made to the US Examiner, the ether phospholipid numbers in Table 22 for the material prepared in Example 7 were not divided in a similar way. When the raw ether phospholipid data disclosed in Table 22 is adjusted to properly express ether phospholipid percentages on a weight-to-weight basis relative to whole krill oil, the ether phospholipid value is 7.8% (w/w), not 15% (w/w) or 10% (w/w).

[4] Of course, if this science is correct, there is a disadvantage to having ether phospholipids in krill oil. However, there appears to be no platelet testing in the AU '345 patent that would have revealed the problem.

It appears that this "superior results" argument convinced the US Examiner, since a Notice of Allowance followed on May 20, 2015 (with no written reasons for the allowance).

While the above-quoted statement that "greater than 3% ether phospholipids have superior activity," there is no evidence in the specification for ether phospholipid amounts other than that in Table 22 and Table 23. Table 22 presents a single data point for total ether phospholipids (15.2%) relative to the total phospholipids (47.9%) that are produced by the method described in Example 7. Table 23 presents the fatty acid composition of the ether phospholipid alkylacylphosphatidylcholine (AAPC). Moreover, the claims specify "about 3%" – not "greater than 3%." In any event, neither the specification nor the file history provides any more insight into what "about 3%" should encompass.

We submit that, where the specification is ambiguous as to the meaning of a term, the ordinary meaning will apply. In this case, the term "about" should instead be given its ordinary meaning of "approximately". Accordingly, we submit that "about" 3% should be interpreted broadly to include amounts lower than 3% that are approximately 3%.

THE CLAIM ELEMENTS OF AU '345 AND SUMMARY OF THE PRIOR ART REFERENCES

A. Earliest Priority Date for the Claims of the AU'345 application

AU '345 claims the benefit of four (4) United States Provisional Applications:

i) 61/024,072, filed on Jan. 28, 2008;
ii) 60/983,446, filed on Oct. 29, 2007;
iii) 60/975,058, filed on Sep. 25, 2007; and
iv) 60/920,483, filed on March 28, 2007 (Exhibits 1002-1005).

Support for the claim element "ether phospholipid" – required by each claim of AU '345 – was not introduced until the filing of U.S. Application No. 61/024,072. Consequently, the earliest priority date for the claims of the AU '345 is January 28, 2008 (**Earliest Priority Date**).

B. Comparison of the claims of AU '345 to the Prior Art

The claims of AU '345 are all composition claims and are primarily directed to a composition having (i) "a capsule"; (ii) "a krill oil"; and (iii) "from about 3% to about 10 % (w/w) ether phospholipids." Additionally, claim 1 includes a limitation of "greater than about 100 mg/kg astaxanthin esters".

Catchpole et al. (Exhibit 1006) teaches both "a krill lipid extract" (thus, a krill oil) and a percentage of "ether phospholipids" that is within the claimed range. Indeed, Catchpole et al. (Exhibit 1006) specifies all of the elements in Claim 1 except the specific term "capsule" (although Catchpole et al. specify a "product"). Nonetheless, encapsulating krill oil was well known at the time. The "capsules" of Claims 1, 12, and 18 are obvious over Tuo et al. (Ex. 1017) and/or Sampalis et al. (Ex. 1018), as discussed below.

i.) A capsule

Claims 1 and 12 of AU '345 recite a "capsule" while Claim 18 recites "a soft gel capsule", within which the disclosed krill oil resides. Tuo et al. (Exhibit 1017) and Sampalis et al. (Exhibit 1018) report that krill oil capsules were used in clinical studies. For example, Tuo et al. (Exhibit 1017) notes that:

> Subjects were randomly assigned to take two gel capsules containing 1 g of krill oil or 1 g of fish oil (18% EPA and 12% DHA) daily at mealtime for a duration of 3 months. (see page 68).

Similarly, Sampalis et al. (Exhibit 1018) specified:

> Each patient was asked to take two 1-gram soft gels of either NKO or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial. (see page 174).

It is also well known that krill oil is somewhat unpalatable and encapsulation is necessary to make krill oil more acceptable in the marketplace.

ii.) An effective amount of krill oil

As discussed above in the context of claim interpretation, the term "effective amount" is not defined in AU '345. Tuo et al. shows that 1 gram/day, 2 grams/day and 3 grams/day showed a benefit, depending on the indication[5]. Thus, given the known health benefits, one skilled in the art would be motivated to encapsulate the krill oil of Catchpole et al. according to the teachings of Tuo et al. (Exhibit 1017) with regard to amounts that are "effective." Similarly, one skilled in the art would be motivated to encapsulate the krill oil of Beaudoin et al. (Exhibit 1013) according to the teachings of Tuo et al. (Exhibit 1017) with regard to amounts that are "effective." For example, Tuo et al. and Sampalis I each teach administering an encapsulated krill oil in an effective amount during a human trial to determine health benefits. Accordingly, one of skill in the art looking to improve the administration of a krill oil including ether phospholipids disclosed in Beaudoin et al., as evidenced by Table 22 of the AU '345 specification, would be motivated to look at how others have administered krill oils for use in similar methods, such as the encapsulated krill oils disclosed in Tuo et al. and Sampalis I.

iii.) From About 3% To About 10% Ether Phospholipids

Claim 1 of AU '345 specifies a krill oil comprising "from about 3% to about 10% ether phospholipids." Yet, AU '345 only provides a limited presentation of ether phospholipid data (e.g., Table 22 and Table 23). Indeed, Table 22 provides but one data point for ether phospholipids based on the extraction method of Example 7. This was compared with ether phospholipid data of krill oil extracted from the commercially available Neptune Krill Oil™ (NKO).

As noted above, during the US prosecution history, the Examiner asserted Beaudoin et al. (Exhibit 1013) and argued that this reference disclosed a krill oil having ether phospholipid concentration encompassed

[5] One of the studies cited by Tuo et al. (as reference 30) is the paper by Sampalis et al. (Exhibit 1018). Importantly, Tuo et al. reports these studies involved taking these amounts for 45-60 days, and as long as 90 days.

by the '905 Claims 1, 12 and 18. The Patent Owner argued that the Examiner had misunderstood Table 22 and provided a correction of the disclosed NKO ether phospholipid data (from 8.2% down to 2.46%). Yet, the Patent Owner failed to similarly adjust the ether phospholipid values in Table 22 ("Krill oil obtained in Example 7") in the same manner. The ether phospholipids presented for "Example 7 Krill oil" in Table 22 totals 15.2%. However, this total ether phospholipid value is relative to total phospholipids (e.g., 47.9%). *Id.* Consequently, when adjusted to properly express ether phospholipid percentages on a weight-to-weight basis relative to whole krill oil, the ether phospholipid value is 7.8% (w/w), not 15% (w/w) or 10% (w/w).

Furthermore, there is no data in AU '345 regarding any krill oil composition comprising an ether phospholipid concentration lower than 7.8% (w/w), much less 3% (w/w) or "about" 3% (as presently claimed).

In any event, the ether phospholipid amount (2.46%) inherently disclosed in Beaudoin et al. (Exhibit 1013) (as evidenced by Table 22 of the AU'345 application) is "about 3%" and the amount explicitly disclosed in Catchpole et al. (4.8% w/w) (Exhibit 1006) is encompassed by the AU '345 claims.

iv.) From About 27% To 50% w/w Non-Ether Phospholipid

Claims 1, 12 and 18 provide a range for non-ether phospholipids (such as phosphatidylcholine). However, the "non-ether phospholipid" (e.g., phosphatidylcholine) ranges disclosed in Catchpole et al. (39.8%) (Exhibit 1006), Beaudoin et al. (62.6%) (Exhibit 1013) and Grantham et al. (50%) (Exhibit 1012) and are encompassed by the claims of AU '345.

v.) 30% - 60% Total Phospholipids

Claims 1, 12 and 18 in AU '345 recite that the krill oil comprises "from about 30% to 60% (w/w) total phospholipids." The only specific data provided in AU '345 within this contemplated range is "50.55 wt %" as listed in Table 21 and "30%" or "47.9%" as listed in Table 22. It should be noted that AU '345 does not disclose any composition having 60% (w/w) total phospholipid.

In any event, the "total phospholipid" ranges disclosed in Beaudoin et al. (62.6%) (Exhibit 1013) and Grantham et al. (50%) (Exhibit 1012) and are encompassed by the claims of AU '345. Table 16 of Catchpole et al. (Exhibit 1006) shows that total phospholipids would be approximately 45% (this number comes from adding up the numbers from Extract 2 (both ether phospholipids and non-ether phospholipids). Moreover, the Background section admitted that the "phospholipid content in the krill lipid extract could be as high as 60% w/w . . ." in prior art preparations. (page 1, lines 29 to 30 of AU '345)

vi.) From About 20% To 50% w/w Triglyceride

Claims 1, 12 and 18 in AU '345 recite that the krill oil comprises "from about 20% to 50% (w/w) triglycerides". The only data presented in AU '345 is limited to krill oil compositions comprising

triglyceride concentrations of: i) 33% (Table 2); and ii) 25.9% (Table 21). Data supporting the upper limit of 50% triglycerides is not disclosed in AU '345.

In any event, the "triglyceride" ranges disclosed in Grantham et al. (8% - 50%) (Exhibit 1012) are encompassed by the claims of AU '345. Moreover, Beaudoin (Exhibit 1014) shows that significant amounts of triglycerides are in krill oil, the amounts depending on the extraction conditions (see Table 14).

While Catchpole et al. (Exhibit 1006) does not provide triglyceride levels in Table 16, this does not mean such levels were not obtained. Indeed, based on the similarities of the process used in Example 18 of Catchpole et al. (Exhibit 1006) and that used in Example 7 of the AU'345 application, the resulting krill oil of Example 18 would be expected to have triglyceride concentrations of between 20%-50% (w/w). *Id.* Thus, Catchpole et al. (Exhibit 1006) inherently provides this feature of Claims 1, 12 and 18 of the claims of AU '345. (The inherent teaching of a prior art reference is a question of fact which arises both in the context of anticipation and obviousness.)

However, triglyceride levels in krill oil were not of much interest. There is only a minor level of omega-3 fatty acids in the krill triglycerides (approximately 2.5 % EPA and 1 % DHA as a percentage of total fatty acids in the triglycerides). It is known by the skilled person that the vast amount of omega-3 fatty acids are to be found associated with the krill oil phospholipids. Most of these fatty acids are attached to the phospholipids, with a small percentage being free fatty acids.

On the other hand, the omega-3 fatty acids in krill were of great interest. Once the health benefit importance of omega-3 fatty acids was recognized by the medical community it became apparent that krill oils could be improved as a supplement if the oils had higher phospholipid concentrations. Thus, as of 2008, one skilled in the art was motivated to enrich krill phospholipids. While phospholipids are usually a minor component of most biomasses and therefore not economically viable to recover, krill is a significant exception. There is also a large price differential between fish oil and krill oil that makes the manufacture and sale of krill oil attractive (fish oils (bulk price $1–10/kg) and krill oils (bulk price > $200/kg)).

vii.) 20% to 35% omega-3 fatty acids

Claims 7, 13 and 19 specify 20% to 35% omega-3 fatty acids. However, the Background section of AU '345 admits that prior art krill extracts show "*...the EPA/DHA content as high as 35% (w/w). See, e.g., Sampalis et al., WO 03/011873.*" (Ex 1019) (see the specification of AU '345 at page 1, lines 29 to 30). Thus, this feature adds nothing.

viii.) greater than about 100 mg/kg astaxanthin esters

Claim 1 defines a lower limit of 100 mg/kg, and claims to 2 to 4 define concentrations greater than 200, 300 and 400 mg/kg astaxanthin esters, respectively. The background of the specification makes it clear that it is an inevitable consequence of extraction of krill oil that astxanthin will also be extracted.

We refer the examiner to the first third-party observation filed on 12 October 2015, and the second third-party observation filed on 22 December 2015. With reference to the first third-party observation, the opponent asserted that a pending claim (claim 15 at the time) having the following features

- Encapsulated krill oil comprising:
- a capsule containing an effective amount of krill oil , said krill oil comprising from about 3% to 15% ether phospholipids; and
- greater than about 100 ppm astaxanthin.

lacked novelty in view of prior use of Antarctica Select™

Antarctica Select™ (Aqua Source products Inc.) contains 100% wild krill oil produced by Neptune Technologies & Bioresources, Inc. Antarctica Select™ was already on the market in e.g. Canada before any priority date or the filing date of the Patent in dispute. We also referred to:

- D2 shows the product declaration of Antarctica Select™
- D12 shows pictures of the Antarctica Select™ container with lot no. 20509121.

AquaSource Products Inc. which is the producer of Antarctica Select™ states that the krill oil used in Antarctica Select lot no. 20509121 was produced in 2004 by Neptune Technologies & Bioresources Inc., encapsulated in 2005 and put on the market in 2005 (see D3, Declaration from Risa Enge; the owner of AquaSource Products Inc.).

As can be seen from the product declaration on the container, Antarctica Select contains 1.8 mg/1000mg (1800 mg/kg) astaxanthin.

Callaghan Innovation Laboratory was engaged to perform an analysis of the phospholipids and ether phospholipids content of the Antarctica Select capsules lot no. 20508121.The result from the laboratory analysis performed 18 March 2015 revealed that the krill oil in the capsules contained 12.9 % phospholipids on a w/w basis and 3.3% ether phospholipids on a w/w basis (D5).

Methods for detection of ether phospholipids were first established in about 2006. From the above evidence, the following can be concluded:

- A product (encapsulated krill oil) containing 1800 mg/kg astaxanthin and at least 3.3 % w/w ether phospholipids was on the market before the first priority date claimed by AU 2014256345.
- The amount of astaxanthin and the measured 3.3 % ether phospholipids on a w/w base are in the same ranges as claimed in claim 1 of AU 2014256345.

As will be demonstrated below, claim 1 lacks an inventive step when Antarctica Select™ is combined with Catchpole et al. in combination with Tuo et al.

With reference to the second third-party observation filed on 22 December 2015, the opponent asserted that a pending claim (claim 48 at the time) lacked an inventive step in view of D4 (Catchpole), D8 (Beaudoin) with support from D3 (Sampalis)

As will be demonstrated below, claim 1 lacks an inventive step when Antarctica Select™ is combined with Catchpole et al. in with Beaudoin et al. (Exhibit 1014)

We invite the Examiner to review the arguments raised in the prosecution of the co-pending European application (EP 2144618) where the Opposition Division has accepted the "Antarctica Select" evidence as public prior use.

ix.) Summary

The prior art accompanying this submission, together with the admissions in the Background section of AU '345, show that all of the elements of the claims of AU '345 were disclosed and well known in the prior art. Accordingly, we submit that the Examiner should find the claims of AU '345 unpatentable as obvious over the prior art submitted herewith.

DETAILED SUBMISSIONS

In the following, we provide a detailed explanation of the basis of each challenge to claims 1-20 of the claims of AU '345 and where each element of each claim can be found in each prior art reference. The standards for obviousness are briefly reviewed, followed by an analysis of each claim.

A. The Standards for Obviousness/Inventive step

The present opposition is governed by the *Patents Act 1990* (the **Act**) as amended by the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (the **Raising the Bar Act**). Amendments to sections 7, 40 and 60 of the Act apply to the present case as a consequence of Schedule 1, items 55(1)(e) and 55(4)(b) of the Raising the Bar Act – the request for examination was filed after 15 April 2013.

It is a requirement of subsection 18(1) of the *Act* that the invention, so far as claimed in any claim, involves an inventive step. Subsection 7(2) states that an invention is taken to involve an inventive step unless it would have been obvious to a person skilled in the art in the light of the common general knowledge, considered alone or together with the prior art.

A document is prior art for this purpose if it is "any single piece of prior art information", or a combination of such prior art in prescribed circumstances (subsection 7(3)). The requirement that the information would have been ascertained, understood and regarded as relevant no longer applies (it removed by

Item 3 of Schedule 1 of the *Raising the Bar Act*). The Explanatory Memorandum states at page 43 that the consequence is that "the prior art base for inventive step will be information made publicly available before the relevant priority date."

The test for whether an invention is obvious is to ask whether it would have been a matter of routine to proceed to the claimed invention. In *Wellcome Foundation Ltd v V.R. Laboratories (Aust.) Pty Ltd* [1981] HCA 12 at [45], 148 CLR 262 at 286 Aickin J stated:

> *"The test is whether the hypothetical addressee faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not."*

In *Aktiebolaget Hassle v Alphapharm Pty Ltd (**AB Hässle**)* [2002] HCA 59 at [53]; [2002] HCA 59; 212 CLR 411, the High Court accepted the approach taken in *Olin Mathieson Chemical Corporation v Biorex Laboratories Ltd* [1970] RPC 157 at [187] where Graham J posed the reformulated Cripp's question:

> "*Would* the notional research group at the relevant date, in all the circumstances, ... *directly be led as a matter of course to try* [the claimed combination] *in the expectation that it might well* produce a [useful or better result]?" (emphasis in original)

Both approaches require that the person skilled in the art has a reasonable expectation of success, which is explicit in the expectation that an approach "might well" succeed and implicit in steps characterised as routine and to be tried as a matter of course (*Generic Health Pty Ltd v Bayer Pharma Aktiengessellscaft* [2014] FCAFC 73 at [71]). The reasonable expectation does not require a guarantee of success and includes some possibility that the steps taken will not achieve the intended result (*AB Hässle* at [74], [76]).

In this case, the relevant prior art to the AU '345 application can be found in the fields of biomass processing and organic oil extraction. As of the AU '345 Earliest Priority Date, one of ordinary skill in the art would have been degree-qualified or equivalent in marine sciences, organic chemistry or associated sciences with an understanding, either through education or experience, of organic chemistry or marine biology.

B. Claims 1-20 Are Obvious

The combination of prior art references, discussed below, together with the admissions in the US prosecution history and in the AU '345 specification, disclose each and every element of the claims of AU '345 in such a context that suggests the claimed combinations to one of skill in the art with a reasonable expectation of success. Moreover, we submit that the results of the combination were predictable.

1.) An encapsulated krill oil comprising 3-10% ether phospholipids and greater than about 100 mg/kg astaxanthin esters, is obvious in light of Catchpole et al., (Exhibit 1006), in view of

Tuo et al. (Exhibit 1017) , in view of Antarctica Select™ or that the presence of astaxanthin in krill oil is an inevitable consequence of the solvent extraction process

Claim 1 specifies, inter alia, a capsule of krill oil having between 3-10% ether phospholipids. Catchpole et al. (Exhibit 1006) teaches these elements of Claim 1 other than the capsule (although it does teach a "product.") Specifically, it teaches a krill lipid extract resulting from supercritical extraction that is "highly enriched" in ether phospholipids:

> The composition of extract 2 and residual powder are shown in table 16. The alkylacylphosphatidylcholine (AAPC), a type of alkylacylphospholipid, is highly enriched in the concentrated phospholipids-rich extract..." (emphasis added) Catchpole et al. pg 24 ln 12 - 14

These elements are compared to the teachings of Catchpole et al. in Chart I below:

Chart I: Catchpole's Teachings compared to specific claim elements

Claim elements	Relevant Disclosure
a capsule	"a product" that contains desirable level of phospholipids ... *pg 3 ln 27-28*
an effective amount of krill oil	This example shows the fractionation of krill lipids from krill powder ... *pg 24 ln 1* Example 18 begins with 5619.9 grams of starting material; Table 16 shows that the yield of extract 2 was 4.3% of the starting material, or 241.6 grams
from about 3% - 10% ether phospholipids	The alkylacylphosphatidylcholine (AAPC), a type of alkylacylphospholipid, is highly enriched in the concentrated phospholipids-rich extract, whilst alkylacylphosphatidylethanolamine (AAPE), another type of alkylacylphospholipid ... *pg 24 ln 13 - 15.* ... [4.6% APCC + 0.2% AAPE (w/w of lipid extract] ... *pg 24 Table 16.*

Catchpole et al. (Exhibit 1006) generally discloses the extraction of phospholipids from a variety of plant and animal biomass using supercritical carbon dioxide and ethanol. In particular, Catchpole et al. (Exhibit 1006) teaches an ether phospholipid concentration of 4.8% in krill lipid extracts, which is within the range specified in Claim 1 of AU '345. Catchpole et al. makes it clear that the goal of the work is to produce "product" with high phospholipid levels. Catchpole et al. (Exhibit 1006), pg 3 ln 27-28. A capsule is just one type of product, and as shown by Tuo et al. (Exhibit 1017) and Sampalis et al. (Exhibit 1018) (both of which were quoted and discussed above), the use of krill oil in gram amounts in capsules, including soft gel capsules, is well known.

Indeed, it is well known that krill oil is somewhat unpalatable and encapsulation is necessary to make krill oil more acceptable in the marketplace (see relevant discussion above). Because of this, one skilled in the art would be motivated to encapsulate the krill extract of Catchpole et al. (Exhibit 1006) in the manner and amounts found by Tuo et al. (Exhibit 1017) to be effective, for example such as a soft gel capsule, and in order to market an krill oil having enriched phospholipids (including both ether and non-ether phospholipids). Catchpole et al. provides over 240 grams of material (see table above).

Thus, the requirements set forth above are satisfied. First, all the claimed elements were known in the prior art. Catchpole et al. shows that krill oil extracts with enriched ether phospholipid levels were known. Tuo et al. and Sampalis I show that it was known to package krill oil in capsules. Second, putting the krill oil in capsules by known methods produces no change in their respective functions, and the combination yielded nothing more than predictable results.

The obviousness of AU '345 Claim 1 is further based upon these further matters:

i) material substitution - where the AU '345 claims merely replaces "ether phospholipids" for other documented components of krill oil having health-related attributes;

ii) modification of prior known elements without change of benefit in that there is no proof that ether phospholipids have any health-related benefit (indeed, the AU '345 specification attributes the test results in Example 9 to omega-3 fatty acids); and

iii) reasonable predictability of modification to prior known element, in that Catchpole et al. teaches that ether phospholipids are enriched when supercritical extraction with an increased amount of co-solvent is used. Here, ether phospholipids were known to be a composition of krill oil, and the art had not ascribed any benefit as to their presence. While the Applicant may have increased the ether phospholipid concentration, they provide no evidence that ether phospholipids themselves provide any advantage. Further, the concentrations claims for phospholipids are close enough to those described in the prior art, that it would be considered an obvious material substitution as no resulting benefit has been described.

As noted above, the '905 Patent claims were allowed only after an allegation was made of unexpected results:

> " . . . Applicants obtained unexpected results which demonstrate that the claims krill oil compositions with greater than 3% ether phospholipids have superior activity to the prior art krill oils with lower ether phospholipid levels."

While the US Examiner was perhaps persuaded by the Applicant's assertions of superior results with krill oils having "greater than 3% ether phospholipids," the actual evidence fails on many levels when it is looked at carefully.

First, there is no experiment in the AU '345 specification that specifically tests the impact (if any) of ether phospholipid levels in krill oil. Example 9 purports to test the krill oil of Example 7 (as analyzed in Table

22), i.e. Example 9 tests for the effects of all components within krill oil (e.g., for example, total phospholipids, astaxanthin, omega-3 fatty acids) and undesirable components such as trimethylamine (TMA) and tremethylamine (TMAO). Example 9 does not purport to test the impact, if any, of increased ether phospholipid levels. The krill oil as a whole was tested – krill oil with many other ingredients. Example 9 does not hold all of the other ingredients constant in a comparison to show the impact of increasing ether phospholipid concentrations. Indeed, there is no such data in the entire specification. Without such an experiment, nothing can be attributed to the ether phospholipids in terms of function for the range specified. The alleged health-related parameters can only be interpreted as a result of the combined action of these components. Of course, one would expect that each component need not contribute an equal effect on these health-related parameters. In fact, it would not be surprising if at least two of these components, particularly TMA and TMAO, had opposite effects.

Second, a krill oil having 3% ether phospholipids (or even one with "about 3%") was not tested in Example 9. Nor was a krill oil with 4% or 5% (or other lower amounts in the range) tested. Table 22 indicates the AAPC level was 13%, the LAAPC level was 0.9% and the AAPE was 1.5%. At best, this amounts (when added together) to one point (e.g. the raw number is approximately 15% and the normalized number is 7.8%) in the range specified for Claim 1. There is no other ether phospholipid amount provided in the entire specification. Thus, the assertion of superior results for "greater than 3%" (which convinced the Examiner to allow the US claims) has no empirical support whatsoever.

Third, there is nothing in the specification to suggest that the alleged health benefits come from the ether phospholipids.[6] Rather, the known ingredients with health benefits are alleged to be omega-3 fatty acids[7] and astaxanthin:

> ***Omega-3 fatty acid*** supplementation may alleviate the inflammatory condition in adipose tissue and thus ideally complement the principal strategies of weight reduction i.e. low calorie diet and exercise. There are clinical studies in humans that demonstrate that omega-3 enhance the effect of very low calorie diet and exercise in reducing body fat mass. Kunesova et al., Physiological research/Academia Scientiarum Bohemoslovaca (2006), 55(1), 63-72. Although diet and exercise regime may fail to result in consistent decrease in weight in long term, the effect of omega-3 fatty acids alleviating the inflammatory condition in the adipose tissue may persist generating a condition that can be described as "healthy adipose tissue". Previously, it was shown that dietary omega-3 fatty acids can be used to reduce inflammation in adipose tissue without influencing level of obesity. Todoric et al., Diabetologia (2006), 49(9), 2109-2119. Reduction in adipose tissue inflammation was demonstrated by an increase in circulating levels

[6] Regarding the presence of ether phospholipids in krill oil, the AU '345 specification explains that ether phospholipids are expected to be present in krill oil but does not state that ether phospholipids alone have any advantageous health benefits.

[7] Dependent Claims 7, 13 and 19 specify that the "krill oil further comprises from about 20% to 35% omega-3 fatty acids." However, as shown later in this submission, such amounts were known in the prior art.

of adiponectin. Adiponectin is an adipose tissue derived anti-inflammatory hormone. .... Itoh et al. found that 1.8 g/d of EPA increased adiponectin, a marker of adipose tissue derived inflammation, in a group of overweight subjects with metabolic syndrome. Itoh et al., Arteriosclerosis, Thrombosis, and Vascular Biology (2007), 27(9), 1918-1925. (emphasis added) (Page 21, line 31, to page 22, line 15)

and

> It has also been shown previously that ***astaxanthin is a powerful antioxidant***, useful for prevention of oxidative stress in vivo and in Zucker rats using vitamin E. See, e.g., Aoi et al., (2003). Antioxidants & Redox Signaling. 5(1):139-44; Laight et al., Eur. J. Pharmacol. 377 (1999) 89. (emphasis added) (page 22, line 33, to page 23, line 2)

The specification indicates a number of particular ether phospholipids:

> In some embodiments, the ether phospholipids are selected from the group consisting of alkylacylphosphatidylcholine, lysoalkylacylphosphatidyl-choline, alkylacylphosphatidylethanolamine, and combinations thereof. In some embodiments, the ether lipids are greater than 90% alkylacylphosphatidylcholine. (page 3, line 12)

However, there are no alleged health benefits mentioned in the specification with respect to these particular compounds – or any other ether phospholipids.

The statement about alleged superior results in the '905 file history points to Example 9 and Figures 4-5, 7-8 and 10. However, the text of Example 9 does not suggest that it is a study of the impact of ether phospholipids. Rather, by the plain language of the example, it tests different omega-3 sources:

> The purpose of this experiment was ***to investigate the effect of different omega-3 fatty acid sources on metabolic parameters*** in the Zucker rat. (page 45, line 8 to 9)

Contrary to the assertion of "superior results" in the US file wrapper, there is nothing in the specification that links the named component of Claim 1 to a medical benefit. While Example 9 indicates the benefits of omega-3 fatty acids were tested, Claim 1 is silent as to omega-3 fatty acids.

Putting aside these very serious problems for a moment, the data relied on is also problematic. Example 9 used four groups of rats (n=6 per group). This is a small sample size. Example 9 states that all data in "the following figures" (e.g., Figures 2 - 10) are displayed with "mean ± SE" (SE = standard error of the mean). See, AU '345 at page 45, line 20. However, only a subset of these Figures display standard error bars, and even then only half of the range is presented thereby making comparison of overlapping standard error bars between treatment groups difficult. To explain, for the Figures where standard error bars are present, namely Figures 2, 6, 7, 8 and 9, there is no indication of any statistical significance (e.g., p-value). Most statistical tests require a minimum of three (3) data points on which to perform an analysis to generate a p-value. Even though Example 9 reports data collected from four groups of six (6)

rats, this is still considered a small enough sample size to require a statistical analysis to determine whether a real effect is present in the dataset. A statistical analysis, such as an analysis of variance (ANOVA), would compensate for the small sample size as well as compare various groups against the same control without introducing a Type 1 error bias. However, there appears to be no statistical analysis provided in the specification (no p-values) for the Example 9 results. This is curious, since p-values are provided for Figure 11 and Example 12 (but these figures were not part of the "superior results" argument made in the US file wrapper). A visual comparison of the mean values or as to whether the standard error bars overlap is insufficient to interpret the data and no conclusions can be drawn.

Another overarching concern is the fact that all of the data generated in Example 9 involves Zucker rats.[8] The literature has indicated that such results may not be translatable to type 2 diabetes mellitus in humans:

> There are substantial differences between these animal models and human T2DM that limit reliable, reproducible, and translatable insight into human T2DM.

Wang et al., Exhibit 1022 (see Abstract). One should not freely infer anything from these results in this obese rat model that would necessarily apply to humans.[9]

Turning now to the Figures themselves, a review of this data reveals less than compelling results. Figure 4 purports to measure insulin levels. However, the literature indicates that Zucker rat insulin levels are in marked contrast to those in the human disease state:

> Hyperinsulinemia is seen at 3-4 weeks of age. When these rats reach about 30 weeks of age, plasma insulin levels typically return to normal, which is in marked contrast to the human disease state. See Wang et al. (Exhibit 1022) (p.137).

Example 9 indicates that the testing was done in this high period ("Zucker rats were 4 wk old at the start of the study . . ."). To explain, the Zucker obese rat is known to have significant fluctuation in insulin levels during the first few weeks of age. For example, hyperinsulinemia is observed during weeks 3-4 followed by a tapering of the levels such that by week 30 insulin levels are normal. See Wang et al. (Exhibit 1022) (p.137). Consequently, one must be cognizant of this adaptive period when considering and interpreting data. It is generally known that the optimum period to use the Zucker obese rat is between 10 - 20 weeks of age, when hyperinsulinemia is well past its peak and tapering slowly. This timeframe provides the optimal homeostatic timeframe of the Zucker obese rat during which to perform

[8] This diabetes rat model was first developed in the 1960's subsequent to the observation of a morbidly obese rat appearing in an M13 wild type rat population. It was determined that this morbidly obese rat exhibited a spontaneous mutation in the leptin receptor (leptin is a hormone responsible for fat burning metabolism). Researchers have been using two different leptin hormone receptor mutation strains to study diabetes that are commonly known as the Zucker "fatty" rat and the Zucker "obese" rat. The AU'345 specification makes clear that the Zucker rat used in Example 9 is the Zucker "obese" rat.

[9] During the past fifty (50) years of research using the Zucker diabetic rat models, there is sufficient data to conclude that direct extrapolations cannot be made between these rat models and human beings. See Wang et al., Exhibit 1022 (Abstract). Consequently, any alleged health-benefits of krill oil observed in the Zucker obese rats cannot, and should not, be considered evidence that the same effects are observed in humans.

data collection. Steep changes in insulin levels during the early weeks of age can confound data interpretation. The AU'345 specification states that the experiments were performed using Zucker obese rats that were of four (4) weeks of age. This is age is at the beginning of the precipitous drop in insulin levels and could result in considerable variability in data collected at this time.

Even putting aside the ability to translate this data to humans, Figure 4 has no standard error bars and no p-values, so one cannot tell whether the purported difference in insulin levels from the Zucker rats given different sources of omega-3 fatty acids is meaningful.

Figure 5 purports to measure the HOMA IR results. The HOMA model is used to yield an estimate of insulin sensitivity and β-cell function from fasting plasma insulin and glucose concentrations. Yet, it does not appear that the experiment involving fasting. Moreover, Figure 5 has no standard error bars and no p-values. Nonetheless, the data shows that Superba is inferior to fish oil (FO), which is devoid of phospholipids including ether lipids, and so it can be concluded that ether lipids provide no surprising benefit in HOMA IR. As the data was collected using the Zucker obese diabetic rat model, these data cannot be extrapolated to humans in any predictive manner. Consequently, one cannot tell whether the differences between the means are meaningful.

Figure 7 purports to show the effect of dietary omega-3 fatty acids on lipid accumulation in the liver. There are standard error bars in the figure, but the Superba krill oil standard error bars appear to overlap in part with the standard error bars of the other krill oil (Neptune or NKO). While overlapping standard error bars are not definitive,[10] it is not clear that they are statistically significant (no p-values are provided). Again, these results were obtained in Zucker rat, not humans. These data suggest that the Superba krill oil has no surprising result as when compared with the NKO krill oil for reducing liver lipid accumulation.

Figure 8 purports to show the effect of dietary omega-3 fatty acids on lipid accumulation in the muscle. There are standard error bars, but both krill oil standard error bars appear to overlap in part; indeed, they may overlap with the standard error bars from the control (standard error bars appear to overlap between the control, FO and NKO and Superba groups). While overlapping standard error bars are not definitive, it is not clear that they are statistically significant (no p-values are provided). FO contains no ether lipids, and so it can be concluded that ether lipids provide no surprising benefit in lipid accumulation. As the data was collected using the Zucker obese diabetic rat model, these data cannot be extrapolated to humans in any predictive manner. These data suggest that the Superba krill oil has no surprising result as when compared with the NKO krill oil for reducing muscle lipid accumulation.

Figure 10 purports to show the relative concentrations of DHA in the brain in Zucker rats supplemented with omega-3 fatty acids. There are standard error bars, but the Superba standard error bars appear to

[10] Indeed, they could not overlap and still not be statistically significant.

overlap in part with the standard error bars of the other krill oil (Neptune or NKO). While overlapping standard error bars are not definitive, it is not clear that they are statistically significant (no p-values are provided). As the data was collected using the Zucker obese diabetic rat model, these data cannot be extrapolated to humans in any predictive manner. These data suggest that the Superba krill oil has no surprising result as when compared with the NKO krill oil for promoting DHA transfer into the brain.

While the applicant did not point to the other data associated with Example 9, it is worth noting that these other figures appear to show no significant difference. For example, Figure 2 purports to show blood lipid profiles in Zucker rats fed different forms of omega-3 fatty acids (TAG=FO, PL1=NKO and PL2=Superba). There are standard error bars, but the Superba standard error bars appear to overlap in part with the standard error bars of the other krill oil (Neptune or NKO). While overlapping standard error bars are not definitive, it is not clear that they are statistically significant (no p-values are provided). These data suggest that the Superba krill oil has no surprising result as when compared with the NKO krill oil for reducing cholesterol (CHOL), high density lipoprotiens (HDL), triglycerides (TAG) and/or low density lipoproteins (LDL); no surprising results are evident when compared to fish oil (noted in error as TAB in the legend instead of FO), which contains no significant amounts of phospholipids, let alone ether lipids.

Figure 3 purports to show plasma glucose concentration in Zucker rats fed different forms of omega-3 fatty acids. The literature indicates that "Hyperglycemia is the hallmark of [human] T2DM." See Wang et al. (Exhibit 1022) (p.136). However, the literature also indicates that "Zucker fatty rats are not hyperglycemic." *Id.* Oddly, Figure 3 appears to show an increase in glucose levels in Zucker rates given all sources of omega-3 fatty acids. It is not at all clear how such an increase (if true) could be a health benefit. Moreover, Figure 3 has no standard error bars and no p-values, so one cannot tell whether the purported difference in glucose levels is meaningful. It would appear that the mean for the other krill oil (Neptune or NKO) is very close to the mean value for Superba krill oil. This may explain why the applicants did not point to this figure when arguing superior results. Further and more detailed information in relation to this point can be found in **Appendix A.**

Figure 6 presents data of the effect of omega-3 fatty acids on tissue necrosis factor (TNF) release from peritoneal macrophages where the standard error bars appear to overlap between the FO, NKO and Superba krill oil groups. The AU'345 specification provides no explanation as to how this experiment was performed, e.g., either *in vitro*, *in vivo* or *in situ*. As the data was collected using the Zucker obese diabetic rat model, these data cannot be extrapolated to humans in any predictive manner. These data suggest that the Superba krill oil has no surprising result as when compared with the NKO krill oil for reducing TNF release from peritoneal macrophages. Furthermore, the data suggests that Superba has not surprising benefit compared to fish oil (FO), which contains no significant amounts of phospholipids, let alone ether phospholipids. It cannot be concluded, based on this data, that ether lipids provide a surprising benefit in reducing TNF release from peritoneal macrophages.

Figure 9 of the AU'345 specification presents data of the effect of omega-3 fatty acids on heart tissue triglyceride (TAG) accumulation where the standard error bars appear to overlap between the NKO and Superba krill oil groups. As the data was collected using the Zucker obese diabetic rat model, these data cannot be extrapolated to humans in any predictive manner. These data suggest that the Superba krill oil has no surprising result as when compared with the NKO krill oil for reducing triglyceride accumulation in heart tissue. It is not clear that the alleged differences in lipid accumulation in liver (Figure 7) and muscle (Figure 8) are meaningful, when there are no differences in lipid accumulation in the heart (Figure 9).

Thus, when the data is looked at closely, it is not clear that the krill oil prepared in Example 7 and tested in Example 9 displays meaningfully better results than the commercially available Neptune (NKO) oil. Certainly, nothing can be concluded about "ether phospholipids" in this regard.

One reason may be because the rats were fed *ad libitum*.[11] Unmeasured feeding introduces an uncontrolled variable of the amount each animal consumed. Consequently, the data may be confounded by a dose-effect, both within and between the independent variables. As such, no conclusions of health-benefit can be drawn from the dataset supporting Example 9.

From all of the above, it should be clear that the allegations of unexpected results have no experimental basis. Yet, one need not rely only on the comparisons between the krill oil prepared in Example 7 and the commercially available Neptune (NKO) oil to show this. Indeed, the data associated with Example 9 provides another control, i.e. fish oil. Rather than looking at the (alleged) differences between NKO and Superba, one can look for instances where the results from fish oil were as good as (or better than) those from Superba. When this is done, it is clear that the allegation that ether phospholipid levels were allegedly responsible for superior activity is not a tenable position.

The numbers associated with the bar graphs in Figures 2, 4-6 and 8 of AU '345 (which constitute the majority of the data alleged to show unexpected results in the US prosecution) reveals that the results with fish oil were as good as (or better than) those from krill oil (Superba). Yet, fish oil has no appreciable phospholipids (the omega-3 fatty acids are attached to the triglycerides). Commercial fish oils are primarily composed of glycerides of fatty acids. By contrast, the omega-3 fatty acids in krill oils are attached to phospholipids. This difference comes from the way commercial fish oil is produced. Therefore, it is not possible to attribute the results to the presence of phospholipids, let alone ether phospholipids.

Putting this in a legal context, it is impossible for there to be a nexus between the data and the ether phospholipid feature of the AU '345 claims. Without a nexus, the allegation of unexpected results is meaningless.

[11] This is a Latin term meaning "to satisfaction" and is essentially a free-feeding paradigm.

In relation to unexpected results, for such (secondary) considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the *claimed invention.* Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention. In other words, if the feature that creates the commercial success was known in the prior art, the success is not pertinent. The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims, and in such a situation, the applicant must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range.

Here, there is no data showing the particular range of either phospholipids specified in the claims is critical. Example 9 provides test results with krill oil containing many ingredients, including ingredients recognized to provide health benefits in the prior art, namely omega-3 fatty acids and astaxanthin. Fish oil has omega-3 fatty acids, but no appreciable phospholipids. Thus, the alleged superior results stem from something other than what is claimed in Claims 1, 12 and 18. Indeed, the results stem from something in the prior art. As such, the alleged superior results should not have been considered. The alleged novel feature of ether phospholipids is a meaningless limitation.

Finally, this situation is particularly problematic because the claims specify a broad range, yet the specification provides a single data point for the amount of ether phospholipids. There is no showing of unexpected results over the entire claimed range. Thus, the alleged unexpected results are not commensurate in scope with the claims and cannot be used to rebut obviousness.

We refer to the comments above in relation to the Antarctica Select™ product, which is a product (encapsulated krill oil) containing 1800 mg/kg astaxanthin and at least 3.3 % w/w ether phospholipids was on the market before the first priority date claimed by AU 2014256345. When combined with Catchpole et al., (Exhibit 1006), claim 1 lacks an inventive step.

Alternatively claim 1 lacks an inventive step when Catchpole et al., (Exhibit 1006), is combined with the knowledge that the presence of astaxanthin in krill oil is an inevitable consequence of the solvent extraction process,

2.) Claim 12 Is Unpatentable as Obvious over Catchpole et al. in Combination with Tuo et al.

Independent Claim 12 specifies "about" 3-10% ether phospholipids along with some additional components, namely "from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and from about 20% to 50% w/w triglycerides." As noted above, Catchpole et al. (Exhibit 1006) teaches a phosphatidylcholine (PC) concentration of 39.8% and an ether phospholipid concentration of 4.8% in krill lipid extracts. This means that the total phospholipids were at least 45%. While Catchpole et al. does not call out the level of

triglycerides, this does not mean such levels were not obtained. Triglycerides are a known component of krill oil; the Japanese application by Maruyama et al. (Exhibit 1025), for example, shows this. See **Appendix B**. Indeed, based on the similarities of the process used in Example 18 of Catchpole et al. (Exhibit 1006) and that used in Example 7 of AU '345 the resulting krill oil of Example 18 would be expected to have triglyceride concentrations of between 20%-50% (w/w). *Id.* Thus, Catchpole et al. (Exhibit 1006) inherently provides this feature of Claims 12.[12]

However, triglyceride levels in krill oil were not of much interest. There is only a minor level of omega-3 fatty acids in the krill triglycerides (approximately 2.5 % EPA and 1 % DHA as a percentage of total fatty acids in the triglycerides). The vast amount of omega-3 fatty acids are to be found associated with the krill oil phospholipids. Most of these fatty acids are attached to the phospholipids, with a small percentage being free fatty acids. The AU '345 application provides no evidence the triglycerides provide a benefit, let alone a benefit associated with (and throughout) the claimed range.

As noted previously, one would be motivated to encapsulate the krill oil of Catchpole et al. in order to make it more palatable. Thus, one skilled in the art would use the gram amounts taught in Tuo et al. to be effective.

Thus, the legal requirements for inventive step are not satisfied. First, all the claimed elements were known in the prior art. Catchpole et al. shows that krill oil extracts with enriched ether phospholipid levels were known. Tuo et al. and Sampalis I show that it was known to package krill oil in capsules in gram amounts. Second, putting the krill oil in capsules by known method produces no change in their respective functions, and the combination yielded nothing more than predictable results.

3.) Claim 12 Is Unpatentable as Obvious over Catchpole et al. in Combination with Beaudoin et al. (Exhibit 1014) and Tuo et al.

As noted above, independent Claim 12 specifies "about" 3-10% ether phospholipids along with some additional components. As noted above, Catchpole et al. (Exhibit 1006) teaches a phosphatidylcholine (PC) concentration of 39.8% and an ether phospholipid concentration of 4.8% in krill lipid extracts. This means that the total phospholipids were at least 45%. A Claim Chart (see below) is provided to highlight these features:

Claim Chart II: Catchpole's Teachings vs Claim 12

Claim 12	Relevant Disclosure
a capsule	"a product" that contains desirable level of phospholipids ... *pg 3 ln 27-28*
an effective amount of	This example shows the fractionation of krill lipids from krill powder ... *pg 24*

[12] The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness.

krill oil	*In 1* Example 18 begins with 5619.9 grams of starting material; Table 16 shows that the yield of extract 2 was 4.3% of the starting material, or 241.6 grams
from about 3% - 10% ether phospholipids	The alkylacylphosphatidylcholine (AAPC), a type of alkylacylphospholipid, is highly enriched in the concentrated phospholipids-rich extract, whilst alkylacylphosphatidylethanolamine (AAPE), another type of alkylacylphospholipid ... pg 24 ln 13 - 15. ... [4.6% APCC + 0.2% AAPE (w/w of lipid extract] ... *pg 24 Table 16.*
from about 27% to 50% w/w non-ether phospholipids	The bulk of the phospholipids-rich extract (extract 2) was obtained ... *pg 24 ln 9-10* ... [39.8% phosphatidylcholine (PC) w/w of lipid extract] ... pg 24 Table 16
total phospholipids from about 30% to 60% w/w	Table 16 shows that total phospholipids would be approximately 45%
from about 20% - 50% triglycerides	Not specifically reported

While Catchpole et al. does not report on triglyceride levels, Beaudoin et al. (Exhibit 1014) shows that triglycerides are extracted in krill oil, and the amount varies according to the extraction procedure. Indeed, Table 14 of Beaudoin et al. shows that extraction under one set of conditions generated 19% triglycerides (Fraction I); extraction under a second set of conditions generated 66% triglycerides (Fraction II). Thus, one skilled in the art would understand from Beaudoin et al. that the concentration of triglycerides in krill oil can be engineered to be in the range specified in Claim 12. Here, the AU '345 application provides no teaching regarding the criticality of triglyceride concentrations. As such, it cannot provide a basis for patentability. There is no evidence in the record pointing to any critical significance in the claimed molar proportions or ranges.

Thus, the legal requirements for inventive step are not satisfied. First, all the claimed elements were known in the prior art. Catchpole et al. shows that krill oil extracts with enriched ether phospholipid levels were known. Tuo et al. and Sampalis show that it was known to package krill oil in capsules. Second, putting the krill oil in capsules by known method produces no change in their respective functions, and the combination yielded nothing more than predictable results.

The obviousness of Claim 12 under Catchpole et al., Beaudoin et al. and Tuo et al. is further based upon the principal that the concentrations for phospholipids are close enough to those described in the prior art, that it would be considered an obvious material substitution as no resulting benefit has been described.

Contrary to the assertion of "superior results" in the US file wrapper, there is nothing in the specification that links ANY of the components of Claim 12 to a medical benefit. While Example 9 indicates the benefits of omega-3 fatty acids were tested, Claim 12 is silent as to omega-3 fatty acids.

Moreover, a closer look at the data shows no meaningful differences (as detailed above). Finally, there is no nexus between the alleged superior results and the elements of Claim 12, let alone for the entire range specified for the components of Claim 12.

4.) Claim 18 Is Unpatentable as Obvious over Catchpole et al. in Combination with Tuo et al. or Sampalis et al.

Claim 18 of AU '345 is virtually identical to Claim 12, except for the fact that it specifies "soft gel" capsules. As noted above, Catchpole et al. (Exhibit 1006) teaches a phosphatidylcholine (PC) concentration of 39.8% and an ether phospholipid concentration of 4.8% in krill lipid extracts. This means that the total phospholipids were at least 45%. The elements of Claim 18 are compared to the teachings of Catchpole et al. below:

Claim Chart III: Catchpole's Teachings compared to AU '345 Claim 18

Claim 18	Relevant Disclosure
a soft gel capsule	"a product" that contains desirable level of phospholipids ... *pg 3 ln 27-28*
an effective amount of krill oil[13]	This example shows the fractionation of krill lipids from krill powder ... *pg 24 ln 1* Example 18 begins with 5619.9 grams of starting material; Table 16 shows that the yield of extract 2 was 4.3% of the starting material, or 241.6 grams
from about 3% - 10% ether phospholipids	The alkylacylphosphatidylcholine (AAPC), a type of alkylacylphospholipid, is highly enriched in the concentrated phospholipids-rich extract, whilst alkylacylphosphatidylethanolamine (AAPE), another type of alkylacylphospholipid ... pg 24 ln 13 - 15. ... [4.6% APCC + 0.2% AAPE (w/w of lipid extract] ... *pg 24 Table 16.*
from about 27% to 50% w/w non-ether phospholipids	The bulk of the phospholipids-rich extract (extract 2) was obtained ... pg 24 ln 9-10 ... [39.8% phosphatidylcholine (PC) w/w of lipid extract] ... *pg 24 Table 16*
total phospholipids from about 30% to 60% w/w	Table 16 shows that total phospholipids would be approximately 45%
from about 20% - 50%	Not disclosed.

[13] Claim 18 has the term "Antarctic" in the preamble. As the term "Antarctic" is not repeated in the body of the claim, it may not have patentable weight.

triglycerides	

While Catchpole et al. does not report on triglyceride levels, this does not mean such levels were not obtained. Triglycerides are a known component of krill oil. Indeed, based on the similarities of the process used in Example 18 of Catchpole et al. (Exhibit 1006) and that used in Example 7 of the AU'345 application, the resulting krill oil of Example 18 would be expected to have triglyceride concentrations of between 20%-50% (w/w). *Id.* Thus, Catchpole et al. (Exhibit 1006) inherently provides this feature of Claims 18.

However, triglyceride levels in krill oil were not of much interest. There is only a minor level of omega-3 fatty acids in the krill triglycerides (approximately 2.5 % EPA and 1 % DHA as a percentage of total fatty acids in the triglycerides). The vast amount of omega-3 fatty acids are to be found associated with the krill oil phospholipids. Most of these fatty acids are attached to the phospholipids, with a small percentage being free fatty acids. The AU '345 application provides no evidence the triglycerides provide a benefit, let alone a benefit associated with (and throughout) the claimed range.

As noted previously, one would be motivated to encapsulate the krill oil of Catchpole et al. in order to make it more palatable. Thus, one skilled in the art would use the gram amounts taught in Tuo et al. and/or Sampalis et al. to be effective.

Thus, the legal requirements for inventive step are not satisfied. First, all the claimed elements were known in the prior art. Catchpole et al. shows that krill oil extracts with enriched ether phospholipid levels were known. Tuo et al. and Sampalis show that it was known to package krill oil in capsules, including soft capsules. Second, putting the krill oil in capsules by known method produces no change in their respective functions, and the combination yielded nothing more than predictable results.

The obviousness of Claim 18 of the AU '345 application is further based upon the legal principal that the concentrations for phospholipids are close enough to those described in the prior art, that it would be considered an obvious material substitution as no resulting benefit has been described.

Contrary to the assertion of "superior results" in the US file wrapper, there is nothing in the specification that links ANY of the components of Claim 18 to a medical benefit. While Example 9 indicates the benefits of omega-3 fatty acids were tested, Claim 18 is silent as to omega-3 fatty acids.

Moreover, a closer look at the data shows no meaningful differences (as detailed above). Finally, there is no nexus between the alleged superior results and the elements of Claim 18, let alone for the entire range specified for the components of Claim 18.

5.) Claim 18 Is Unpatentable as Obvious over Catchpole et al. in Combination with Tuo et al. or Sampalis et al. and further in view of Beaudoin et al.

Claim 18 of the AU '345 application is virtually identical to Claim 12, except for the fact that it specifies "soft gel" capsules. As noted above, Catchpole et al. (Exhibit 1006) teaches a phosphatidylcholine (PC) concentration of 39.8% and an ether phospholipid concentration of 4.8% in krill lipid extracts. This means that the total phospholipids were at least 45%.

While Catchpole et al. does not call out triglyceride levels in the krill oil, Beaudoin et al. (Exhibit 1014) shows that triglycerides are extracted in krill oil, and the amount varies according to the extraction procedure. Indeed, Table 14 of Beaudoin et al. shows that extraction under one set of conditions generated 19% triglycerides (Fraction I); extraction under a second set of conditions generated 66% triglycerides (Fraction II). Thus, one skilled in the art would understand from Beaudoin et al. that the concentration of triglycerides in krill oil can be engineered (by simply adjusting the extraction conditions) to be in the range specified in Claim 18. Here, the AU '345 application provides no teaching regarding the criticality of triglyceride concentrations. As such, it cannot provide a basis for patentability (there is no evidence in the record pointing to any critical significance in the claimed molar proportions or ranges).

Thus, the legal requirements for inventive step are not satisfied. First, all the claimed elements were known in the prior art. Catchpole et al. shows that krill oil extracts with enriched ether phospholipid levels were known. Tuo et al. and Sampalis show that it was known to package krill oil in capsules. Second, putting the krill oil in capsules by known method produces no change in their respective functions, and the combination yielded nothing more than predictable results.

6.) An encapsulated krill oil comprising 3-10% ether phospholipids and greater than about 100 mg/kg astaxanthin esters, is obvious in light of Beaudoin et al. in combination with Tuo et al. and in view of Antarctica Select™ or that the presence of astaxanthin in krill oil is an inevitable consequence of the solvent extraction process.

Beaudoin et al. (Exhibit 1013) teaches an effective amount of krill oil and "from about 3% ether phospholipids". As noted above, the Applicant has admitted (during the US prosecution history) to a) Beaudoin et al.'s process being the process for the production of Neptune krill oil (NKO) and b) an interpretation of the data presented in the AU'345 application Table 22 such that the weight-to-weight calculation of ether phospholipids (as adjusted by the total phospholipids) is 2.46%. Beaudoin's 2.46% is "about 3%" since it is close enough that one skilled in the art would have expected the same properties.

We submit that in the case where the claimed ranges overlap or lie inside ranges disclosed by the prior art a *prima facie* case of obviousness exists. Similarly, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties.

Furthermore, the AU '345 application has not shown any criticality for the lower limit of the ether phospholipid range. We submit that a change in form, proportions, or degree will not sustain a patent, and that the mere carrying forward of an original patented conception involving only change of form, proportions, or degree, or the substitution of equivalents doing the same thing as the original invention, by substantially the same means, is not such an invention as will sustain a patent, even though the changes of the kind may produce better results than prior inventions.

Claim Chart IV: Beaudoin's Teachings vs claim features

Claim features	Relevant Disclosure
a capsule	Not disclosed.
an effective amount of krill oil	These compounds are indicative of favourable pharmaceutical or cosmetological properties of the krill extract ... Thus, krill extract is a good candidate for transdermal delivery of medicines. *col 7 ln 34 - 39.*
from about 3% - 10% ether phospholipids	Aker has provided analysis of Beaudoin's krill oil (e.g., Neptune Krill oil) and admits to the USPTO that it contains 2.46% ether phospholipids (*supra*).

Because of the statements made during the US prosecution history, an ether phospholipid amount can be attributed to Beaudoin et al. (Exhibit 1013) of 2.46%. While a capsule is not disclosed, Claim 1 is obvious in view of Beaudoin et al. in combination with Tuo et al. (Exhibit 1017) which teaches krill oil encapsulation.

Thus, the legal requirements for inventive step are not satisfied. First, all the claimed elements were known in the prior art. Beaudoin et al. (as admitted during the US prosecution history) shows that krill oil extracts with enriched ether phospholipid levels were known. Tuo et al. and Sampalis show that it was known to package krill oil in capsules. Second, putting the krill oil in capsules by known method produces no change in their respective functions, and the combination yielded nothing more than predictable results.

The obviousness of Claim 1 of the AU '345 application under Beaudoin et al. and Tuo et al. is further based upon the knowledge that ether phospholipids were known to be a composition of krill oil, and the art had not ascribed any benefit as to their presence. The concentrations claims for phospholipids are close enough to those described in the prior art, that it would be considered an obvious material substitution as no resulting benefit has been described.

We refer to the comments above in relation to the Antarctica Select™ product, which is a product (encapsulated krill oil) containing 1800 mg/kg astaxanthin and at least 3.3 % w/w ether phospholipids was on the market before the first priority date claimed by AU 2014256345. When combined with Beaudoin et al., claim 1 lacks an inventive step.

Alternatively claim 1 lacks an inventive step when Beaudoin et al. is combined with the knowledge that the presence of astaxanthin in krill oil is an inevitable consequence of the solvent extraction process,

7.) Claim 12 is Unpatentable as Obvious over Beaudoin et al. in Combination with Tuo et al.

Beaudoin et al. (Exhibit 1013) teaches 62.6% total phospholipids and an ether phospholipid concentration of 2.46% in krill lipid extracts (as admitted during the prosecution history). The 2.46% satisfies the Claim 12 language of "from about 3% ether phospholipids". A Claim Chart is provided below.

Claim Chart V: Beaudoin's Teachings Of the AU'345 application Claim 12

Claim 12	Relevant Disclosure
a capsule	Not disclosed.
an effective amount of krill oil	These compounds are indicative of favourable pharmaceutical or cosmetological properties of the krill extract ... Thus, krill extract is a good candidate for transdermal delivery of medicines. *col 7 ln 34 - 39.*
from about 3% - 10% ether phospholipids	Aker has provided analysis of Beaudoin's krill oil (e.g., Neptune Krill oil) and admits to the USPTO that it contains 2.46% ether phospholipids (*supra*).
from about 27% to 50% w/w non-ether phospholipids	To analyze lipid composition 780 μg of each extract was loaded on silica-gel plates and fractionated by thin layer chromatography ... *col 5 ln 11 - 12.* Phospholipids or other material: Fraction I: 54.1 ± 6.1 %' Fraction II: 8.5 ± 1.6 % [total phospholipids = 62.6 % of lipid extract (e.g., oil). *col 14, Table 12.*
total phospholipids from about 30% to 60% w/w	To analyze lipid composition 780 μg of each extract was loaded on silica-gel plates and fractionated by thin layer chromatography ... *col 5 ln 11 - 12.* Phospholipids or other material: Fraction I: 54.1 ± 6.1 %' Fraction II: 8.5 ± 1.6 % [total phospholipids = 62.6 % of lipid extract (e.g., oil). *col 14, Table 12.*
from about 20% - 50% triglycerides	Table 14 shows 19% when extracted under one set of conditions (Fraction I); extraction under a second set of conditions generated 66% triglycerides (Fraction II).

Beaudoin et al. (Exhibit 1014) shows that triglycerides are extracted in krill oil, and the amount varies according to the extraction procedure. Indeed, Table 14 of Beaudoin et al. shows that extraction under one set of conditions generated 19% triglycerides (Fraction I); extraction under a second set of conditions generated 66% triglycerides (Fraction II). Thus, one skilled in the art would understand from Beaudoin et al. that the concentration of triglycerides in krill oil can be engineered to be in the range specified in Claim 12. Here, the AU '345 application provides no teaching regarding the criticality of

triglyceride concentrations. As such, it cannot provide a basis for patentability, as there is no evidence in the record pointing to any critical significance in the claimed molar proportions or ranges.

The obviousness of Claim 12 of the AU '345 application under Beaudoin et al. and Tuo et al. is further based upon the understanding that the concentrations claims for phospholipids are close enough to those described in the prior art, that it would be considered an obvious material substitution as no resulting benefit has been described.

Claim 12 of the AU '345 application is obvious in view of Beaudoin et al. in combination with Tuo et al. (Exhibit 1017) which teaches krill oil encapsulation compositions and effective amounts of krill oil to improve health.

8.) Claim 18 is Unpatentable as Obvious over Beaudoin et al. in Combination with Tuo.

Beaudoin et al. (Exhibit 1013) teaches 62.6% total phospholipids, an effective amount of krill oil and an ether phospholipid concentration of 2.46% in krill lipid extracts (as admitted during the US prosecution history). Beaudoin et al. (Exhibit 1014) shows that triglycerides are extracted in krill oil, and the amount varies according to the extraction procedure. Indeed, Table 14 of Beaudoin et al. shows that extraction under one set of conditions generated 19% triglycerides (Fraction I); extraction under a second set of conditions generated 66% triglycerides (Fraction II). Thus, one skilled in the art would understand from Beaudoin et al. that the concentration of triglycerides in krill oil can be engineered to be in the range specified in Claim 18. A Claim Chart is provided below.

Claim Chart VI: Beaudoin's Teachings Of the AU'345 application Claim 18

Claim 18	Relevant Disclosure
a soft gel capsule	Not disclosed.
an effective amount of krill oil	These compounds are indicative of favourable pharmaceutical or cosmetological properties of the krill extract ... Thus, krill extract is a good candidate for transdermal delivery of medicines. *col 7 ln 34 - 39.*
from about 3% - 10% ether phospholipids	Aker has provided analysis of Beaudoin's krill oil (e.g., Neptune Krill oil) and admits to the USPTO that it contains 2.46% ether phospholipids (*supra*).
from about 27% to 50% w/w non-ether phospholipids	To analyze lipid composition 780 μg of each extract was loaded on silica-gel plates and fractionated by thin layer chromatography ... *col 5 ln 11 - 12.* Phospholipids or other material: Fraction I: 54.1 ± 6.1 %' Fraction II: 8.5 ± 1.6 % [total phospholipids = 62.6 % of lipid extract (e.g., oil). *col 14, Table 12.*
total phospholipids from about 30% to 60% w/w	To analyze lipid composition 780 μg of each extract was loaded on silica-gel plates and fractionated by thin layer chromatography ... *col 5 ln 11 - 12.*

	Phospholipids or other material: Fraction I: 54.1 ± 6.1 %' Fraction II: 8.5 ± 1.6 % [total phospholipids = 62.6 % of lipid extract (e.g., oil). *col 14, Table 12.*
from about 20% - 50% triglycerides	Table 14 shows 19% when extracted under one set of conditions (Fraction I); extraction under a second set of conditions generated 66% triglycerides (Fraction II).

Beaudoin et al. teaches 62.6% total phospholipids and (based on statements in the file history) has an ether phospholipid concentration of 2.46% in krill lipid extracts. Claim 18 is obvious in view of Beaudoin et al. in combination with Tuo et al. (Exhibit 1017) which teaches krill oil encapsulation compositions and effective amounts of krill oil to improve health.

Here, the AU '345 application provides no teaching regarding the criticality of "about 3% ether phospholipids". As such, it cannot provide a basis for patentability as there is no evidence in the record pointing to any critical significance in the claimed molar proportions or ranges.

The obviousness of Claim 18 of the AU '345 application 'under Beaudoin et al. and Tuo et al. is further based upon the knowledge that the concentrations for phospholipids are close enough to those described in the prior art, that it would be considered an obvious material substitution as no resulting benefit has been described.

9.) The feature of a krill oil comprising at least 30% total phospholipids, is obvious in light of Catchpole et al., (Exhibit 1006), in view of Tuo et al. (Exhibit 1017), since Table 16 of Catchpole et al. shows that total phospholipids obtained were approximately 45%

The feature of a krill oil comprising at least 30% total phospholipids is obvious. As shown above, Table 16 of Catchpole et al. indicates at least a level of 45% total phospholipids.

10.) The feature of a the krill oil comprising at least 30% phosphatidylcholine, is obvious in light of Catchpole et al., (Exhibit 1006), in view of Tuo et al. (Exhibit 1017), since Table 16 of Catchpole et al. shows a level of phosphatidylcholine of 39.8%.

The feature a the krill oil comprising at least 30% phosphatidylcholine is obvious in view of Catchpole *et al.*, (Exhibit 1006), in view of Tuo et al. (Exhibit 1017), since Table 16 of Catchpole et al. shows a level of phosphatidylcholine of 39.8%.

11.) The feature of "a polar solvent extract of krill" Is Obvious Under Catchpole et al.

The AU '345 application provides no definition of "a polar solvent" and only exemplifies one polar solvent, ethanol. See the Examples of AU '345. Catchpole et al. teaches that polar co-solvents, such as ethanol, may be used in the extraction of a krill lipid extract (e.g., a krill oil):

> The solvent of the present invention preferably comprises:
> (a) an alcohol selected from: methanol, ethanol, n-propanol, isopropanol and mixtures thereof; and
> (b) 0 - 40% v/v water
> More preferably the solvent comprises between 0 and 20% v/v water. Most preferably the solvent comprises between 1 and 10% v/v water.
> Preferably the alcohol is ethanol. (see Catchpole et al., Exhibit 1006, pg 7 In 22 - 28.)

As such, the feature "a polar solvent extract of krill" fails to provide additional patentable subject matter to overcome the obviousness of Claim 1.

12.) The feature of "said capsule contains a phytonutrient derived from a source other than krill" Is Obvious Under van Lengerich et al.

The AU '345 application provides a list of exemplary phytonutrients for inclusion in the krill oil composition. (page 20, lines 19 to 24). However, van Lengerich et al. shows that the addition of bioactive compounds (e.g., phytonutrients) to oils, including krill oils, was well known in the art:

> Encapsulants can either comprise an active oil component, or can comprise a solid active, sensitive encapsulant component dispersed in oil. Readily oxidizable oil encapsulants may comprise, for example, castor oil, algae-based oil or oil derived from algae, flax oil or flax seed oil, fish oil, or any other oil containing polyunsaturated fatty acids (PUFA) such as omega-3 fatty acids, such as eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), docosapentaenoic acid, and linolenic acid, omega-6 fatty acids, fat soluble vitamins such as vitamins A, D, E, and K, gamma linoleic acid, cod liver oil, flavorants, flavor oils, fragrances, active-ingredient containing extracts, e.g. chlorophyll or herbals, agricultural and pharmaceutical and other bioactive components soluble in oil, and mixtures thereof. In embodiments of the invention, the readily oxidizable oil encapsulant may be any oil derived from any vegetable, animal, marine life, or microorganism which contains a substantial amount, for example at least 5% by weight of a readily oxidizable component. Examples of oils which may contain a substantial amount of a readily oxidizable component are oils derived from soybeans and corn, sunflower oil, rapeseed oil, walnut oil, wheat germ oil, canola oil, krill oil, oil derived from yeast, black currant seed oil, sea buckthorn oil, cranberry seed oil, and grape seed oil. (see van Lengerich et al., col 13 In 15 - 37 (Exhibit 1024) (emphasis added).

As such, the feature "said capsule contains a phytonutrient derived from a source other than krill" fails to provide additional patentable subject matter to overcome the obviousness of Claim 1.

13.) Claim 1 Is Obvious Under Catchpole et al. and Tuo et al. and in view of Antarctica Select™ or that the presence of astaxanthin in krill oil is an inevitable consequence of the solvent extraction process.

The analysis above in relation to claim 12 can be readily applied to Claim 1, as the claims are virtually identical. Catchpole teaches amounts in the claimed ranges for ether phospholipids, non-ether phospholipids and total phospholipids. While Catchpole et al. (Exhibit 1006) does not provide triglyceride levels in Table 16, this does not mean such levels were not obtained. Indeed, based on the similarities of the process used in Example 18 of Catchpole et al. (Exhibit 1006) and that used in Example 7 of the AU '345 application, the resulting krill oil of Example 18 would be expected to have triglyceride concentrations of between 20%-50% (w/w). *Id.* Thus, Catchpole et al. (Exhibit 1006) inherently provides this feature of Claims 6 of AU '345.

Moreover, triglyceride levels in krill oil were not of much interest. There is only a minor level of omega-3 fatty acids in the krill triglycerides. The vast amount of omega-3 fatty acids is associated with the krill phospholipids. *Id.* As such, Claim 1 is obvious.

We additionally refer to the comments above in relation to the Antarctica Select™ product, and that the presence of astaxanthin in krill oil is an inevitable consequence of the solvent extraction process,

14.) Claims 7, 13 And 19 Are Obvious In view of the Admitted Prior Art, or Under Sampalis et al. or Tuo et al. or Catchpole et al.

Claims 7, 13 and 19 depend from Claims 1, 12 and 18, respectively. The basis for obviousness of Claims 1, 12 and 18 has been established above (incorporated here by reference). Claims 7, 13 and 19 introduce the claim limitation of "from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids." However, the Background section of the AU '345 application admits of such levels in the prior art krill oils:

> The phospholipid content in the krill lipid extract could be as high as 60% w/w and the EPA/DHA content as high as 35% (w/w). See, e.g., WO 03/011873. (page 1, lines 28 to 30)

Moreover, Sampalis et al. II (Exhibit 1019) (pg 27, Table 2) discloses a krill oil comprising omega-3 fatty acids of 27.35% (EPA) and 24.9% (DHA) which are clearly encompassed by the claims of the AU '345 application.

Additionally, Tou et al. (Exhibit 1017) further suggests that it was known that it would be desirable to increase omega-3 fatty acid concentrations in krill oil because of their known health-related benefits:

... the omega3 polyunsaturated fatty acids (w-3 PUFAs), particularly eicosapentanoic acids (EPA, 20:5ω-3) and decosahexanoic acid (DHA, 22:6ω -3), have been linked to reduced risk of CVD. Thus, the nutritive value of krill oil was evaluated due to the consumer's desire for foods that are low in fat and SFAs and high in ω -3 PUFAs. (Tuo et al., Exhibit 1017 pg 64, rhc.

Finally, Catchpole et al. reports the extraction of phospholipids from krill oil, such phospholipids inherently associated with omega-3 fatty acids. For example, Tuo et al. and Sampalis II disclose that the omega-3 fatty acids of krill oil are attached to phospholipids. As such, Claims 7, 13 and 19 fail to provide additional patentable subject matter to overcome the obviousness of Claims 1, 12 and 18, respectively.

15-18. Claims 8, 14 And 20 Are Obvious In View of Catchpole et al., Tuo et al., Bunea, Sampalis I or Sampalis II

Claims 8, 14 and 20 depend from Claims 1, 12 and 18, respectively. The basis for obviousness of Claims 1, 12 and 18 has been established above (incorporated here by reference). Claims 8, 14 and 20 introduce the claim limitation of "from about 70% to 95% of said omega-3 fatty acids are attached to said phospholipids". It was well known in the art at the time of filing that krill oil has omega-3 fatty acids attached to phospholipids, and the claimed percentages would be deemed an inherent naturally occurring property:

> Bunea et al.[24] attributed the greater lipogenic action of krill oil to the ω-3 PUFAs in krill being associated with phospholipids; the ωPUFAs in fish are mainly associated with triglycerides.

Tuo et al., Exhibit 1017, pg 66 rhc. (Note: Bunea et al.[24] is Exhibit 1011), and

> The association between phospholipids and long chain omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing their bioavailability, and ultimately improving the omega-3:omega-6 ratio.

Sampalis et al.(I), Exhibit 1018, pg 178 lhc. Sampalis et al. (II) (Exhibit 1019) specifically calls out percentages of free fatty acids:

> Free fatty acids are present in the extract in an amount of at least 4% w/w and preferably at least 5% w/w.

Sampalis et al. (II) (Exhibit 1019), pg 28 ln 6-7. Indeed, Sampalis II notes that phospholipids with the fatty acids attached "are more efficacious and of higher value." Finally, Catchpole et al. reports the extraction of phospholipids from krill oil, and such phospholipids inherently have the omega-3 fatty acids attached. As such, Claims 8, 14 and 20 fail to provide additional patentable subject matter to overcome the obviousness of Claims 1, 12 and 18, respectively.

19.) Claims 9 And 15 Are Obvious Under Grantham et al.

Claims 9 and 15 depend from Claims 1 and 12. The basis for obviousness for Claims 1 and 12 has been established above (incorporated here by reference). Claims 9 and 15 provide the limitation that "said krill is Euphausia superba". However, Grantham et al. (Exhibit 1012) demonstrates that it was well known at the time of filing that Euphausia superba was a harvested species of krill:

> Commercial catches of krill would seem to consist predominantly of Euphausia superba. Grantham et al. (Exhibit 1012) pg 3 § 2.1.

As such, Claims 9 and 15 fail to provide additional patentable subject matter to overcome the obviousness of Claims 12 and 18, respectively.

20-21. Claims 10 And 16 Are Obvious Under Tuo et al. And Sampalis et al.

Claims 10 and 16 depend from Claims 1 and 12. The basis for obviousness for Claims 1 and 12 has been established above (incorporated here by reference). Claims 10 and 16 provide the limitation that "said capsule is a soft gel capsule". Tuo et al. and Sampalis et al. demonstrate that it was well known in the art at the time of filing that soft gel capsules can contain krill oil:

> Subjects were randomly assigned to take two gel capsules containing 1 g of krill oil or 1 g of fish oil (18% EPA and 12% DHA) daily at mealtime for a duration of 3 months.

Tuo et al. Exhibit 1017, pg 68 lhc, and

> Each patient was asked to take two 1-gram soft gels of either NKO or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial.

Sampalis et al., Exhibit 1018, pg 174 rhc. As such, Claims 8 and 16 fail to provide additional patentable subject matter to overcome the obviousness of Claims 12 and 18, respectively.

22-24. Claims 11 And 17 Are Obvious Under Sampalis I, Bunea et al., Sampalis II or Grantham et al.

Claims 11 and 17 depend from Claims 1 and 12. The basis for obviousness for Claims 1 and 12 has been established above (incorporated here by reference). Claims 11 and 17 introduce the limitation of "less than about 0.45% w/w arachidonic acid". Grantham et al. (Exhibit 1012) reported krill lipid extracts that contained arachidonic acid levels as low as 0.4% (pg 13, Table 7). Such a closeness in range is deemed obvious because the AU'345 application does not provide any data showing the criticality of the 0.45% threshold (*supra*).

Those of skill in the art were well aware at the time of filing of the AU'345 application that arachidonic acid is an inflammatory compound such that it is desirable to reduce its concentration as much as possible. For example, Sampalis et al. I (Exhibit 1018) and Bunea et al. disclose that it was desirable to reduce krill oil arachidonic acid (e.g., omega-6 fatty acids) levels due to their involvement in inflammation:

> Long-chain omega-6 fatty acids, such as arachidonic acid, predominating in the phospholipids of cell membranes can encourage the production of pro-inflammatory type-2 prostaglandins (PGE_2), while omega-3 fatty acids promote the production of anti-inflammatory prostaglandins.[19-20]

Sampalis et al. I, Exhibit 1018, pg 173 lhc, and

> Omega-6 fatty acids, mainly arachidonic acid, have been shown to initiate an inflammatory process by triggering a flux of inflammatory PGs and LTs [3,4].

Bunea et al., Exhibit 1011, pg 421 lhc. Consequently, one of skill in the art would be motivated to optimize a krill oil for health-related benefit to reduce the arachidonic acid level as much as possible.

> Sampalis et al. II (Exhibit 1019) reported very low to zero levels of arachidonic acid in the extract:
> Arachidonic acid content of the extract is generally very low to non-existent . . .

Sampalis et al. II (Exhibit 1019) pg 26 ln 21-22. As such, Claims 11 and 17 fail to provide additional patentable subject matter to overcome the obviousness of Claims 1 and 12, respectively.

CONCLUSION

Given the issues with the US claims summarised above, and given the submissions made herewith in view of the cited prior art, and given the admissions made on the face of the specification of AU '345, we submit that the claims are obvious and should not be allowed to proceed to acceptance

COMMENTS RESPONSIVE TO THE APPLICANTS LETTER DATED 5 MAY 2016

Background

In the first third party submission filed on 12 October 2015, the Opponent noted that Antarctica Select™ is an encapsulated krill oil comprising 1800 mg/kg astaxanthin and at least 3.3 % w/w ether phospholipids, a non-ether phospholipid content of at least 10%, a total phospholipid content of at least 13%. The triglyceride content of the Antarctica Select™ was analyzed by Nofima BioLab and found to be of 24% on w/w basis. The same information was referred to in the second set of third party observations filed on 22 December 2015. The submission was that certain claims lacked an inventive step in view of Catchpole and Antarctica select™ with support from the Nofima Biolab analysis.

Applicant's letter dated 5 May 2016

Under the heading "Further Material Filed Under Section 27" on page 2 of the Applicant's letter, the Applicant states that:

> "...the D7 Nofima analysis is inconsistent with the D6 Callaghan data. At the very least, the inconsistency in the data makes it unreliable and the D7 Nofima data actually supports patentability. In particular, the D6 Callaghan data allegedly demonstrates a total phospholipid content of Antarctica Select of either 9.5 g/100g or 12.9 g/100g (it is noted that Callaghan data itself is internally inconsistent). The D7 Nofima data allegedly demonstrates that the total polar lipid content (which would include all subspecies of phospholipids) of Antarctica Select is 4.7 g/100g.
>
> The data presented by the third party opponent is thus inconsistent and cannot be relied upon to establish the phospholipid content of Antarctica Select. Furthermore, as one of skill in the art would readily appreciate, it is highly unlikely that a sample with only 4.7 g/100g of total polar lipids would contain from 3% to 10% w/w (i.e., 3 to 10 g/100g) ether phospholipids as claimed, especially when the amount of lysophosphotidylcholine is allegedly 4.3 g/100g."

Opponent's response

In response, the Opponent points out to the Examiner that the method used by Nofima is different from the method used by Callaghan. Callaghan used NMR and is the state of the art for PL analysis as it gives a signal for all 31P containing molecules in the sample. In HPLC, as used by Nofima, a signal is only obtained for the PL species that actually elutes from the column. Hence, if a PL species is adsorbed on the column it is not eluted and detected and the results obtained will be lower. That is why it is standard in the art to use NMR to quantify phospholipids in krill oil. Triglyceride content is different as it is neutral and will not/to a lesser degree suffer from this issue.

In summary, the data presented previously is <u>not inconsistent</u> and <u>can be relied upon</u> to establish the phospholipid content of Antarctica Select.

Appendix A

Figure 3 of the AU'345 specificationpresents data showing plasma glucose levels in Zucker obese rats following omega-3 administration in "different forms". The legend of Figure 2 indicates that these "different forms" of omega-3 fatty acids are fish oil (FO), Neptune Krill Oil (NKO; PL1)) and Superba krill oil (PL2). However, Example 9 states that omega-3 supplementation was done by adding fish oil, NKO or Superba to "a diet." One of skill in the art would assume that this referenced "diet" is a standard laboratory rat chow (e.g., solid food pellets). It can only be interpreted that the "different forms" of omega-3 in Figure 3 are: "diet chow/fish oil", "diet chow/NKO" and "diet chow/Superba". Consequently, other components besides omega-3 fatty acids are present in the administered fish oil (FO), Neptune Krill Oil (NKO;PL1) or Superba krill oil (PL2) and could have an effect on the presented data.

The administration of omega-3 fatty acids was seen to increase plasma glucose levels in all oil groups as compared to the control, and the AU'345 specification fails to explain this. As 4 week old Zucker obese rats are known to be hyperinsulinemic (e.g., not hyperglycemic) these data suggest that these oils antagonize the biological effect of insulin, thereby raising blood glucose levels. Such an interpretation is supported within the AU'345 specification when referencing studies that fish oils antagonize insulin spikes subsequent to an oral glucose load. Further, this data contradicts the AU'345 specification contemplated embodiment that krill oil "reduces insulin resistance". Insulin resistance is well known to result in high plasma glucose levels.

The data in Figure 3 suggests that krill oil would be expected to exacerbate insulin resistance, not reduce insulin resistance. If krill oil reduced insulin resistance, the plasma glucose levels in Figure 3 would be expected to decrease, not increase. Even so, Figure 3 has no standard error bars, even though Example 9 suggests they should be present. Further, nothing in the AU'345 specification mentions any statistical significance of the data (e.g., p-values). As the data was collected using the Zucker obese diabetic rat model, these data cannot be extrapolated to humans in any predictive manner. Consequently, one cannot tell whether the differences between the means are meaningful.

Appendix B

In the 1990s, a Japanese group, motivated to use phospholipids as a memory improving agent, extracted phospholipids from krill:

> "The present invention relates to a method for separation extraction of phospholipids from krill, and in particular relates to a method of separating with high purity phosphatidyl ethanolamine and phosphatidyl choline which have important physiological activity in the body, and relates to technology where the separated phosphatidyl choline and phosphatidyl ethanolamine and the like can be used as a memory improving agent."

Japanese Patent 2909508 (Exhibit 1025) (see "Field of Industrial Application").[14] The Japanese group used solvent extraction to obtain purified phospholipids:

> "The first invention that is to be patented is a krill phospholipid fractioning method, comprising dehydrating raw krill using a vacuum freeze-drying method, extracting total lipids from the krill using ethanol, removing the ethanol from the total lipids, dissolving the total lipids in acetone, separating into a soluble fraction and an insoluble fraction, washing the insoluble fraction with more acetone to obtain crude phospholipids, and then separating the crude phospholipids into 90 to 95% phosphatidyl choline and phosphatidyl ethanolamine using adsorption column chromatography with ethanol as an eluate and silica gel as a filler."

Japanese Patent 2909508 (Exhibit 1025) (see "Means for Resolving Problems"). Their process yielded high concentrations of phospholipids and triglycerides from krill:

Table 1 Lipid Composition of Dried Krill

Lipid composition	weight %
Phosphatidyl choline	31.1
Phosphatidyl ethanolamine	7.5
Triglycerides	43.2
Free fatty acids	6.5
Others	5.7

Table 1(above) shows a good recovery of phospholipids, along with triglycerides and a small percentage of "free fatty acids."

[14] The Japanese application by Maruyama et al. was filed in 1989 and published in 1990; the patent issued in 1999.

Australian Government
IP Australia

ABN 38 113 072 755
P 1300 651 010
Int +61 2 6283 2999
www.ipaustralia.gov.au

18 July 2016

Pizzeys Patent and Trade Mark Attorneys Pty Ltd
PO Box 291
WODEN ACT 2606
Australia

RECEIVED
21 JUL 2016

Notification of Further Material Filed Under Section 27

Application Number: 2013227998

Applicant Name: Aker BioMarine Antarctic AS

Your Ref: 4074IAKE/TB

Further material has been filed under the provisions of Section 27(1) of the Patents Act 1990 in relation to the above patent application. This further material was received on 15 July 2016.

A copy of this further material has been enclosed for your information and will be considered by the examiner during examination of the application.

If you need any further information please contact 1300 65 1010. Alternatively, please visit us at www.ipaustralia.gov.au

Yours Faithfully

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The Commissioner of Patents
IP Australia
PO Box 200
Woden ACT 2606

15 July 2016

Our Ref: 89655AUM00

Contact:
Michael Zammit, PhD

Dear Commissioner

Third Party Observation against AU 2013227998

VERY URGENT: THIRD PARTY SUBMISSION IN

RELATION TO THE APPLICANT'S RESPONSE DATED 13 JULY 2016

We refer to the above matter.

In brief overview,

- AU 2013227998 (the **AU '998 application**) is one of the divisional standard applications from AU 2011213836, which again is a divisional from AU 2008231570 (national phase entry from WO 2008/117062 titled Bioeffective krill oil compositions);
- a first Examination Report issued on 17 July 2015;
- a first set of third party observations were filed on 10 October 2015;
- the Applicant filed voluntary amendments and a response to the first Examination Report on 16 June 2016;
- a second set of third party observations were filed on 16 June 2016;
- a second Examination Report issued on 8 July 2015; and
- the Applicant filed voluntary amendments and a response to the second Examination Report on 13 July 2016 (the **Applicant's 13 July response**).

The Opponent considers that the claims as proposed to be amended in the Applicant's 13 July response lack an inventive step in view of the prior art, and asks the Examiner to refuse the AU '998 application.

The Opponent provides the following comments (the third set of third-party observations) which explain why the Applicant's comments are incorrect, why the amended claims are invalid in view of the prior art, and why the application should not proceed to acceptance.

This (third) third-party submission should be read in conjunction with, and in light of, the Opponent's first and second set of third party observations.

COMMENTS IN RESPONSE TO THE APPLICANT'S RESPONSE ON 13 JULY 2016

Test for inventive step

The test for whether an invention is obvious (non-inventive) is to ask if it would have been a matter of routine to proceed to the claimed invention. In *Wellcome Foundation Ltd v V.R. Laboratories (Aust) Pty Ltd* [1981] HCA 12 at [45]; 148 CLR 262 (**Wellcome**) at 286, it was stated:

> *"The test is whether the hypothetical addressee faced with the same problem would have taken as matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not."*

The High Court in *Aktiebolaget Hassle v Alphapharm Pty Ltd* [2002] HCA 59; 212 CLR 411 (**Alphapharm**) at 433 stated that it is also permissible to use the reformulated "Cripps question":

> *"Would the notional research group at the relevant date, in all the circumstances, which include a knowledge of all the relevant prior art and the facts, directly be led as a matter of course to try the invention as claimed in the expectation that it might well produce a solution to the problem."*

However, it has since been accepted that the Cripps question is not of universal application. As stated in *Generic Health Pty Ltd v Bayer Pharma Aktiengsellschaft* [2014] FCAFC 73 at [71]:

> *"We do not think that the plurality in Alphapharm were saying that the reformulated Cripps question was the test to be applied in every case. Rather, it is a reformulation of the test which will be of assistance in cases, particularly those of a similar nature to Alphapharm."* (emphasis added)

It is clear from the authorities that any potential solution to a problem will be obvious if it would have been a matter of routine to try that solution (Wellcome).

During examination, Examiners must apply the balance of probabilities test in weighing up factual matters that form the basis for an objection (Examiner's manual at 2.13.5.2A Balance of Probabilities). Factual matters are most relevant in the context of novelty and inventive step, i.e. what a document would disclose to a skilled person, or what would be a matter of routine for the skilled addressee, should be determined on the balance of probabilities.

The amended claims

The Applicant has made 2 substantive amendments to the claims:

a.) cancelling the term "about" with reference to the defined concentration of phosphatidylcholine (**PC**); and

b.) amending claims 1 to 5 to define "A ~~polar~~ *Euphausia superba* krill oil..."

We submit that these amendments do nothing to cure the invalidity issues, as discussed below.

The Applicant's 13 July response – phosphatidylcholine concentration

The Applicant states that the amended claims are novel in view of D4 and D5 as these documents fail to disclose compositions containing greater than 40% or 45% PC. The Applicant then states that:

> "...there is nothing in the art that suggests any way in which the non-inventive artisan could or would arrive at higher levels of phosphatidylcholine in any krill oil extraction."

The Opponent disagrees.

D4 relates to a process for separating a feed material into soluble and insoluble components, comprising providing a solvent comprising: (i) supercritical or near-critical CO2, and (ii) a co-solvent comprising one or more C1-C3 monohydric alcohols, and water, wherein the co-solvent makes up at least 10% by mass of the CO2, and the water content of the co-solvent is 0 to 40 % by mass. The feed material is contacted with the solvent the solvent is subsequently removed. The soluble components and the solvent are subsequently separated.

Whilst the PC concentration in the extract in Example 18 is slightly below the concentration defined in the amended claims, the disclosure of D4 clearly teaches that the co-solvent can be varied. The skilled person would understand that the co-solvent (alcohol) is polar, and that phospholipids are polar, and that providing more or less of a polar co-solvent in the CO2 solvent will affect the total amount of phospholipids extracted. On the balance of probabilities, it would be a matter of routine to vary the concentration of co-solvent to affect the amount of PC extracted. The Applicant has adduced no evidence or documentation which unequivocally shows this not to be the case. The Applicant merely relies on an unfounded assertion.

We invite the Examiner to review page 2, lines 27 to 31 of D4:

> "It is known that the use of CO2 with organic co-solvents such as ethanol allows extraction of some phosphatidyl choline and to a much lesser extent phosphatidyl ethanolamine. For example, Teberikler et al [4] describe a process for extraction of PC from a soybean lecithin. Using 10% ethanol in CO2 at 60°C they found that PC was easily extracted, while PE and PI were extracted to a very low extent. Extraction at 12.5% ethanol at 80°C gave a four-fold increase in solubility of PC."

Whilst this example relates to a starting material which is different to krill, the same principle will still apply to krill. There is no reason to suspect otherwise, and there is certainly no evidence from the Applicant to the contrary.

In summary, we submit that D4 directly leads the skilled person to vary the (polar) co-solvent concentration, which will necessarily and inevitably affect the amount of polar compounds extracted from the feed material. It is a matter of routine to proceed from D4 to the claimed invention (higher levels of extracted phosphatidylcholine) with an expectation of success.

Cancelling the term "about" has not cured the inventive step issues in the claims.

The Applicant's 13 July response – astaxanthin concentration and *Euphausia superba*

The Applicant asserts that D4 and D5 fail to disclose the required astaxanthin levels, and goes further to state that "...the assertions of the report as to astaxanthin levels in the art are factually incorrect." Three reasons are provided, which are discussed below.

First reason

The Applicant asserts that:

> "...Example 18 of D4 discloses that an extract is made from a freeze-dried krill powder. There is no mention as to what species of krill is in the freeze dried krill powder or how it was made (i.e., from fresh krill, aged krill, frozen krill, etc.). As one of skill in the art knows, there are over 70 species of krill, each of which have different phospholipid and astaxanthin contents. Claim 1 has been amended to refer specifically to *Euphausia superba*. D4 is silent as to the krill species."

The skilled person would know that all species of krill include astaxanthin to some extent. On the balance of probabilities, the krill powder in D4 would also have included astaxanthin to some extent.

There is no disclosure in D4 to the contrary, and no discussion in D4 of somehow removing the astaxanthin before freeze drying or extraction.

The Applicant seeks to create the impression that *Euphausia superba* is somehow special or different to other species of krill. This is simply not the case. There is no teaching in the AU '998 application that *Euphausia superba* will give a different result to the other species.

The Background section of AU '998 makes it clear at page 1, lines 20 to 21, that prior art solvent extraction methods to produce krill oil also produces astaxanthin esters in the extract. For example, prior art solvent extraction method WO 00/23546 produced at least 75 or 90 mg/kg astaxanthin esters along with the extracted krill oil. Another prior art method to produce krill oil extract (see page 1, line 31, to page 2, line 4, of the AU „"998 application) also yielded astaxanthin in the extract. It is an inevitable consequence of extraction of krill oil that some astxanthin will also be extracted.

The Applicant's comments in its "first reason" are irrelevant.

Second reason

The Applicant asserts that the astaxanthin content can be altered during krill processing, and suggests that freshly caught krill is preferred.

The prior art is replete with disclosures noting that krill can decompose over time after being caught, which is why it is common in the art to utilise the krill soon after it is caught. The other main options are to freeze the krill quickly after being caught (to -80°C), or to freeze dry it to remove all the moisture. These 2 processes preserve the krill meal for extended periods of time.

Contrary to the Applicant's submission, it is very unlikely that "the starting material of D4 or D5 would contain only degraded, oxidized free astaxanthin as opposed to astaxanthin esters." As the Examiner would understand, freezing a biomass, or freeze-drying it, preserves it for extended periods of time. The paragraph bridging pages 12 and 13 of the specification even describes that the lipids in krill are surprisingly stable against oxidative deterioration, and that "freeze drying has been regarded as the method of choice to avoid oxidative breakdown of lipids." The structural similarity of astaxanthin and the lipids in krill mean, on the balance of probabilities, the freeze-dried krill in D4 would not contain "degraded, oxidized free astaxanthin as opposed to astaxanthin esters", as asserted by the Applicant.

The Applicant seeks to create the impression that use of a freeze-dried krill in D4 would contain degraded astaxanthin. This is not the case. The Applicant has adduced no evidence to support is assertion.

The Applicant's comments in its "second reason" are irrelevant.

Third reason

The Applicant asserts that:

- Extract 1 of D4 contained no phospholipids, and was substantially all neutral lipids; and that
- Extract 2 of D4 contained phospholipids.

The Applicant then submits that astaxanthin esters would have been present in Extract 1 but not Extract 2. Further, the Applicant asserts:

> "The instant specification, in contrast, teaches that a neutral asta oil can be used to create a blended produce with the desired composition. D4 fails to teach this, and indeed fails to provide a compositional analysis for Extract 1 or indicate that it is in any way useful."

In other words, the Applicant effectively concedes that the AU '998 application repeats the method outlined in D4, and then attempts to argue that blending a "neutral asta oil" with an extract high in phospholipids is inventive. However, combining extracts is known in the art, and one need only look to the very next example in D4 (see page 24-25) where extract 2 and 3 were combined.

In formulating a desired krill oil, it is a matter of routine to blend to different extracts to obtain an oil with the desired combination of components. It would have been obvious to try and blend different extracts with an expectation of success.

The Applicant's comments in its "third reason" are irrelevant.

Moreover, in relation to the Applicant's assertion that all the astaxanthin will be removed by the first (neutral) extraction (Extract 1), this is simply factually incorrect. We invite the Examiner to review Example 5 (page 40) of the AU '998 application:

> "The asta oil obtained in Example 1 was blended with the polar lipids obtained in example 4 in a ratio of 46:54".

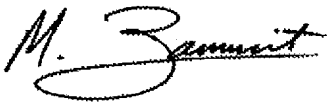
The 'asta oil' from Example 1 contains 1245 mg/kg[1]. However, the final blended product obtained in Example 5 contains 1302 mg/kg astaxanthin esters[2]. This shows that the polar phase contains a substantial amunt of astaxanthin, otherwise the level of astaxanthin in the blended product would have been only about half.

Given these facts, it would seem that the onus is now on the Applicant to demonstrate, with evidence, that the krill oil composition of D4 would not inevitable contain astaxanthin esters.

CLOSING COMMENTS

Given the submissions made herewith in view of the cited prior art, and given the admissions made on the face of the specification of AU '998, and given the submissions in the previous third party observations, we submit that on the balance of probabilities the claims are obvious and should not be allowed to proceed to acceptance.

Yours respectfully
Shelston IP



Michael Zammit, PhD
Registered Patent Attorney
Email: *MichaelZammit@ShelstonIP.com*

[1] Table 4, page 25 of the AU '998 application
[2] Table 20C, page 41 of the AU '998 application

Australian Government
IP Australia

ABN 38 113 072 755
P 1300 651 010
Int +61 2 6283 2999
www.ipaustralia.gov.au

28 September 2016

Pizzeys Patent and Trade Mark Attorneys Pty Ltd
PO Box 291
WODEN ACT 2606
Australia

Notification of Further Material Filed Under Section 27

Application Number: 2013227998

Applicant Name: Aker BioMarine Antarctic AS

Your Ref: 40741AKE ITB

Further material has been filed under the provisions of Section 27(1) of the Patents Act 1990 in relation to the above patent application. This further material was received on 22 September 2016.

A copy of this further material has been enclosed for your information and will be considered by the examiner during examination of the application.

If you need any further information please contact 1300 65 1010. Alternatively, please visit us at www.ipaustralia.gov.au

Yours Faithfully

Patents and Plant Breeder's Rights Administration

Shelston IP

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The Commissioner of Patents
IP Australia
PO Box 200
Woden ACT 2606

22 September 2016

Our Ref: 89655AUM00

Contact:
Michael Zammit, PhD

Dear Commissioner

Third Party Observation against AU 2013227998

Urgent

We refer to the above matter.

In brief overview,

- AU 2013227998 (the **AU '998 application**) is one of the divisional standard applications from AU 2011213836, which again is a divisional from AU 2008231570 (national phase entry from WO 2008/117062 titled Bioeffective krill oil compositions);
- a first Examination Report issued on 17 July 2015;
- a first set of third party observations were filed on 10 October 2015;
- the Applicant filed voluntary amendments and a response to the first Examination Report on 16 June 2016;
- a second set of third party observations were filed on 16 June 2016;
- a second Examination Report issued on 8 July 2015;
- the Applicant filed voluntary amendments and a response to the second Examination Report on 13 July 2016 (the **13 July response**);
- a third set of third party observations were filed on 15 July 2016;
- a third Examination Report issued on 18 July 2016; and
- the Applicant filed a response to the third Examination Report on 15 September 2016 (the **Applicant's response**) in which no voluntary amendments were filed.

Sydney
Level 21,
60 Margaret Street
Sydney NSW 2000
Australia
T +61 2 9777 1111

Brisbane
7 Clunies Ross Court
Brisbane Technology Park
Eight Mile Plains, QLD 4113
Australia
T +61 7 3147 8020

Newcastle
Level 1, IDC House
University Drive
Callaghan, NSW 2308
Australia
T +61 2 4921 7366

Auckland
BDO Tower, Level 22
123 Albert Street
Auckland 1010
New Zealand
T +64 9 638 5300

Shelston IP Pty Ltd ABN 23 608 104 070 email@ShelstonIP.com www.ShelstonIP

The claims which are pending are those filed by the Applicant in its 13 July response.

The Opponent considers that the pending claims lack an inventive step in view of the prior art, and asks the Examiner to refuse the AU '998 application.

The Opponent provides the following comments (the fourth set of third-party observations) which explain why the Applicant's comments in its response dated 15 September 2016 are incorrect, why the claims are invalid in view of the prior art, and why the application should not proceed to acceptance.

This (fourth) third-party submission should be read in conjunction with, and in light of, the Opponent's first, second, and third set of third party observations.

SUMMARY OF THIRD EXAMINATION REPORT

In brief overview, the third Examination Report noted the following matters which led the Examiner to conclude that the pending claims lack an inventive step in view of D4.

A *Euphausia superba* krill oil extract

With regards to providing a *Euphausia superba* krill oil extract, as opposed to any krill oil extract, the selection of *Euphausia superba* is one of several obvious known alternatives to a skilled person (as evidenced by the Applicant's own AU'998 patent specification). There is no evidence of a surprising result or advantage to be gained from specifically extracting oil from *Euphausia superba*.

Greater than 40% phosphatidylcholine

With regards to providing greater than 40% phosphatidylcholine (**PC**), it is known from D4, and is a matter of routine, that varying the ethanol and CO2 content while extracting phospholipids can alter the PC level which is extracted. There is no evidence of a surprising result or advantage to be gained from providing an extract with 0.2% more PC than the extract of D4 (which comprises 39.8% PC). Further, the PSA would be led to modify the method of extracting krill oil phospholipids from D4 and arrive at an extract with at least greater than 40% PC.

Astaxanthin ester content

With regards to astaxanthin ester content:

- given the structural similarity of astaxanthin and lipids in krill meal, the freeze dried krill meal of D4 would not only contain degraded, oxidized free astaxanthin as opposed to astaxanthin esters (see also D2);
- the phospholipid extract of D4 would likely contain astaxanthin esters because the primary extraction of neutral lipids would not remove all the astaxathin esters from the krill meal (see D4 and the Applicant's own AU'998 patent specification).

Conclusion

The only difference between D4 and the present application is that the krill oil is:

- specifically extracted from *Euphausia superba*, and
- that it has greater than 40% PC.

In the absence of any evidence of a surprising result or advantage to be gained, both of these differences are features that any skilled worker in the art would optimize either as a matter of design

choice (with respect to the krill species) or using conventional manufacturing methods (with respect to the PC content) and therefore cannot contribute to providing an inventive step.

COMMENTS IN RESPONSE TO THE APPLICANT'S RESPONSE ON 15 SEPTEMBER 2016

At pages 1 and 2 of the Applicant's response, the Applicant points out to the Examiner that in "*...the case of a combination patent the invention will lie in the selection of integers, a process which will necessarily involve rejection of other possible integers...*", and emphasises that "*It is the selection of integers out of, perhaps many possibilities, which must be shown to be obvious.*"

This is a *de facto* admission by the Applicant that there is no interaction of the various integers of claim 1, and it is a mere combination of known features which are readily available by prior art processes.

In making this submission, the Applicant appears to be indicating that, in view of D4, the invention lies in the selection of:

i. providing a *Euphausia superba* krill oil extract, as opposed to any krill oil extract; and

ii. providing a minimum of 0.2% more PC than D4 (i.e. greater than 40% PC).

This must be so, given that:

iii. there is no dispute that D4 teaches an ether phospholipid concentration within the claimed range; and

iv. the phospholipid extract of D4 is likely to contain astaxanthin esters within the claimed range (see third Examination report).

The Applicant goes on to submit that "...the [third Examination Report] ... incorrectly focus upon each individual integer in isolation rather than the combination of integers claimed." This is an obvious attempt by the Applicant to muddy what are otherwise clear waters.

We reiterate that in one single prior art document, namely D4, all the features of claim 1 are disclosed, with the caveat of items i.) and ii.) above. However,

a.) there is no evidence of a surprising result or advantage to be gained from extracting oil specifically selected from *Euphausia superba*, and rejecting the other species of krill; and

b.) there is no evidence of a surprising result or advantage to be gained from providing an extract with greater than 40% PC, and rejecting an extract having a mere 0.2% less PC (as disclosed in D4).

In relation to item a.), we invite the Examiner to note that D4 does not explicitly state that the krill powder which was extracted was not *Euphausia superba*. Indeed it is more likely that the krill powder in D4 was *Euphausia superba*, given that inventors of D4 were working in New Zealand and the krill used in the experiments was likely to have been sourced locally from Antarctica. It is well known that *Euphausia superba* krill are the most common krill, and are found mostly in the waters of the Antarctic. Accordingly, on the balance of probabilities, it is most likely inherent that D4 extracted *Euphausia superba* krill.

Further, we again reiterate that the Applicant seeks to create the impression that *Euphausia superba* is somehow special or different to other species of krill. This is simply not the case. There is no teaching in the AU '998 application that *Euphausia superba* will give a different result to the other species. It is a matter of routine to extract oil from *Euphausia superba*.

In relation to item b.), it is a matter of routine to modify such well known methods of extracting krill oil phospholipids (such as disclosed in D4) and arrive at an extract with at least greater than 40% PC.

Given these matters, it appears that the only remaining issue relates to the astaxanthin ester content of D4, and which is the focus of much of the Applicant's submission. We comment on this issue below.

Discussion of astaxanthin in krill

We invite the Examiner to review the Applicant's GRAS Notice (GRN) No. 371 (**Annexure A**).

On page 22, the authors note the following:

> **2.5. Astaxanthin**
>
> In addition to lipids, one of the minor components of biological importance of the oil is astaxanthin. In Krill, either one or both of the alcoholic hydroxyl functional groups of astaxanthin may be esterified to fatty acids. Thus astaxanthin from krill are found almost exclusively in esterified form. Takaichi *et al.* (2003) determined that only five kinds of fatty acids, dodecanoate, tetradecanoate, hexadecanoate, hexadecenoate, and octadecenoate were esterified to astaxanthin in krill. Assuming one C16 fatty acids in each position gives a molecular weight of the esterified molecule of 1110 or approximately twice as much as astaxanthin alone. Hence to specify the astaxanthin content of krill oil, one can consider the molar concentration or the amount of astaxanthin diol. Because of the general unfamiliarity with molar concentrations, Aker Biomarine declares its product on the basis of astaxanthin diol. Thus the levels presented in Table 1 for astaxanthin of 100 ppm means the product contains 100 μg/g of the diols, regardless of fatty acids that may be esterified.

Therefore, from the Applicant's own information, it is clear that astaxanthin from krill are found almost exclusively in the esterified form. We also note that the Applicant adopts a convention of referring to 'astaxanthin' which means the diol form of astaxanthin. In other words, the term 'astaxanthin' conveys a meaning which is not the free form, but rather a shorthand for the esterified form.

Turning now to the AU '998 application, Table 16 on page 37 provides data on various polar krill oil extracts. For example, 'Neptune KO' is commercially available Neptune brand krill oil (**NKO**) having 30% phospholipids (see Table 22 on page 44). This table confirms that, at most, the free astaxnthin content is 2% compared to the total of the free and esterified forms (11 mg/kg / 472 mg/kg), and in each case astaxanthin is present in predominantly the esterified form. Importantly, this table shows that it is a matter of routine to produce a krill oil composition (NKO) having above 100 mg/kg astaxanthin esters.

Table 16. Compositional data for the novel krill oil composition obtained and NKO krill oil.

Compounds	Neptune KO	Ethanol extracted KO	Polar KO	Neutral KO
Astaxanthin esters	472 mg/kg	117 mg/kg	580 mg/kg	98 mg/kg
Astaxanthin free	11 mg/kg	< 1 mg/kg	<1 mg/kg	<1 mg/kg
Total cholesterol	1 g/100g	12 g/100g	< 0,5 g/100g	5,7 g/100g

We do note that other examples in the AU '998 specification distinguish astaxanthin and astaxanthin esters (see Tables 17C and 19C and 20C). Further, we note that on page 11 of the AU '998 application, the Applicant provides a definition of the term 'astaxanthin esters' which refers to the "...fatty acids esterified to OH group in the astaxanthin molecule.'

Unfortunately, however, the Applicant has not been consistent in its use of terminology in the AU '998 application, and it seems that the word 'astaxanthin' has been used in some places as a shorthand for

'astaxanthin esters'. For example, lines 8 to 10 on page 3 of the AU '998 application (see below) refers to compositions having 3 to 10% ether phospholipids (just as per pending claim 1) and 'from about 400 to 2500 mg/kg astaxanthin'. We submit that the skilled person would understand this reference to mean 'astaxanthin esters'. This must be the case as free astaxanthin is present in only small quantities compared to the esterified forms (see discussion above). This would be obvious for the skilled person to immediately comprehend and understand.

> In some embodiments, the present invention provides compositions comprising: from about 3% to 10% ether phospholipids on a w/w basis; from about 35% to 50% non-ether phospholipids on w/w basis, so that the total amount of ether phospholipids and non-ether phospholipids in the composition is from about 48% to 60% on a w/w basis; from about 20% to 45% triglycerides on a w/w basis; and from about 400 to about 2500 mg/kg astaxanthin. In some embodiments, the ether phospholipids are selected from the group consisting of alkylacylphosphatidylcholine, lyso-alkylacylphosphatidylcholine, alkylacylphosphatidylethanolamine, and combinations thereof. In some embodiments, the

Another example can be found at page 12 lines 9 to 12 (see extract below). The paragraph indicates that the invention relates to 'high levels of astaxanthin', not astaxanthin esters as per the claims. We submit that it is clear to the skilled person that the specification has used 'astaxanthin' as an abbreviation of 'astaxanthin esters'.

> **DETAILED DESCRIPTION OF THE INVENTION**
>
> This invention discloses novel krill oil compositions characterized by containing high levels of astaxanthin, phospholipids, included an enriched quantities of ether phospholipids, and omega-3 fatty acids. The krill oils compositions are extracted from krill meal using supercritical fluid extraction (SFE) with a co-solvent modifier. The krill meal has been processed on board a ship in Antarctica using live krill as starting material in order to ensure

We also refer to Example 7 on pages 42 to 43 of the AU '998 application where a 23% ethanol extraction was undertaken at 300 bar pressure, 333°K and maintained for 3 hours and 40 minutes. The total phospholipid content was 50.55 wt% and 'astaxanthin' was measured at 2091 mg/kg (Table 21). Given that free astaxanthin is only present at very low concentrations compared to the esterified forms, the skilled person would understand that it was astaxanthin esters which were measured at 2091 mg/kg, and not the free form.

The terms 'astaxanthin' and 'astaxanthin esters' are sometimes used interchangeably in the AU '998 application. The analysis method used is HPLC to separate 3 peaks; free astaxanthin, astaxanthin monoester and astaxanthin diester. Only astaxanthin is used as a standard. Therefore, the results are indicated as astaxanthin, although it is actually astaxanthin esters.

In summary,

- astaxanthin from krill are found almost exclusively in the esterified form (see Table 16);
- Table 16 shows that it is a matter of routine to produce a krill oil composition having above 100 mg/kg astaxanthin esters; and
- the AU '998 application has used the term 'astaxanthin' as an abbreviation of 'astaxanthin esters' in several places.

The Applicant's response

On page 2 of the Applicant's response, the Applicant seizes on Table 4, p.25 of the AU '998 application which refers to the asta oil containing 1245 mg/kg 'astaxanthin'. For the reasons discussed above, we submit that the skilled person would understand the reference to 'astaxanthin' to mean 'astaxanthin esters'.

The Applicant then provides 2 prior art documents which describe different methods to measure free astaxanthin and astaxanthin esters, and then asserts that the specification deliberately reports one or the other "...depending on what analytical technique was used". However, the specification is silent in this regard, and what is more likely is that the AU '998 application has used the term 'astaxanthin' as an abbreviation of 'astaxanthin esters'.

At page 4 of the Applicant's response, the Applicant tabulates the specific steps in Example 17 of D4 and compares the steps to Examples 4 and 7 of the AU '998 application. The Applicant then makes the following statement at page 5 of its response.

> The table above reveals a key difference between Example 18 of D4 and Example 7 of the instant specification. In Example 18 of D4, the first extraction step used neat CO_2 and extraction was continued until no further extract was obtained. This is in contrast to Example 7 of the instant specification, where the first extraction step utilized 5% ethanol as a polar co-solvent. Thus, the results obtained in Example 7 of the instant application cannot be used to speculate as to the astaxanthin content the extract in Example 18 of D4 because the methods are substantially different. The argument is clearly mistaken in attempting to make this comparison – the phospholipid fraction rich fraction of D4 was quite simply ***not*** prepared in a similar manner to the phospholipid extract of Example 7.

In essence, the Applicant asserts that using neat CO2 will produce a "substantially different" outcome to an extraction utilising 5% ethanol as a co-solvent. This is incorrect. The Applicant's own specification at page 12, lines 14 to 18 (see below), clearly describes that there is no difference in extracting using neat supercritical CO2 or in combination with a low amount of ethanol such as 5%, and either will extract the neutral faction.

DETAILED DESCRIPTION OF THE INVENTION

This invention discloses novel krill oil compositions characterized by containing high levels of astaxanthin, phospholipids, included an enriched quantities of ether phospholipids, and omega-3 fatty acids. The krill oils compositions are extracted from krill meal using supercritical fluid extraction (SFE) with a co-solvent modifier. The krill meal has been processed on board a ship in Antarctica using live krill as starting material in order to ensure the highest possible quality of the krill meal. The krill oils are extracted from the krill meal in two stages, in step 1 the neutral fraction is extracted using neat supercritical CO_2 or in combination with 5% ethanol. The neutral fraction consisted mostly of triglycerides and cholesterol. In stage 2, the polar lipids (phospholipids) are extracted by adding at least 20%

At page 4 of the Applicant's response, the Applicant then goes further and compares Example 4 of the AU '998 application with Example 18 of D4 as per the following:

18A-C. Importantly, the analysed extract contained very little or no neutral lipids, with the content of triacylglycerols and cholesterol being reported as less than 0.5 g/100 g. The astaxanthin ester content is not reported for the polar lipid extract for the probable reason that there was no astaxanthin in the samples. Nevertheless, it is apparent that if the neutral lipid content of the extract is less than 0.5g/100g, then there would be little or no astaxanthin esters present as they are neutral lipids and would have been extracted with the neutral lipids in the first step.

In essence, the Applicant attempts to show that an example within its own specification using CO2 with 20% ethanol "probably" contains no astaxanthin esters, and attempts to drawn an analogy to the Example 18 of D4 to assert that it, too, "probably" had no astaxanthin esters.

Firstly, this is mere speculation. Secondly, and more importantly, the point the Applicant attempts to make is irrelevant, as the proper question to be answered is whether it would be obvious or a matter of routine to prepare a krill oil composition comprising > 100 mg/kg astaxanthin esters. Putting aside the comments above that the phospholipid extract of D4 would likely contain astaxanthin esters because the primary extraction of neutral lipids would not remove all the astaxathin esters from the krill meal, there can be no question that it was common and routine in the art to blend oils to achieve a predetermined concentration of certain components. As discussed in the previous third party submissions, krill oil includes astaxanthin esters, which are known for their antioxidant properties. The skilled person knows this to be the case and that it was a desirable objective in the art to manufacture oils rich in omega-3 and astaxanthin esters.

Thirdly, this is simply incorrect. We reiterate our comments in the previous third party submission in relation to Example 5 (page 40) of the AU "998 application: "The asta oil obtained in Example 1 was blended with the polar lipids obtained in example 4 in a ratio of 46:54". The 'asta oil' from Example 1 contains 1245 mg/kg. However, the final blended product obtained in Example 5 contains 1302 mg/kg astaxanthin esters. This shows that the polar phase contains a substantial amount of astaxanthin esters, otherwise the level of astaxanthin esters in the blended product would have been only about half.

Turning back to page 2 of the Applicant's response, the Applicant asserts that:

> "...the Extract 2 identified in Example 17 of D4 would **not** contain 100 mg/kg astaxanthin esters in combination with the listed integers required by claim 1. ... the report's conclusion that 100 mg/kg

astaxanthin esters are inevitably present in the extracts of D4 is based on errors of analysis." (emphasis in the original)

With all due respect to the Applicant, this submission misses the point. The question is not one of novelty (and of whether the D4 extract inevitably comprises astaxanthin esters within the claimed range – although we maintain that this is the case), it is of inventive step, and whether it is a matter of routine to provide a krill oil extract with the features in claim 1.

We reiterate that, as admitted by the Applicant, claim 1 defines a combination, and the various integers of claim 1 can therefore result from a blend of oils. As the Opponent has already established, it is a matter of routine to blend oils. The proper question is therefore whether it was a matter of routine to produce a krill oil (whether directly or via a blend) which has astaxanthin esters within the claimed range, and the other features of claim 1.

In summary, we have shown that:

1. Example 18 of D4 is likely to have been extracted from *Euphausia superba*, but even if it was not the actual species used there is no inventive step in selecting *Euphausia superba* from another known and obvious alternative.

2. Example 18 of D4 is likely to contain > 100 mg/kg astaxanthin esters, but even if the actual amount extracted was lower than the claimed amount, the proper question is whether it would be obvious to produce an oil with > 100 mg/kg astaxanthin esters. The existence of commercially available krill oils having > 100 mg/kg astaxanthin esters (e.g. NKO at 472 mg/kg) is evidence that this was a known and desired outcome in the art.

3. There is no inventive step in producing a krill oil extract with 0.2% more PC than Example 18 of D4. D4 directly leads the skilled person to modify the method of extracting to arrive at an extract with greater than 40% PC.

We submit that the Applicant's submission has done nothing to shift the balance of probabilities into its favour, and that the claims clearly lack and inventive step in view of at least D4 and the common general knowledge in the art.

CLOSING COMMENTS

Given the submissions made herewith in view of the cited prior art, and given the admissions made on the face of the specification of AU '998, and given the submissions in the previous third party observations, we submit that on the balance of probabilities the claims are obvious and should not be allowed to proceed to acceptance.

Yours respectfully
Shelston IP

Michael Zammit, PhD
Registered Patent Attorney

Email: *MichaelZammit@ShelstonIP.com*

Annexure A: GRAS Notice (GRN) No. 371 available from http://www.fda.gov

GR 

ORIGINAL SUBMISSION

000001

Soni & Associates Inc.

749 46th Square
Vero Beach, FL 32968, USA
Telephone: 772-299-0746
Facsimile: 772-299-5381
E-mail: sonim@bellsouth.net

December 14, 2010

Office of Food Additive Safety (HFS-255)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Subject: Notification of GRAS Determination for Krill Oil

Dear Sir/Madam:

In accordance with proposed 21 CFR 170.36 (Notice of a claim for exemption based on a GRAS determination) published in Federal Register (62 FR 18938-18964; April 17, 1997), I am submitting in triplicate, as the agent of the notifier, Aker Biomarine Antarctic AS, Norway, a Generally Recognized As Safe (GRAS) notification for Superba® Krill Oil.

Superba™ Krill Oil extracted from Antarctic krill, *Euphausia superba* is intended for use as a food ingredient in non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk whole and skim; processed fruit and fruit juices; and medical foods, at use levels ranging from 0.05 to 0.50 g per serving (reference amounts customarily consumed, 21 CFR 101.12). The intended use of Superba® Krill Oil is estimated to result in a maximum daily intake of 8.28 g/person.

If you have any questions or require additional information, please feel free to contact me by phone at 772-299-0746 or by email at sonim@bellsouth.net.

Sincerely,

(b) (6)

Madhu G. Soni, Ph.D.

Enclosures:

Soni & Associates Inc.

749 46th Square
Vero Beach, FL 32968, USA
Telephone: 772-299-0746
Facsimile: 772-299-5381
E-mail: sonim@bellsouth.net

GRAS NOTIFICATION

I. Claim of GRAS Status

A. Claim of Exemption from the Requirement for Premarket Approval Requirements Pursuant to Proposed 21 CFR § 170.36(c)(1)

Aker Biomarine Antarctic AS, Norway, has determined that high phospholipid krill oil is Generally Recognized As Safe, and therefore, exempt from the requirement of premarket approval, under the conditions of its intended use. This determination is based on scientific procedures as described in the following sections, under the conditions of krill oil's intended use in food, among experts qualified by scientific training and expertise.

Sig (b) (6)

Date 12/14/10

Madhu G. Soni, Ph.D., FACN

Agent for:

Aker Biomarine Antarctic AS
Fjordalléen 16, 0115 Oslo
Norway

B. Name and Address of Notifier:

Hogne Vik, M.D., Ph.D.
EVP Documentation
Aker Biomarine Antarctic AS
Fjordalléen 16, 0115 Oslo
Norway

Tel: +47 24 13 00 00
Fax: +47 24 13 01 10
Email: hogne.vik@akerbiomarine.com

C. Common or usual name of the notified substance:

The common name of the substance of this notification is high phospholipid krill oil. The specific substance of this GRAS determination is Superba™ Krill Oil extracted from Antarctic krill, *Euphausia superba*. Superba™ Krill Oil is rich in omega-3 fatty acids, most of which are attached to phospholipids. Superba™ Krill Oil also contains astaxanthin ester.

D. Conditions of use:

High phospholipid krill oil is intended for use as a substitute or alternative to fish oils in the following food categories: non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk whole and skim; processed fruit and fruit juices; and medical foods[1], at use levels ranging from 0.05 to 0.50 g per serving (reference amounts customarily consumed, 21 CFR 101.12). The intended use of Superba™ Krill Oil, in the above mentioned food categories, is estimated to result in a maximum daily intake of 8.28 g/person. The proposed use of Superba™ Krill Oil will provide a maximum daily consumption of up to 2.20 g/person/day of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

E. Basis for GRAS Determination:

In accordance with 21 CFR 170.30, high phospholipid krill oil has been determined to be Generally Recognized As Safe (GRAS) based on scientific procedures. A comprehensive search of the scientific literature was also utilized for this determination. There exists sufficient qualitative and quantitative scientific evidence, including human and animal data to determine safety-in-use for Superba™ Krill Oil. Recently, high phospholipid krill oil (GRN 000242) has been the subject of a GRAS notification, while two of its important component fatty acids, EPA and DHA as part of fish or algal oil, have been the subject of multiple GRAS notifications. In response to these notices, FDA did not question the conclusions that the use of high phospholipid krill oil or sources of fatty acids (EPA and DHA) is GRAS under the conditions described in the notices. The safety

[1] Under Section 5(b) of the Orphan Drug Act (ODA), a Medical Food is defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and that is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. The intended use of krill oil in medical foods will be as per these and other applicable regulations.

determination of high phospholipid krill oil is based on the totality of available scientific evidence that includes human observations and a variety of preclinical and clinical studies. Based on the available safety-related information, the estimated daily intake, if ingested daily over a lifetime, is safe.

F. Availability of Information:

The data and information that forms the basis for this GRAS determination will be provided to the Food and Drug Administration upon request and are located at the offices of:

Madhu G. Soni, Ph.D., FACN,
Soni & Associates Inc.,
749 46th Square,
Vero Beach FL, 32968
Phone: (772) 299-0746; E-mail: sonim@bellsouth.net

II. Detailed Information About the Identity of the Notified Substance:

A. Trade Name:

The subject of this notification will be marketed as Superba™ Krill Oil

B. Physical Characteristics

Superba™ Krill Oil is dark red colored viscous oil

C. Chemical Abstract Registry Number:

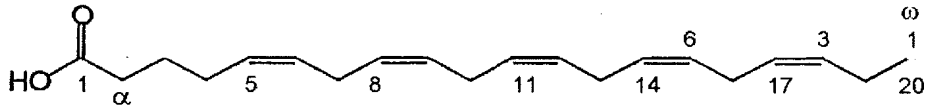
Not available

D. Chemical Formula:

Not applicable

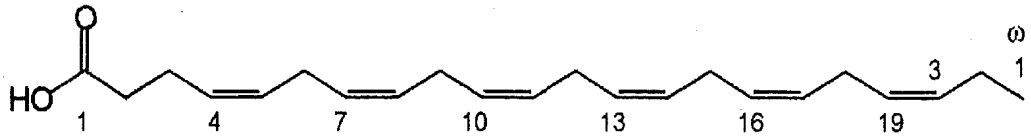
E. Structure:

The important constituents of high phospholipid krill oil are the fatty acids, EPA and DHA. The structures of these two fatty acids presented in Figure 1.



$CH_3CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}(CH_2)_3COOH$

Eicosapentaenoic acid (EPA)



$CH_3CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}CH_2\mathbf{CH=CH}(CH_2)_2COOH$

Docosahexaenoic acid (DHA)

Figure 1. Chemical structures of EPA and DHA

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F. Typical Composition and Specifications

Typical compositional analysis and specifications of Superba™ Krill Oil are presented in Table 1. Analytical results of five lots from non-consecutive batches (Appendix I) indicate that the product consistently meets these specifications. The major components of Superba™ Krill Oil are triglycerides and phospholipids high in omega-3 fatty acids such as EPA (C 20:5 n-3 fatty acid) and DHA (C 22:6 n-3 fatty acid). The maximum amount of EPA + DHA present in Superba™ Krill Oil will be 23.5 ± 2 g/100 g of the oil. No processing aids or additives, with the exception of residual amounts of ethanol solvent, are included in the final Superba™ Krill Oil product. Likewise due to naturally occurring astaxanthin esters that aid in its preservation, addition of an exogenous antioxidant is not required. Based on an 18 month stability test at different storage temperatures, the shelf life of Superba Krill Oil is set to 18 months when stored at 2-8°C. The results of pesticides and other environmental contaminants including PCBs, dioxins, furans and dioxin like PCBs, organochlorine pesticides, PBDEs, PAHs, and elements and heavy metal analyses from multiple batches of the product are presented in Appendix II.

Table 1. Typical compositional analysis and specifications of Superba™ Krill Oil

Parameter	Limits	Assay method
Appearance	Dark red viscous oil	Visual
Lipid composition		
Total phospholipids (g/100 g)	43 ± 3	N A88[1]/AM-AKMB-012
- Omega-3 phospholipids of total PL[2] % (w/w)	>70	Calculation
Triglycerides (g/100 g)	<50	N A88[1]/AM-AKMB-012
Fatty acid profile		
Total omega-3 (expressed as g/100 g)	23.5 ± 2	AOCS Ce 1b-89/AM-ABM-013
-C 20:5 n-3 (EPA)(expressed as g/100 g)	14 ± 2	AOCS Ce 1b-89/AM-ABM-013
-C 22:6 n-3 (DHA)(expressed as g/100 g)	6.5 ±1	AOCS Ce 1b-89/AM-ABM-013
Total omega-6	<3.0	AOCS Ce 1b-89/AM-ABM-013
Stability index		
Peroxide value (mEq peroxide/kg)	<2	AOCS Cd 8b-90/AM-058
Antioxidants		
Astaxanthin[4] (mg/kg)	100 ± 20 (minimum)	N A23[3]/AM-ABM-011
Water and Ethanol		
Water activity at 25°C	<0.5	AOAC 978.18
Ethanol content (% w/w)	<3.0	GC
Microbiology		
Total plate count (cfu/g)	<2500	NF EN ISO 4833/CQ-MO-231
E. coli (1 sample at 10 g)	Negative	Petrifilm Select EC
Coliform bacteria, 37°C (cfu/g)	<10	NordVal Ref. No. 014
Salmonella negative (PCR) (1 sample at 10 g)	Negative	AES 10/4-025/04
Mold and Yeast (cfu/g)	<10	NordVal Ref. No. 016

[1]Based on Homan and Anderson (1998) and Moreau (2006)
[2]Omega-3 phospholipid: defined as phospholipid where on average one out of two possible positions is occupied by an omega-3 fatty acid.
[3]Based on Schierle J. & Härdi W. (1994); [4]Expressed as astaxanthin diols.

As available research highlights the potential for seafood to contain substantial amounts of arsenic, an extensive chemical analysis of both organic and inorganic arsenic was undertaken from multiple batches (see Appendix II). These results show that while the total arsenic levels in krill oil ranged from 4 to 6 ppm, the vast majority of this arsenic was in organic form. The inorganic arsenic as measured in the form of arsenite and arsenate was below the level of quantification at 0.05 ppm.

G. Lipid and Fatty Acid Profile:

The lipid profile composition and fatty acid profile of krill oil is presented in Table 2 and 3, respectively. Analysis of *trans*-fatty acids from four different batches revealed the presence of total *trans*-fatty acids of <0.2% (Appendix III).

Table 2. Lipid profile, including phospholipids

Lipids	Percent Oil
Triacylglycerol	38
Diacylglycerol	0.8
Monoacylglycerol	<1
Free fatty acids	5.4
Cholesterol	1.1
Cholesterol ester	<0.5
Phosphatidylethanolamine	1.6
Phosphatidylinsotol	<1
Phosphatidylserine	<1
Phosphatidylcholine	39
Lysophosphatidylserine	3.7
Total polar lipids	44.7
Total neutral lipids	45.6

Table 3. Details of representative fatty acid profile

Fatty acid	Percent*	Fatty acid	Percent*
C14:0	7.7	C20:4 n-6	0.4
C16:0	15.4	C22:0	<0.1
C18:0	0.9	C22:4 n-6	0.5
C20:0	<0.1	C18:3 n-3	1.4
C22:0	0.1	C18:4 n-3	<0.1
C16:1 n-7	4.9	C20:4 n-3	0.5
C18:1 (n-9) + (n-7) + (n-5)	12.1	C20:5 n-3	14.7
C20:1 (n-9) + (n-7)	0.9	C21:5 n-3	0.4
C22:1 (n-11) + (n-9) + (n-7)	0.7	C22:5 n-3	0.3
C24:1 n-9	0.1	C22:6 n-3	6.2
C16:2 n-4	0.5		
C16:3 n-4	0.2	SFA	24.1
C18:2 n-6	1.2	MEFA	18.7
C18:3 n-6	0.2	PUFA (n-6)	1.9
C20:2 n-6	<0.1	PUFA (n-3)	24.0
C20:3 n-6	0.1	Total PUFA	26.6
		Total Fatty Acids	68.2

*Percent of total oil; Data from representative batch (A)-U301/006/A10

H. Manufacturing process

Superba™ Krill Oil is derived from shrimp-like, marine crustaceans of the order *Euphausiacea*, *Euphausia superba*. These organisms have a circumpolar distribution with the highest concentrations found in the Atlantic sector. Antarctic krill exist in large numbers in the open sea and are consumed as food by humans. The Antarctic krill used in the production of Superba™ Krill Oil are naturally occurring organisms fished from the wild. The harvested Antarctic krill is cooked and dried on the vessel to prepare krill meal. The steps involved in the manufacturing are summarized in Figure 1. The raw material that is extracted, krill meal, is a biomass composed of lipids, carbohydrates, and proteins. By using a solvent extraction process, the proteins and free carbohydrates are removed. Thus the oil is produced by subjecting the krill meal to ethanol extraction. The solvent used is food-grade quality and is removed from the product in accordance with current good manufacturing practice.

Following extraction, the defatted krill meal and the ethanol oil solution are separated. The ethanol-oil solution is then concentrated by evaporation and stored. The ethanol-oil solution is analyzed for ethanol, neutral and polar lipids, and astaxanthin content. Several batches are blended and the ethanol-oil solution is clarified by centrifugation. The ethanol is then evaporated from the oil solution and the final product is analyzed to verify the conformity with product specifications. The final product is filled into suitable containers and stored at 2-8°C and can be shipped by land, air, or boat. Processing aids, including solvents (which is removed by evaporation) used in the manufacturing process are food-grade quality as specified in the 5th Edition of Food Chemicals Codex. The Superba™ Krill Oil production process is controlled under the Hazard Analysis Critical Control Points (HACCP) system and points for likely contamination of the oil are strictly monitored. Additionally, the quality of the final product and production lots are routinely tested for specifications including solvent residue, microorganisms, heavy metals, and pesticides.

I. Manufacturing of Superba™ Krill Oil Process Diagram

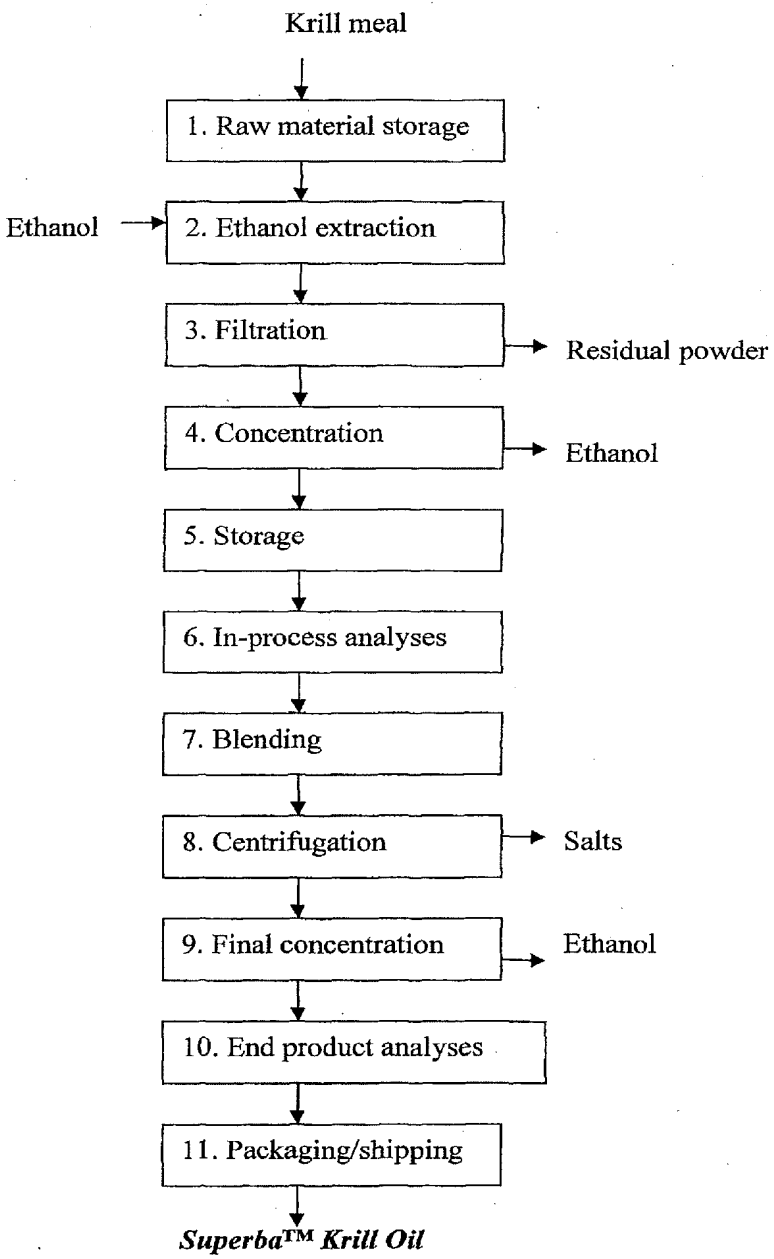

Figure 2. Manufacturing process of Superba™ Krill Oil

J. Intended Technical Effects

Superba™ Krill Oil is intended for use as a nutrient supplement as defined in 21 CFR 170.3(o)(20). It is intended for use by the general population at levels ranging from 0.05 to 0.50 g/serving for addition to the following food categories: non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk products; processed fruit and fruit juices; and in medical foods. It is recognized that there are Standard of Identity requirements for some of these foods, located in Title 21 of the Code of Federal Regulations. If used in such foods, the name will be changed so as not to be confused with the standardized food. Available information indicates that use levels are self-limiting because of their strong taste that can be detected, depending on food type, at levels greater than 0.30-0.50 g/serving. It is intended to be used as a replacement for fish oil. The intended use of Superba™ Krill Oil is in the same foods and at the same levels of addition as those described in GRN 242 for krill oil. The use of Superba™ Krill Oil in foods is not intended to function as a color additive as defined in 21 CFR 70.3(f).

III. Summary of the Basis for the Notifier's Determination that Krill Oil is GRAS

An independent panel of recognized experts, qualified by their scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, was requested by Aker Biomarine Antarctic AS to determine the Generally Recognized As Safe (GRAS) status of high phospholipid krill oil. A comprehensive search of the scientific databases for safety and toxicity information on krill oil and its component omega-3 fatty acids (EPA and DHA) was conducted through August 2010 and was utilized for this assessment. Based on a critical evaluation of the pertinent data and information summarized here and employing scientific procedures, the Expert Panel members have individually and collectively determined by scientific procedures that the addition of high phospholipid krill oil to the foods (non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk; processed fruit and fruit juices) containing no other ingredients that are good sources of EPA or DHA, when not otherwise precluded by a Standard of Identity, and to Medical Foods, meeting the specification cited above and manufactured in according with current Good Manufacturing Practice, is Generally Recognized As Safe (GRAS) under the conditions of intended use, as specified herein.

In coming to this decision that krill oil is GRAS, the Expert Panelists relied upon the conclusions that neither high phospholipid krill oil nor any of its constituents pose any toxicological hazards or safety concerns at the intended use levels, as well as on published toxicology studies and other articles relating to the safety of the product. It is also the opinion of the Expert Panelists that other qualified and competent scientists, reviewing the same publicly available toxicological and safety information, would reach the same conclusion.

IV. Basis for a Conclusion that Superba™ Krill Oil is GRAS for its Intended Use.

TABLE OF CONTENT

DETERMINATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF KRILL OIL AS A NUTRIENT

1. INTRODUCTION

The undersigned, an independent panel of recognized experts (hereinafter referred to as the Expert Panel)[2], qualified by their scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, was convened by Soni & Associates Inc., at the request of Aker Biomarine Antarctic AS, Norway, to determine the Generally Recognized As Safe (GRAS) status of high phospholipid krill oil as a nutrient [21 CFR 170.3(o)(20)][3] in non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk whole and skim; processed fruit and fruit juices; and in medical foods at use levels ranging from 0.05 to 0.50 g/serving resulting in maximum estimated daily intake of 8.3 g/person/day. A comprehensive search of the scientific literature for safety and toxicity information on krill oil and omega-3 fatty acids was conducted through August 2010 and made available to the Expert Panel. The Expert Panel independently and critically evaluated materials submitted by Aker Biomarine Antarctic AS and other information deemed appropriate or necessary. Following an independent, critical evaluation, the Expert Panel conferred and unanimously agreed to the decision described herein.

1.1. Background

Krill is the common name given to the order Euphausiacea of shrimp-like marine crustaceans. The current taxonomic placement of *E. superba* is summarized in Table 4. These small invertebrates, also known as euphausiids, are found in oceans around the world. The name krill is a Norwegian word that means "young fry of fish", which is also often attributed to other species of fish. Krill is a vital component of the marine food chain for baleen whales, whale sharks, seals, and a few seabird species. In Japan and Russia, krill is also used for human consumption. Since the 19th century or may be even earlier, krill has been harvested as a food source for humans (*okiami*) in Japan. Antarctic krill is closely related to shrimp and are consumed as human food in a similar way. Commercially, krill is used for aquaculture and aquarium feeds, as bait in sport fishing, or in the pharmaceutical industry. In the Southern Ocean one species, *Euphausia superba* is abundant. Commercial fishing of krill is done primarily in the Southern Ocean and in the waters around Japan. Approximately 40% of the Japanese Antarctic krill catch is processed for human consumption, and Antarctic krill has been sold as a food for human consumption since the mid-1970s.

In recent years, krill has received considerable attention because it is a rich source of high-quality protein, with the advantage over other animal proteins of being low in fat and rich in omega-3 fatty acids (Tou *et al.*, 2007). Antioxidant levels in krill are higher than in fish, suggesting benefits against oxidative damage. Antarctic krill oil has been reported to contain high levels (30%) of EPA and DHA as well as astaxanthin esters in concentrations of 200 to 400 ppm (Zhu *et al.*, 2008; Kidd, 2007). Additionally, krill oil is also a rich source of phospholipids, vitamin A, and other nutrients (Ruben *et al.*, 2003).

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[2] See also attachments (curriculum vitae) documenting the expertise of the Panel members.
[3] "Nutrient supplements": Substances which are necessary for the body's nutritional and metabolic processes.

Table 4. Classification of *Euphausia superba*

Kingdom	Animalia
Phylum	Arthropoda
Subphylum	Crustcia
Class	Malacostrasa
Superorder	Eucarida
Order	Euphausiacea
Family	Euphausidae
Genus	Euphausia
Species	*Euphausia superba*

1.2. Chemistry and Biological Activity

The important constituents of krill oil, omega-3 fatty acids, also known as n-3 polyunsaturated fatty acids (PUFA) belong to an essential fatty acid family characterized by their first double bond at carbon atom number 3 counted from the methyl or omega end of the carbon chain constituting the backbone of fatty acids. Omega-3 fatty acids are chemically and biologically distinct from omega-6 fatty acids, where the first double bond is at carbon atom number 6. There are two subgroups of omega-3 fatty acids. One, α-linolenic acid (ALA), derived from plant oils such as canola oil, rapeseed oil and linseed oil, is composed of 18 carbon atoms with three double bonds (nomenclature; 18:3). The other group is derived from seafood, and the major marine omega-3 fatty acids are EPA (20:5) and DHA (22:6) (Figure 1). In humans, ALA can, to a limited extent, be elongated and desaturated to EPA and DHA. Otherwise, EPA and DHA are only acquired from seafood.

In a recent review article, Calder (2006) discussed the biological role and mechanism of action of long-chain omega-3 fatty acids. It is well known that the omega-6 fatty acid, arachidonic acid, gives rise to the eicosanoid family of mediators (prostaglandins, thromboxanes, leukotrienes, and related metabolites). These mediators have inflammatory actions in their own right and also regulate the production of other mediators including inflammatory cytokines. Consumption of long chain omega-3 fatty acids decreases the amount of arachidonic acid in cell membranes and the availability for eicosanoid production. Additionally, these fatty acids also decrease the production of the classic inflammatory cytokines, such as tumor necrosis factor, interleukin-1 and interleukin-6, and the expression of adhesion molecules involved in inflammatory interactions between leukocytes and endothelial cells. These latter effects may occur by eicosanoid-independent mechanisms including modulation of the activation of transcription factors involved in inflammatory processes. Because of their potential health benefits, omega-3 fatty acids have been commonly consumed and extensively studied for their physiological effects.

1.3. Description, Manufacturing Process and Specifications

Superba™ Krill Oil is a dark red colored viscous oil with a seafood odor. Typical food grade specification and composition of Superba™ Krill Oil produced by Aker Biomarine Antarctic AS are summarized in Tables 1, 2, and 3. The primary constituents of Superba™ Krill Oil are triglycerides and phospholipids which are rich in EPA and DHA fatty acid. Detailed information about the identity of krill oil along with specifications, composition, and manufacturing are described earlier in Section II. Analytical results of five different batches indicate that the product consistently meets the specifications (Appendix I). The results of

pesticide, PCBs and dioxins, and furans analyses are presented in Appendix II. The *trans*-fatty acid profile from four batches of Superba™ Krill is presented in Appendix III.

In an extensive study, Winther *et al.* (2010) used high performance liquid chromatography-electrospray tandem mass spectrometry to elucidate the phospholipids in Superba™ Krill Oil extracted from *Euphausia superba.* The study was carried out in order to map the species of the choline-containing phospholipid classes: phosphatidylcholine and lyso-phosphatidylcholine. A total of 69 choline-containing phospholipids were detected, whereof 60 phosphatidylcholine substances, among others seven with probable omega-3 fatty acids in both sn-1 and sn-2. The phosphatidylcholine concentration was estimated to be 34 ± 5 g/100 g oil (n = 5). The results of this study reveal the composition of phospholipids of Superba™ Krill Oil and the presence of long chained, heavily unsaturated fatty acids. This study also verifies previous findings and offer new insights into the composition of krill oil. In addition to EPA and DHA, the other major fatty acids present in krill oil are palmitic acid, myristic acid, oleic acid, and palmitoleic acid.

1.4. Similarity with Fish oils

The available information suggests a considerable similarity, particularly omega-3 fatty acids, between krill oil and fish oil from different fish sources. In response to a number of GRAS notices, the FDA has acknowledged the GRAS status of different forms of fish oil. As per 21 CFR 184.1472, menhaden oil has been affirmed as GRAS. Additionally, the FDA has not questioned GRAS notifications submitted on tuna oil (FDA, 2002), salmon oil (FDA, 2004a), and anchovy oil (FDA, 2004b). In FDA's review of tuna oil, the fatty acid content of tuna oil was compared to menhaden oil (FDA, 2002). The fatty acid composition of krill oil is compared with those of FDA's comparison of tuna and menhaden oil in Table 5. Krill oil contains a high level of the desirable n-3 unsaturated fatty acids that is comparable to other oils.

Table 5. Comparison of fatty acid profile of Superba™ Krill Oil with tuna oil and menhaden oil* (g/100g)

Fatty acid	Tuna oil	Menhaden oil	Krill oil
14:0	20.3	9.0	7.7
16:0	20.0	19.0	15.4
18:0	6.0	3.0	0.9
16:1	4.5	12.0	4.9
18:1	15.0	13.0	12.1
22:1	1.0	-	0.6
18:2	1.5	1.0	1.2
18:3	1.0	1.0	0.2
20:5 (EPA)	6.0	14.0	14.7
22:6 (DHA)	26.5	8.0	6.2

*Values for tuna and menhaden oils adapted from FDA response to GRN 109 (FDA, 2002)

1.5. Technical effects

Superba™ Krill Oil is intended for addition to a limited number of conventional foods as a nutritional ingredient. It is intended for use as a dietary ingredient as a source of omega-3 fatty acids, which are found in their phospholipid form. Supplementation with the omega-3-fatty acids EPA and DHA has been shown to have a wide variety of biological effects. The intended use is for the general population at levels ranging from 0.05 to 0.50 g/serving for addition to the

following food categories: non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk products; processed fruit and fruit juices; and medical foods. It is recognized that there are Standard of Identity requirements for some of these foods, and as such, Aker Biomarine Antarctic AS does not intend to refer to them by the commonly recognized names such as milk, or yogurt.

The use of Superba™ Krill Oil in foods may impart a color to food products. However, the intended use of Superba™ Krill Oil would fall outside the definition of "color additive" because: the intended use levels are low enough to impart a significant color to food products, consistent with the "non-apparent color" Exemption [21 CFR 70.3(f)]; the intended use of Superba™ Krill Oil as a nutrient would contribute a color in a manner consistent with the "unimportant color" exemption addressed in 21 CFR 70.3(g); and the intended use of Superba™ Krill Oil is to provide consumers with an additional source of a nutrient in the diet and does not relate to any use of the ingredient as a color additive [21 CFR 70.3(f)].

1.6. Current Uses

Krill oil has been reportedly used in human food in Japan, Russia, Ukraine, and France since the 1970s. Based on information described in FDA dockets, in 2003 a New Dietary Ingredient Notification was submitted on the use of krill oil as a dietary supplement (FDA, 2003). The FDA filed the notice without any objections. The supplement is sold in 300 and 500 mg capsules with a recommended dose of 1 to 2 capsules/day. Krill oil has been available as a dietary supplement in North America for several years, European Union, Norway, and Taiwan. In the GRN 242 (FDA, 2008), it is stated that a total of 120,000 kg of krill oil has been consumed by customers as a dietary supplement without any reports of serious adverse effects.

Based on information from FDA's GRAS Notice Inventory[4] website, in February 2008 Neptune Technologies submitted a GRAS notification to the FDA on krill oil (FDA, 2008). The notice indicated that krill oil obtained from krill is intended to be added to a limited number of different food categories. The notice informed the FDA that krill oil is GRAS, through scientific procedures, for use as a food ingredient in non-alcoholic beverages, breakfast cereals, cheeses, frozen dairy desserts, milk products, processed fruit and fruit juices, and medical foods at a use level to provide 150 to 500 mg of the oil per serving. On October 14, 2008,[5] the FDA issued a "No Questions" letter for the GRAS notice.

Recently, on October 12, 2009, the use of krill oil received an approval as a novel food ingredient in Europe, under Commission Regulation (EC) No 258/97 related to novel foods and novel food ingredients. On December 22, 2009, in response to a notification on behalf of Aker Biomarine Antarctic AS, the Novel Food Board found that Superba™ Krill Oil is substantially equivalent to the krill oil authorized by the commission with respect to composition, nutritional value, metabolism, intended use, and the levels of undesirable substances contained therein (Appendix IV).

1.7. Intended Use Levels and Food Categories

Aker Biomarine Antarctic AS intends to offer Superba™ Krill Oil for incorporation into a limited number of human food categories where krill oil would function as a nutrient

[4]Accessible at: www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing&displayAll=true.
[5]Accessible at: http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn000242.pdf

supplement as defined under 21 CFR 170.3(o)(20). Superba™ Krill Oil is intended for use in the same foods and at the same or lower use levels of addition as described in GRN 242 for krill oil. The proposed food uses as a dietary source of krill oil in foods include addition to: non-alcoholic beverages, breakfast cereals, cheeses, frozen dairy desserts, milk products, and processed fruit and fruit juices. In addition to these categories, it is also intended for use in Medical Food at levels not to exceed 0.50 g/person/day.

1.7.1. Estimated Daily Intake from the Intended Uses

As Aker Biomarine Antarctic AS intends to use its Superba™ Krill Oil in the same foods and at the same use levels of addition as described in GRN 242, estimates of possible daily intake from the proposed use levels were adapted from GRN 242 (FDA, 2008). In the GRN 242, the use of krill oil was proposed at use levels of 0.15 to 0.50 g of the oil/serving (reference amounts customarily consumed, 21 CFR 101.12) of food. The specific food categories, the intended use levels of krill oil, and the resulting intake of krill oil are summarized in Table 5. In the GRN 242, the estimates of possible daily intake of krill oil were calculated using the FDA guidelines using serving size data and the mean consumption (50%) of each type of food of interest from the CSFII 1994-96 database (USDA, 2005). According to the FDA guidelines, a level twice the mean consumption was calculated to estimate use at the 90th percentile consumption level. A summary of dietary intake calculations from the intended food categories is also presented in Table 6.

The intended use levels of krill oil will result in an estimated daily intake at average (50th percentile) and high (90th percentile) consumption of 4.14 and 8.28 g/person, respectively. The resulting intake of total EPA and DHA from the exaggerated estimated daily intake of krill oil (8.30 g/person/day) would be 2.20 g/person/day. Thus the intended food uses for Superba™ Krill Oil are within the allowances FDA has accepted for the GRAS status use of menhaden oil. The acceptable menhaden oil food use does not exceed safe levels of consumption for total EPA and DHA. The maximum estimated consumption of astaxanthin ester, which is present in krill oil at 100 ppm would be 0.83 mg/person/day. The application of krill oil to the same foods and at the same use levels as those described in GRN 242 are unlikely to affect the dietary intake of krill oil from introduction into the market by another supplier who will have to compete in essentially the same market with the same foods. Hence, there is no need for a cumulative intake analysis.

Table 6. Intended Food Uses and Use Levels of Superba™ Krill Oil

Food category	Food subcategory	Use level per serving	Approximate serving size	Food intake (g/p/d) 50%-tile	Krill oil intake[a] (g/p/d) 50%-tile	Krill oil intake (g/p/d) 50%-tile X 2
Breakfast cereals	Cooked cereal	0.05-0.30 g	½ cup of cooked Oatmeal = 117 g	233	0.60	1.19
	Ready-to-eat cereal	0.05-0.30 g	1 cup of corn flakes = 25 g	48	0.60	1.15
Cheeses	Total cheese other than cream or cottage	0.05-0.30 g	1/2 oz. of cheese = 43 g	26	0.18	0.36
	Total cottage cheese	0.05-0.30 g	1/2 cup of cottage cheese = 105 g	50	0.14	0.29
Beverages, Nonalcoholic	Fruit drinks	0.05-0.25 g	8 oz. = 248 g	360	0.22-0.36	0.44-0.73
Milk, whole & skim	Total milk	0.05-0.50 g	1 cup of fluid whole milk = 244 g	216	0.27-0.45	0.53-0.89
Milk products	Sour cream	0.05-0.50 g	1 tablespoon of sour cream = 14 g	6	0.13-0.21	0.26-0.43
	Creams	0.05-0.50 g	1 tablespoon of cream = 15 g	3	0.06-0.10	0.12-0.20
	Yogurt[b]	0.05-0.50 g	No data in USDA survey	0.17 servings	0.05-0.085	0.10-0.17
Frozen dairy desserts	Ice cream, Ice milk	0.05-0.50 g	1/2 cup of hard ice cream = 67 g	132	0.59-0.98	1.18-1.97
Processed fruits/fruit juices	Total orange juice	0.05-0.25 g	6 fl. oz. of orange juice = 187 g	186	0.15-0.25	0.30-0.50
	Total lemon juice	0.05-0.25 g	1 fl. oz. of lemon juice = 30 g	<0.05	0.00	0.00
	Total apple juice	0.05-0.25 g	6 fl. oz. of apple juice = 186 g	150	0.12-0.20	0.24-0.41
Medical foods		0.05-0.50 g[c]	No data in USDA survey			
				Sum of all categories	**3.08-4.14**	**6.16-8.28**

[a] Dietary intake of krill oil for each food type is calculated by multiplying ,g/serving by grams of food consumed divided by grams of food per serving;

[b] Yogurt consumption in the US has been estimated by Neptune to average 60 servings per year or 0.17 servings per day, with a high consumer exposure at 250 servings per year. This estimate is based on sales data with a per capita consumption of 5-6 kg/person;

[c] It is envisioned that these foods would be meal replacements for patients whose diets would consist of these foods entirely for 3 meals per data and therefore, total krill oil consumption in these patients would be 0.90-1.50 g/day.

Adapted from GRN 000242 (FDA, 2008); note that values for low proposed intake are not calculated but the low values from GRN 000242 were considered.

2. DATA PERTAINING TO SAFETY

000017

The safety of krill oil and its biologically important constituents such as omega-3 fatty acids is supported by human observations and clinical trials as well as animal experimental

studies. Because of the physiological role of omega-3 fatty acids in human health, there have been considerable efforts to elucidate the mechanism and biological role of these fatty acids in human nutrition. As a result, the literature is full of information on omega-3 fatty acids. Relevant biological and toxicological studies on krill oil and its constituents (omega-3 fatty acids) are included in the following section in support of the safety conclusions determined in this assessment.

2.1. Absorption and Metabolism

Krill oil consists primarily of phospholipids that are commonly consumed via diet. It is well established and recognized that dietary phospholipids and fatty acids from either plant or animal sources are handled the same metabolically. The composition of Superba™ Krill Oil is well characterized and from this perspective there is nothing unusual that is not found in a commonly consumed diet. The components of krill oil have been extensively studied for their biological and physiological properties. Despite krill oil's complex composition, available information suggest that the major phospholipids and fatty acids are consistent with other lipid sources with differences noted in proportions of phospholipids, minor constituents, and fatty acid content. Given the metabolic sequelae of different dietary lipids, there is no reason to believe that the Superba™ Krill Oil would pose any different health hazards.

In two separate unpublished pharmacokinetics studies, bioavailability of EPA and DHA was investigated from different oils (Meyer, 2009a, 2009b). The first study was a single centre, open-label, randomized four-way crossover study designed to evaluate the 24 hour pharmacokinetic profiles of EPA, DHA, and astaxanthin after single doses of A: Superba™ Krill Oil (8 g), B: Neptune krill oil (8 g), C: Omega-3 enriched fish oil (8 g), and D: Krill powder (8 g). The doses were separated by 72 hours wash-out periods. In this study, 36 healthy male subjects (age 25 - 45 years) were randomized (1:1:1:1) to one of four treatment sequences. Blood samples were collected pre-dose, and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 10, 12, 16, and 24 hours after the dosing. A general trend to increases in levels of EPA, DHA, and astaxanthin across the four study periods was observed in the majority of subjects. This trend to continuous increase was confirmed by regression analysis for EPA and DHA in plasma and in phospholipid fractions. The median tmax for EPA in plasma was 12 hours for all products. With regards to DHA in plasma, the median absolute tmax was longest after Superba™ krill oil (10 hours), shortest after omega-3 enriched fish oil (6 hours), and in between after Neptune krill oil (7 hours) and krill powder (8 hours). All study products were safe and well tolerated (Meyer, 2009a).

In another unpublished open-label, randomized two-way crossover study, changes in EPA and DHA in phospholipid membranes were determined following eight weeks of daily intake of 2 g Superba™ Krill Oil or 2 g omega-3 enriched fish oil in healthy male and female subjects (Meyer, 2009b). A total of 28 healthy male and female subjects (14/sex; aged 25-45 years) took part in this study. Blood for the pharmacokinetic analysis was collected on Day 1 (pre-dose) and on Days 14, 28, 42 and 56 (± 2 days) of each treatment period for the analysis of EPA and DHA in phospholipid fractions and of omega-3 index in RBCs. In addition to daily enquiry of adverse events, a 12-lead ECG, and a standard clinical laboratory assessment (urinalysis, hematology, clinical chemistry) at screening and on Day 56 of period 2 was performed. Steady state in EPA levels and omega-3 index was attained earlier after Superba™ Krill Oil (Day 14) as compared to omega-3 enriched fish oil (Day 28). Steady state in DHA levels was attained later after Superba™ Krill Oil (Day 42) than after omega-3 enriched fish oil (Day 28).

In female subjects, the bioavailability of EPA in plasma (after dose adjustment) in krill oil administered subject was higher compared to fish oil (Meyer, 2009b). Similarly, across males and females, DHA in plasma (after dose adjustment) was higher in subjects receiving krill oil. Statistically significant differences between the treatments could not be demonstrated with respect to omega-3 index in RBCs (after dose adjustment). In subjects receiving krill oil, overall $AUC_{(0\text{-}56D)}$ of EPA and DHA in plasma and omega-3 index in RBCs was determined as 97908, 98261, 4208 ng*h/(mg*ml), respectively. Overall, there were no trends related to the study products in the adverse event reports, in clinical laboratory, ECG, and physical examinations. There were no withdrawals due to adverse effects. Krill oil ingestion decreased the mean serum insulin level, whereas the mean adiponectin level increased. Following omega-3 enriched fish oil administration, both the mean serum insulin level and the mean adiponectin level decreased. No statistically significant treatment effects were seen in the analysis of platelet aggregation, lipid parameters and the other selected clinical chemistry parameters (glucose, CRP, insulin TNF alpha, and adiponectin). The investigator concluded that both krill oil and fish oil were safe and well-tolerated (Meyer, 2009b).

2.2. Human Studies

In a randomized, double-blind parallel arm trial, overweight and obese subjects (n=76; 13 men, 63 women) were randomly assigned to receive double-blind capsules containing 2 g/day of krill oil (n=25), menhaden oil (n=26), or control (olive) oil (n=25) for four weeks (Maki *et al.*, 2009). The objective of this study was to examine the effects of krill oil supplementation on plasma EPA and DHA concentrations, indicators of safety, tolerability, and selected metabolic parameters. The krill oil used in this study was Superba™ Krill Oil, the subject of this GRAS determination. In addition to physical examination, clinical laboratory measurements (plasma chemistry, hematology, urine, and lipids) were performed. At baseline and at the end of week 4, subjects completed a gastrointestinal (GI) tolerability questionnaire, which assessed the presence and severity (on a scale of 0 to 5) of GI symptoms such as gas, bloating, nausea, flatulence, diarrhea, constipation, and cramping over the period of seven days. Subjects also completed a symptom checklist at the end of week 4, which assessed the incidence of or changes in a variety of symptoms (e.g., irritability, nervousness, mood, blurred vision, drowsiness, mental sharpness, and hair and skin changes) in the previous four weeks on a scale of 1 (a lot less) to 5 (a lot more). Adverse events were assessed from the time subjects signed the informed consent form at screening (week -1) and continued through the end of the study.

The changes from baseline to week 4 did not differ significantly among the treatment groups for hematology values or for plasma concentrations of albumin, electrolytes, creatinine, or liver enzymes. Responses for measures of glucose homeostasis, lipoprotein lipids, hs-CRP (high-sensitivity C-reactive protein), and F2-isoprostanes did not vary significantly by treatment group. The results revealed that compared to the control group, plasma EPA and DHA concentrations increased in the krill oil and menhaden oil groups. Blood urea nitrogen declined in the krill oil group as compared with the menhaden oil group. The frequencies of adverse events were similar in the three treatment groups. At week 4, significant differences were observed among the treatment groups in the number of subjects with scores of 4 or higher for gas or bloating ($P = 0.05$) and flatulence ($P = 0.034$). The number of subjects with gas or bloating increased from 2 (8%) at baseline to 5 (20%) at week 4 in the krill oil group and from 1 (4%) at baseline to 5 (20%) in the control group. No significant differences were observed among the treatment groups in the frequencies of any symptoms assessed with the symptom checklist. The

investigators concluded that compared with both menhaden oil and olive oil, krill oil was generally well tolerated and showed no indication of adverse effects on safety parameters (Maki *et al.*, 2009).

Ulven *et al.* (2010) investigated the effects of krill oil (Superba™ Krill Oil) and fish oil on serum lipids and markers of oxidative stress and inflammation. The objective of this study was to evaluate if different molecular forms, triacylglycerol and phospholipids, of omega-3 polyunsaturated fatty acids (PUFAs) influence the plasma level of EPA and DHA differently. In this study, 113 subjects with normal or slightly elevated total blood cholesterol and/or triglyceride levels were randomized into three groups and given either six capsules of krill oil (n = 36; 3.0 g/day, EPA + DHA = 543 mg) or three capsules of fish oil (n = 40; 1.8 g/day, EPA + DHA = 864 mg) daily for 7 weeks. The third group did not receive any supplementation and served as controls (n = 37). Safety was evaluated by assessment of hematology and biochemistry parameters, and by reported adverse events.

Compared to control group, a significant increase in plasma EPA, DHA, and DPA was noted in the subjects supplemented with n-3 PUFAs. However, there were no significant differences in the changes in any of these fatty acids between the fish oil and the krill oil groups. The serum lipids or the markers of oxidative stress and inflammation did not reveal any statistically significant differences between the study groups. The safety assessment did not reveal any patterns in the changes in any of the hematological or serum biochemical variables, vital signs or weight that might indicate a relation with administration of any of the studied products. Clinical symptoms registered during the study included mainly symptoms of common cold or gastrointestinal symptoms. One subject in the fish oil group experienced moderate bruises, and one subject in the krill oil group withdrew from the study because of an outbreak of rash that was possibly related to intake of the study products. There were no apparent differences in the rate of adverse events or blood safety parameters between the krill oil, fish oil or control groups. These observations indicate that krill oil was well tolerated. The results of this study show that krill oil and fish oil are comparable dietary sources of n-3 PUFAs, even if the EPA + DHA dose in the krill oil was 62.8% of that in the fish oil (Ulven *et al.*, 2010).

Sampalis *et al.* (2003) investigated the effects of krill oil on premenstrual syndrome (PMS) and dysmenorrhoea in 70 female adults of reproductive age. The females were randomized to receive either krill oil or fish oil. The subjects consumed two 1 g capsules once per day with meals during the first month. Subsequently, the subjects consumed same dose during the second and third months but for eight days prior to menstruation and for two days during menstruation. During the course of study, no serious adverse effects were reported. Three subjects reported a reduction in the duration of the menstrual cycle during the first month of treatment. In subjects receiving krill oil, a slight increase in the oiliness of the facial skin was noted. No subjects reported gastrointestinal disturbances. However, in fish oil group 64% of the participants reported "unpleasant" reflux following consumption. The results of this study suggest that krill oil softgels were well tolerated.

In another study, Deutsch (2007) investigated the effects of krill oil on markers of chronic inflammation in 90 subjects (age 50 to 68 years) recruited from primary care physicians. The subjects recruited had been diagnosed with cardiovascular disease, rheumatoid arthritis, or osteoarthritis, and were reported to have C-reactive protein levels greater than 1.0 mg/dL. Except for acetaminophen, the subjects were asked not to consume any other pain medication. The

subjects were administered either 100 mg of placebo or 300 mg krill oil/day and were followed for 30 days. C-reactive protein levels and pain and functional impairment scores were assessed during the experimental period on a weekly basis. Compared to baseline, a significant decrease in C-reactive protein levels was observed in subjects consuming krill oil at the end of 7, 14, and 30 days. No adverse effects were associated with the consumption of krill oil.

Bunea *et al.* (2004) evaluated the effects of krill oil on the clinical course of hyperlipidemia in 120 patients (mean age 51 years). The patients were randomized into four groups which were further subdivided according to their body mass index (BMI) (Bunea *et al.*, 2004; FDA 2008). Group 1 was administered either 2 g krill oil/day (BMI<30) or 3 g krill oil/day (BMI>30). Group 2 was administered either 1 or 1.5 g krill oil/day (BMI< or >30, respectively). Group 3 was administered a fish oil capsule that provided 180 mg EPA and 120 mg DHA, and Group 4 was the placebo group. The experimental period was 12 weeks while Group 2 consumed 500 mg krill oil/day for an additional 90 days. No adverse effects were noted in any of the groups.

In an unpublished study described in GRN 242 (FDA, 2008), the safety of krill oil was examined in 25 healthy male and female subjects between the ages of 25 and 53 years. The volunteers consumed two krill oil gelcaps, three times a day for two months. Each gelcap contained 1 g of krill oil that provided 386 mg of omega-3 fatty acids, 416 mg phospholipids, and 0.16 mg of astaxanthin. As described in GRN 242, complete blood counts and biochemical blood tests, medical histories, and vital signs were collected at baseline, one month, and two months. The volunteers were asked about the occurrence of adverse effects and if there was any regurgitation effects of the capsules. The subjects were also asked to stop consuming the gelcaps if they had the following symptoms: low or high blood pressure, difficulty breathing, bleeding, loss of consciousness, unusual migraines or body pain, weight gain, or significant alterations in blood test results. Biochemical parameters examined included cell counts, PTT, creatinine, glucose, alkaline phosphatase, albumin, amylase, total bilirubin, total cholesterol, HDL and LDL cholesterol, triglycerides, urea, and TSH levels. As described in GRN 242, no serious side effects were reported in volunteers consuming 6 g krill oil throughout the experimental period. No regurgitative effects were reported or any unpleasant aftertaste. Of the 25 volunteers, three withdrew for reasons associated with consuming krill oil. One female withdrew due to a known salt tolerance for which consumption of krill oil resulted in a moderate increase in water retention. Two females withdrew because they felt an increasing greasiness of their facial skin which was attributed to consuming krill oil. In the remaining volunteers, no noticeable physical or biochemical changes were observed. A significant decrease in serum total cholesterol, triglycerides, LDL cholesterol, the ratio of total cholesterol to HDL cholesterol, albumin, and amylase were observed. A significant increase in HDL cholesterol was also observed. These effects were not considered adverse effects but beneficial changes in blood lipids and pancreatic function. While a decrease in albumin levels might be indicative of underlying disease processes, their occurrence in the absence of other biochemical abnormalities suggested they were not adverse effects (FDA, 2008).

2.3. Animal Studies

Batetta *et al.* (2009) compared the effects of dietary (n-3) LC-PUFA, in the form of either fish oil or krill oil (Superba™ Krill Oil) balanced for EPA and DHA content, with a control diet containing no EPA and DHA and similar contents of oleic, linoleic, and α-linolenic acids, on ectopic fat and inflammation in Zucker rats, a model of obesity and related metabolic

dysfunction. In this study, male Zucker rats (Harlan) four weeks of age, with an initial weight of 250±30 g, were equally divided into three groups and were fed either a control diet or diets containing krill oil or fish oil for four weeks. The amount of 0.5 g of EPA + DHA per 100 g of diet, equivalent to 0.8% by energy in the rat diet, was chosen. Effects on lipid metabolism, ectopic fat deposition, and susceptibility to inflammation was measured. The investigators concluded that diets rich in (n-3) LCPUFA, and a krill oil-based diet in particular, exert beneficial effects on several metabolic dysfunctions in Zucker rats, which was associated with lower endocannabinoid concentrations in several peripheral tissues. Although the objective of the study was to investigate the efficacy of krill oil, growth and food intake was not affected by krill oil diet. Additionally, the investigators also reported that none of the rats exhibited adverse effects.

In another study, Di Marzo *et al.* (2010) investigated whether in Zucker rats, under the same conditions as described above by Batetta *et al.* (2009), fish and krill oil are also able to influence LC-PUFA and endocannabinoid profiles in the brain. The study design and protocol of this study was identical to the above described study. In this study, only krill oil was able to significantly increase DHA levels in brain phospholipids, with no changes in arachidonic acid. Based on the results of this study, the investigators claimed the beneficial effect of krill oil on the metabolic syndrome is mostly exerted by modifying endocannabinoid levels in peripheral tissues. Similar to the above described study, feeding krill oil in the diet for four weeks did not affect growth and food intake. No differences in growth and food intake among groups, nor any adverse effects of the diets, were observed.

Ruggiero-Lopez *et al.* (1994) investigated the effect of krill oil, as compared to fish and corn oil, on the rat intestinal fucosylation process at weaning, a very sensitive model of the influence of nutritional factors. In this study, the effects of oil were studied over a three-day period immediately after weaning. All the oils were well-tolerated by pups at a level of 10% of the diet. The use of krill oil was not reflected in the enzymatic activities involved in the fucosylation pathway. The investigators concluded that the results of their study confirm the harmlessness of krill derived products and their possible use in human nutrition.

A repeat-dose toxicity study described in GRN 242 (FDA, 2008) was conducted to examine the safety of krill oil in mice for six months. In this study, 96 C57BL6 nude congenic mice (B6NU-T heterozygotes) were fed a diet containing 16.6% krill oil (equivalent to 28.3 g krill oil/kg body weight/day. The animals were examined weekly by a certified veterinarian. At the end of the experiment, all the animals were euthanized by gas exposure and subjected to histopathological examinations. No adverse effects were noted over the experimental period and no histopathological abnormalities were observed in the brain, lungs, heart, stomach, pancreas, liver, kidneys, uterus or prostate, intestines, or skin.

In a follow up investigation to the above described study, also described in GRN 242, the development of UVB-Radiation Induced Skin Cancer in mice was investigated (FDA, 2008). In this study, C57BL6 Nude Congenic mice (B6NU-T heterozygotes) were randomized into two groups (48/sex/group). One group was administered oral, topical, or oral and topical treatments of krill oil. The second group was administered soya oil. In the oral dosing regime, mice were administered diets where 10% of the daily dietary intake consisted of either krill oil or soya oil (equivalent to 17.1 g/kg body weigh/day). In the topical treatment regime, krill oil or soya oil was applied to the skin. The mice were exposed for 30 minutes to UVB radiation, at a distance of 30 cm, daily for 20 weeks. After 20 weeks, the animals were euthanized and subjected to

histological examinations. The occurrence of cancers and pre-malignant tumors in mice administered topical treatments was 12.5% and 31.3%, respectively, as compared to 37.5% and 31.3%, respectively, in the soya oil group. In mice administered both oral and topical treatments, the occurrence of cancers and pre-malignant tumors was reported to be 18.8% and 31.3%, respectively in the krill oil group and 37.5% and 12.5% respectively, in the soya oil group. As compared to the soya oil group, a significant reduction in the incidence of cancers was noted in mice administered krill oil.

2.4. Safety of Omega-3 fatty acids- EPA and DHA

The principal fatty acid constituents of krill oil, EPA, and DHA are typically contained in oily fish, such as salmon, lake trout, tuna, and herring. The composition of EPA and DHA in krill oil, which is the subject of this notification ranges from 14±2 and 6.5 ±1% w/w, respectively. The total of EPA+DHA in krill oil is 23.5 ± 2%. In the 1997 final rule on the GRAS affirmed use of menhaden oil as a direct food ingredient (FDA, 1997) and also regarding the use of omega-3 fatty acids as a dietary supplement in 2005 (FDA, 2005), FDA has critically evaluated the safety of DHA and EPA. The FDA (1997) has affirmed menhaden oil as GRAS in 1997, as a direct human food ingredient with specific limitations of use to ensure that the total daily intake of EPA and DHA would not exceed 3 g/person/day (62 FR 30751; June 5, 1997; 21 CFR 184.1472). In these regulations, the FDA established maximum use levels of menhaden oil in certain foods (62 FR 30751 at 30757; June 5, 1997; amended March 23, 2005) because of concerns over possible adverse effects of consumption of fish oil on bleeding coagulation time, glycemic control, and LDL cholesterol,. The FDA reaffirmed the maximum intake of DHA and EPA to 3.0 g/day from all fish oil sources. To ensure the consumption remains below 3.0 g/day, the agency placed specific limitations, including the category of foods, the functional use of the ingredient, and the level of use.

Besides the menhaden oil GRAS affirmation, the FDA has not questioned multiple GRAS notices for additional sources of EPA and DHA as food ingredients. These notices include GRN 000102, GRN 000105, GRN 000109, GRN 000138; GRN 000146; GRN 000193; GRN 000200; GRN 000217[6]. In these GRAS Notifications, the intended maximum use levels were consistent with those specified in the final rule affirming GRAS status of menhaden oil as a direct human food ingredient with specific limitations of use. Furthermore, the FDA did not object to a GRAS notification for high DHA algal oil (GRAS Notice No. GRN 000137). In this case the notifier estimated that the use of algal oil in a number of food categories at the maximum proposed use levels would result in a mean exposure of no more than 1.5 g DHA/day.

In order to support the safety in use of DHA and EPA, the composition of principal krill oil fatty acids was compared with menhaden oil and tuna oil (Table 5). As noted in Table 5, menhaden oil contains 8% DHA and 14% EPA. The total of DHA+EPA (22%) in menhaden oil is essentially similar to that in krill oil (23%). Similarly, the individual levels of DHA (8% vs 6.5%) and EPA (14% vs 14%) are also essentially similar between menhaden and krill oil. In different FDA GRAS Notifications, the total amount of DHA+EPA ranged from 20 to 41% and was reported as follows: GRN 000105 = 38%, GRN 000109 = 28%, GRN 000138 = 29%, GRN 000146 = 20%, GRN 000200 = 41%, and GRN 000279 = 22%. In all of these notices, the

[6] The FDA response to all these and other GRAS notices is assessable at GRAS Notice Inventory: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing&displayAll=true

maximum levels of use in food categories were adjusted such that the resulting intake of DHA+EPA was similar to or lower than what is currently permitted for menhaden oil under 21 CFR 184.1472. As krill oil is proposed for use as a substitute or alternative to fish oils, the intended use of krill oil will not add to the existing intake of DHA and EPA.

2.5. Astaxanthin

In addition to lipids, one of the minor components of biological importance of the oil is astaxanthin. In Krill, either one or both of the alcoholic hydroxyl functional groups of astaxanthin may be esterified to fatty acids. Thus astaxanthin from krill are found almost exclusively in esterified form. Takaichi *et al.* (2003) determined that only five kinds of fatty acids, dodecanoate, tetradecanoate, hexadecanoate, hexadecenoate, and octadecenoate were esterified to astaxanthin in krill. Assuming one C16 fatty acids in each position gives a molecular weight of the esterified molecule of 1110 or approximately twice as much as astaxanthin alone. Hence to specify the astaxanthin content of krill oil, one can consider the molar concentration or the amount of astaxanthin diol. Because of the general unfamiliarity with molar concentrations, Aker Biomarine declares its product on the basis of astaxanthin diol. Thus the levels presented in Table 1 for astaxanthin of 100 ppm means the product contains 100 µg/g of the diols, regardless of fatty acids that may be esterified.

As mentioned earlier, the intended use of the krill oil will result in a maximum estimated consumption of 0.83 mg astaxanthin/person/day. Although there is no recommended daily allowance (RDA) for astaxanthin, available safety-related information suggests that the estimated daily intake of astaxanthin (0.83 mg) from the intended uses of Superba™ Krill Oil is lower than the generally considered safe levels of 6 mg/day. It has been reported that in consumers with a high intake of fish and seafood, the estimated daily intake of astaxanthin ranges from 1.6 to 4.1 mg/day. Recently, in response to a GRAS notice on *Haematococcus pluvialis* extract containing astaxanthin esters (GRN 000294)[7], the FDA did not question the safety of astaxanthin intake at levels of 1.08 mg/person/day.

2.6. *Trans*-Fatty acids

As shown in Appendix III, high phospholipid krill oil contains only small amount of *trans*-fatty acids (<0.3%). Accordingly, one of the fatty acids vaccenic acid (C18:1, n-7) in Superba™ Krill Oil is almost exclusively present in the *cis*-isomeric form. The vaccenic acid content of high phospholipid krill oil in GRN 243 was reported as about 10% (FDA, 2008). From more common sources such as fat from ruminants and in diary products, vaccenic acid is present naturally as *trans*-fatty acid in the fat of ruminants and in dairy products such as milk and yogurt. In krill oil, the vaccenic acid (C18:1, n-7) primarily occurs in the *cis*-isomeric form. The fatty acid profile presented in Table 3 provides values for C18.1 that includes n-5, n-7, n-9 and n-11. Among these, n-7 represents vaccenic acid, while n-9 represents oleic acid. Additional analysis of C18:1 fatty acids revealed that Superba™ Krill Oil primarily contains C18:1 n-9 + n-11 in *cis* configuration at levels of ~11%, while the levels of vaccenic acid are below 1%. As compared to these low levels, the vaccenic acid content (10%) reported in GRN 243 (FDA, 2008) is significantly higher. It is possible that the differences in manufacturing method may affect the levels of vaccenic acid.

[7] The FDA response is assessable at GRAS Notice Inventory:
http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing&displayAll=true

The presence of vaccenic acid is also reported in edible fats and oils (Wasowicz and Hougen, 1976; Sauer *et al.*, 1997). Several vegetable and animal oils are known to contain lower levels of vaccenic acid, while butter contains higher amounts of various isomers of 18:1 fatty acids in the *trans* configuration. These fatty acids are not believed to exhibit the same clot-forming potential as saturated fatty acids or other *trans*-fatty acids formed by partial hydrogenation of vegetable oils. In a critical review on the health benefits of vaccenic acid, Field *et al.* (2009) noted that epidemiological, clinical, and rodent studies to date have not demonstrated a relationship of vaccenic acid with heart or cardiovascular disease, insulin resistance, or inflammation. Available evidence does not indicate that dietary vaccenic acid poses any safety concerns and levels of this fatty acid in Superba® Krill Oil are very low.

2.7. Other Safety Considerations

As krill oil, the subject of this GRAS determination, is derived from marine organism, it is important to characterize the nature and quantity of impurities/contaminants that might be stored in marine lipids that may pose a health hazard. The potential impurities and incidental constituents present in krill oil arise largely from environmental exposure of the Antarctic Krill. As krill oil is derived from the lipid fraction of krill biomass, Aker Biomarine Antarctic AS routinely analyzes production lots of Superba™ Krill Oil for the presence of dioxins, furans, organochlorine pesticides, PBDEs, PAHs, heavy metals and PCBs. Likely contaminants were analyzed from multiple representative batches. These results, presented in Appendix II, demonstrate the levels of contaminants are low and consistent with levels of other food ingredients.

It is well recognized that arsenic especially in seafood is present in an organic form that is less toxic (EFSA, 2009). Hence, there is a need for speciation data for arsenic. As presented in Appendix II, an extensive chemical analysis of both organic and inorganic arsenic was undertaken from multiple batches of krill oil. These results of eleven different forms of arsenic show that the total arsenic levels in krill oil ranged from 4 to 6 ppm, the majority of which was in organic form. The organic arsenic was found to be primarily in the form of dimethylarsinate, arsenobetaine, and trimethylarsine oxide (Appendix II). The inorganic arsenic as measured by the levels of arsenite and arsenate was below the level of quantification at 0.05 ppm. In a critical scientific opinion on arsenic in food, the European Food Safety Authority (EFSA, 2009) panel reported that on the basis of limited data on inorganic arsenic in foods, fixed values for inorganic arsenic of 0.03 mg/kg in fish and 0.1 mg/kg in seafood were considered realistic for calculating human dietary exposure. The levels of inorganic arsenic in krill oil are lower than these assumptions, particularly for seafood. The EFSA panel also stated that the organic forms of arsenic, arsenobetaine, which is the major form in fish and most seafood, is widely assumed to be of no toxicological concern. The available evidence suggests that arsenic levels in krill oil are similar to other sea-foods. Considering that krill oil contains maximum total arsenic levels of 6 ppm, the intended use Superba™ Krill Oil will result in maximum daily intake of 48 μg/person or 0.08 μg/kg body weight/day. The WHO/FAO (1989) has suggested a provisional maximum tolerable weekly adult intake (PTWI) for inorganic arsenic of 0.015 mg/kg of body weight. Thus, the WHO/FAO provisional maximum tolerable intake is about 130 μg inorganic As/day for a 60 kg individual (15 μg/kg/week x 60 kg / 7 days/week = 128.6 μg/day). The above reported total arsenic intake of 0.08 μg/kg body weight/day is negligible compared to the tolerable daily intake of inorganic arsenic. This also suggests that krill oil consumption does not represent a major increase in the expected total daily arsenic exposure, and especially with regards to inorganic

arsenic. Thus the intended use of Superba™ Krill Oil is unlikely to present any safety hazards to human health.

2.8. Allergenicity and Other Related Concerns

As krill oil is prepared by the separation of lipids from protein of krill meal, consumption of krill oil by individuals allergic to shellfish may trigger an allergic response. Generally, krill oil is contraindicated for individuals who are allergic to crustacean. There is a lack of allergic responses based on the use of krill oil as a dietary supplement. While krill is known to contain allergens, its processing in the production of oil results in a reduction of its protein content to typically less than 1% which is an order of magnitude lower than in krill (about 10-15% protein). While this does not eliminate a risk, the risk is certainly no greater and possibly lower than that naturally contained in the starting materials. Aker Biomarine Antarctic AS will market krill oil in full compliance with the Food Allergen Labeling and Consumer Protection Act of 2004 (Title II of Public Law 108-282) (FDA, 2004). Aker Biomarine Antarctic AS intends to include a warning on food products containing Superba™ Krill Oil to suggest that individuals with seafood allergies, coagulopathy or who are taking anticoagulants or other medications should consult their situation with their physician before taking Superba™ Krill Oil as an ingredient in conventional foods or as nutritional supplements.

3. COMMON KNOWLEDGE ELEMENT

The compositional similarity of krill oil with fish oils from multiple sources that already have GRAS status supports the common knowledge element. The composition of krill oil and common fish oils are published and the similarity in compositions is readily ascertainable in the cited public documents (FDA, 2002, 2004a, 2004b, 2008). As described in GRN 242 (FDA, 2008) documentation exists in the Federal Register for the GRAS status of menhaden oil and on the FDA website for tuna oil, salmon oil, and sardine oil. These documents cite and support the consumption of fish oil resulting in total daily consumption of EPA plus DHA of less than 3 g/person. This GRAS determination is based on the totality of the available evidence, particularly from human observations, in concert with animal experimental studies. Majority of this information as described above, particularly in Sections 2.2 and 2.3 is available in public domain. Furthermore, safety documentation for food uses of krill oil is found in GRN 242, which also constitutes information that is generally available for review and evaluation. The composite information noted thereby fulfills the common knowledge element required for GRAS determination.

4. SUMMARY

Krill, a vital component of the marine food chain, is also consumed by humans, particularly in Japan and Russia. Because it is a rich source of high-quality protein as well as omega-3 fatty acids, krill has received considerable attention in recent years. Two fatty acids, EPA and DHA, that have received considerable attention for their potential health benefits have been reported to be present at high levels (30%) in krill oil. Aker Biomarine intends to use standardized krill oil (Superba™ Krill Oil) as a nutrient at levels of 0.05 to 0.50 g of the oil per serving in non-alcoholic beverages, breakfast cereals, cheeses, frozen dairy desserts, milk products, and processed fruit and fruit juices. In addition to the above categories, krill oil is also intended for use in Medical Food at levels not to exceed 0.50 g/person/day. The intended use of krill oil will result in an estimated daily mean and high (90th percentile) intake of 4.1 and 8.3

g/person/day. The resulting high intake of EPA+DHA is estimated as 2.2 g/person/day. Krill oil has been the subject of a GRAS Notice submitted to the FDA for use as a nutrient. In this case, the FDA responded that they had no questions on the proposed use and did not object to the GRAS determination. The composition of Superba™ Krill Oil is well characterized and is substantially equivalent to the European Commission approved krill oil.

It is well established and recognized that dietary phospholipids and fatty acids from either plant or animal sources are handled the same metabolically. Given the metabolic sequelae, there is no reason to believe that the minor variations in the levels of lipids including phospholipids or fatty acids between these oils would pose any different health hazards. Similar to other phospholipids from other sources, phospholipids from krill oil will be absorbed, transported, and converted into endogenous constituents. The fatty acids present in krill oil are typical components of the diet and are not anticipated to pose any risk at the levels consumed. Furthermore, the different fatty acid chains are unlikely to affect the overall oral toxicity, as the fatty acid portions of molecules are largely cleaved prior to absorption by mucosal cells.

Among the fatty acids of krill oil, there is a potential safety concern for EPA and DHA at high levels of intake. The safety of these two fatty acids has been extensively evaluated by the US FDA in the final rule on the approved use of menhaden oil as a direct food ingredient and subsequently in 2005, regarding the use of omega-3 fatty acids as a dietary supplement. The FDA affirmed the GRAS status of menhaden oil for use in foods provided daily intakes of DHA and EPA did not exceed 3 g/person/day from all fish oil sources. The FDA also permitted the use of a Qualified Health Claim on dietary supplements containing EPA and DHA as well as for conventional foods. The FDA concluded that the use of EPA and DHA omega-3 fatty acids as dietary supplements is safe, provided that daily intakes of EPA and DHA do not exceed 3 g/person/day from conventional food and dietary supplement sources. For the food uses of menhaden oil, the FDA imposed specific limitations in its use in different food categories to ensure that total intake of EPA and or DHA is safe. Further, the FDA concluded that in order to help ensure that a consumer does not exceed an intake of 3 g/person/day of EPA and DHA omega-3 fatty acids from consumption of a dietary supplement with the qualified claim, an EPA and DHA omega-3 fatty acid dietary supplement bearing a qualified claim should not recommend or suggest in its labeling, or under ordinary conditions of use, an intake exceeding 2 g EPA and DHA/day. Given the substitutional (for substances with DHA and EPA) uses of krill oil, the resulting intake of DHA and EPA is unlikely to exceed 2.2 g/person/day and is considered as safe.

The safety of krill oil has been investigated in human clinical and animal experimental studies. Although the majority of these studies were designed to investigate the potential health benefits of krill oil, no adverse effects were noted. These studies support the safety of krill oil. Of the five clinical studies on krill oil, three were more significant with regard to dose and duration. In one clinical trial conducted to examine the safety, krill oil was well tolerated at a dose of 2 g/day for four weeks. In the second study, no adverse effects were noted following the consumption of 6 g krill oil/day for two months. In the third clinical study, participants tolerated krill oil at doses of up to 3 g/day for a period of 12 weeks, followed by an additional 0.5 g/day by some participants for 90 days. In these studies no significant adverse effects of krill oil consumption were noted.

There is sufficient qualitative and quantitative scientific evidence, including human and animal data, to determine safety-in-use for krill oil. The safety of krill oil is based on several

factors that include the inherent safety of the fatty acid, phospholipids and other components in the oil, the compositional similarity of the krill oil with fish oils, extensive knowledge of their metabolism, the expected levels in the diet of EPA and DHA fatty acids, and astaxanthin from the intended use of krill oil, the safety of krill oil as demonstrated in pre-clinical and clinical trials, and the absence of reports of toxicity. Additionally, Antarctic krill also has some history of consumption by humans in Japan and Russia. On the basis of scientific procedures[8], the consumption of krill oil as an added food ingredient is considered safe at levels up to 8.3 g/person/day. The intended uses are compatible with current regulations, *i.e.,* krill oil is used in non-alcoholic beverages, breakfast cereals, cheeses, frozen dairy desserts, milk products, and processed fruit and fruit juices, and Medical Foods.

[8] 21 CFR §170.3 Definitions. (h) Scientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

5. CONCLUSION

Based on a critical evaluation of the publicly available data summarized above, the Expert Panel members whose signatures appear below, have individually and collectively concluded that krill oil (Superba™ Krill Oil), meeting the specifications cited above, and when used as a food ingredient in selected food products (non-alcoholic beverages, breakfast cereals, cheeses, frozen dairy desserts, milk products, and processed fruit and fruit juices, and Medical Foods) at levels of 0.05 to 0.50 g krill oil/serving (reference amounts customarily consumed, 21CFR 101.12) when not otherwise precluded by a Standard of Identity as described in this monograph and resulting in the 90th percentile (high) estimated intake of 8.3 g krill oil/person/day is Generally Recognized As Safe (GRAS).

It is also our opinion that other qualified and competent scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Therefore, we have also concluded that Superba™ Krill Oil, when used as described, is GRAS, based on scientific procedures.

Signatures

(b) (6)

John A. Thomas, Ph.D., F.A.C.T., D.A.T.S. — 12/8/10 — Date

(b) (6)

Stanley T. Omaye, Ph.D., D.A.T.S. — 12/07/10 — Date

(b) (6)

Madhusudan G. Soni, Ph.D., F.A.C.N. — Dec. 10, 2010 — Date

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7. APPENDIX I

Analytical data from different manufacturing lots of Superba™ Krill Oil (Aker Biomarine, 2010)

Parameter	Limits	U133 002 A10	U176 004 A10	U141 001 A10	U141 003 A10	U141 002 A10
Appearance	Dark red viscous oil	Dark red viscous oil	Dark red viscous oil	Dark red viscous oil	Dark red viscous oil	Dark red viscous oil
Lipid composition						
Total phospholipids (g/100g)	43 ± 3	40.3	44.8	40.8	45.3	42.7
-Omega-3 phospholipids[1] of total PL % (w/w)	>70	>70	>70	>70	>70	>70
Triglycerides (g/100g)	<50	39	36	32	32	32
Fatty acid profile						
Total omega-3 (expressed as g/100g)	23.5 ± 2	22.9	22.4	24.5	26.2	25.5
-C 20:5 n-3 (EPA)(expressed as g/100g)	14 ± 2	13.4	14.3	14.7	16.7	16.3
-C 22:6 n-3 (DHA)(expressed as g/100g)	6.5 ± 1	6.5	5.8	6.7	6.7	6.5
Total omega-6	<3.0	1.9	2.0	2.2	2.4	2.4
Stability index						
Peroxide value (mEq peroxide/kg)	<2	<1	<1	<1	<1	<1
Antioxidants						
Astaxanthin (mg/kg)	100 ± 20 (minimum)	164	125	144	96	92
Water and Ethanol						
Water activity at 25°C	<0.5	0.116	0.149	0.143	0.115	0.139
Ethanol content (% w/w)	<3.0	1.8	1.52	1.58	1.37	1.21
Microbiology						
Total plate count (cfu/g)	<2500	<100	<100	<100	<100	<100
E. coli (1 sample at 10 g)	Negative	Negative	Negative	Negative	Negative	Negative
Coliform bacteria, 37°C (cfu/g)	<10	<10	<10	<10	<10	<10
Salmonella negative (PCR) (1 sample at 10 g)	Negative	Negative	Negative	Negative	Negative	Negative
Mold and Yeast (cfu/g)	<10	<10	<10	<10	<10	<10

[1]Omega-3 phospholipid: defined as phospholipid where on average one out of two possible positions is occupied by an omega-3 fatty acid.

Additional Specification and compositional analysis data of Superba™ Krill Oil from five different batches Adapted from Superba™ Krill oil substantial equivalence notification

Parameter	Unit	Batch 233/34/A 8	Batch 234/42/A 8	Batch 234/43/A8	Batch 235/24/A 8	Batch 280/42/A 9	Batch 279/22/ A9
1. Saponification value	Mg KOH/g	N.D	N.D	N.D	N.D	149	160
2. Peroxide value*	eEq/kg	<2	<2	<2	<2	<2	<2
3. Moisture**		0.19	0.251	0.27	0.339	N.D	N.D
4. Total phospholipids	g/100g	46.0	44.3	45.7	44.5	N.D	N.D
5. *Trans*-fatty acids	% of lipids	0.23	0.23	0.23	0.24	N.D	N.D
6. EPA (20:5)		14.8	14.9	14.3	14.9	N.D	N.D
7. DHA (22:6)		8.6	8.7	8.4	8.7	N.D	N.D

Analysis 3-7 was performed by validated methods at an accredited laboratory (NOFIMA). Analysis number 1 was performed at NOFIMA. Adapted from Superba™ Krill Oil substantial equivalence notification.

* As assayed by the relevant AOCS method.

** Moisture expressed as water activity at 25°C. N.D. = not determined.

8. APPENDIX II

Analytical Results of Dioxins, Furans, Organochlorine Pesticides, PBDEs, PAHs, and Heavy Metals from Five Batches, and Marker PCBs from Four Batches of Superba™ Krill Oil

Parameter	Unit	Method	233/34/A8 (262/72/A8)	234/42/A8	234/43/A8	235/24/A8	341/70/A9	average
Dioxins, furans and dioxine like PCBs								
Total PCDDs/PCDFs	ng/kg	EN 1948 modified, HRMS	0.16	0.16	0.17	0.15	0.294	0.187
PCDDs/PCDFs and dioxine like PCBs	ng/kg	EN 1948 modified, HRMS	0.27	0.26	0.26	0.26	0.436	0.297
Organochlorine pesticides								
DDTs/DDDs/DDEs	ug/kg	Internal method, HRGC-HRMS	<1.7	<1.37	<1.43	<1.45	<1.2	
Aldrin	ug/kg	Internal method, HRGC-HRMS	<0.5	<0.5	<0.5	<0.5	<0.5	
Dieldrin	ug/kg	Internal method, HRGC-HRMS	0.72	0.65	0.64	0.57	0.42	
Toxaphen	ug/kg	Internal method, HRGC-HRMS	<3.3	<2.1	<2.2	<2.1	<1.8	
PBDEs								
PBDE #17	ng/g	LRMS	<0.02	<0.01	<0.01	<0.01	<0.02	<0.014
PBDE #28	ng/g	LRMS	<0.02	<0.01	<0.01	<0.01	<0.019	<0.0138
PBDE #49	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #71	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #47	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #66	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #77	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #100	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #119	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #99	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #85	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #126	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #154	ng/g	LRMS	<0.06	<0.04	<0.04	<0.04	<0.077	<0.051

PBDE #153	ng/g	LRMS	<0.06	<0.04	<0.04	<0.04	<0.077	<0.051
PBDE #138	ng/g	LRMS	<0.06	<0.04	<0.04	<0.04	<0.077	<0.051
PBDE #183	ng/g	LRMS	<0.07	<0.06	<0.06	<0.06	<0.096	<0.069
PBDE #190	ng/g	LRMS	<0.07	<0.06	<0.06	<0.06		
PBDE #203	ng/g	LRMS	<0.15	<0.15	<0.15	<0.15		
PBDE #207	ng/g	LRMS	<0.15	<0.12	<0.11	<0.12	<0.479	<0.196
PBDE #209	ng/g	LRMS	<1.48	<1.19	<1.14	<1.16	<1.91	<1.38
PAHs								
Benzo(a)anthracene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Chrysene/triphenylene	ug/kg	GC-MS	0.7		ND	0.6	<0.5	<0.6
Benzo(b)fluoranthene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Benzo(k/j)fluoranthene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Benzo(a)pyrene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Indeno(1,2,3-cd)pyrene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Dibenzo(a,h)anthracene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Benzo(ghi)perylene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.6	<0.53
Dibenzo(a,l)pyrene	ug/kg	GC-MS	<1		ND	<1	<1	<1
Dibenzo(a,i)pyrene	ug/kg	GC-MS	<1		ND	<1	<1	<1
Dibenzo(a,h)pyrene	ug/kg	GC-MS	<1		ND	<1	<1	<1
Dibenzo(a,e)pyrene	ug/kg	GC-MS	<1		ND	<1	<1	<1
Cyclopenta(c,d)pyrene	ug/kg	GC-MS	<1		ND	<1	<1	<1
5-methylchrysene	ug/kg	GC-MS	<1		ND	<1	<1	<1
Benzo-(o)-fluorene	µg/kg	GC-MS					<1	<1
Benzo(a)pyrene	µg/kg	GC-MS					<0.5	<0.5
Arsenic								
Arsenite	mg/kg	Extraction/digestion, HPLC-ICP-MS	<0.005	<0.005	<0.005	<0,005	0.015	0.007
Arsenate	mg/kg	Extraction/digestion, HPLC-ICP-MS	<0.005	<0.005	<0.005	<0.005	<0.005	0.005

Monomethylarsonate	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.075	0.041	0.057	0.062	0.042	
Dimethylarsinate	mg/kg	Extraction/digestion, HPLC-ICP-MS	3.18	3.18	3.3	3.29	3.64	
Arsenobetaine	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.91	0.771	0.886	0.914	0.723	
Arsenocholine	mg/kg	Extraction/digestion, HPLC-ICP-MS	<0.005	<0.005	<0.005	<0.005	<0.005	
Trimethylarsine oxide	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.399	0.42	0.417	0.431	0.519	
Tetramethylarsonium ion	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.063	0.062	0.062	0.064	<0.005	
Arsenosugar a	mg/kg	Extraction/digestion, HPLC-ICP-MS	<0.005	<0.005	<0.005	<0.005	<0.005	
Arsenosugar b	mg/kg	Extraction/digestion, HPLC-ICP-MS	<0.005	<0.005	<0.005	<0.005	<0.005	
Arsenosugar c	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.011	0.008	0.011	0.01	0.02	
Arsenosugar d	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.038	0.036	0.041	0.037	0.022	
Arsenic (As)	mg/kg	Microwave assisted digestion, ICP-MS	5.5	4.9	5.5	5.2	5.6	
Heavy metals								
Pb	mg/kg	§64 LFGB L00.00-19/3, AAS-Gr.	<0.05	<0.1	<0.05	<0.05	<0.04	<0.058
Cd	mg/kg	§64 LFGB L00.00-19/3, AAS-Gr.	<0.01	<0.01	<0.01	<0.01	<0.02	<0.012
Hg	mg/kg	§64 LFGB L00.00-19/4, AAS-cold vapour	<0.005	<0.005	<0.005	<0.005	<0.02	<0.008
Cu	mg/kg	EN ISO 11885, mod., ICP-OES	6.3	7.7	7.2	5.8	10	7.4
Fe	mg/kg	EN ISO 11885, mod., ICP-OES	0.4	0.21	0.18	0.2	<2	0.598
Zn	mg/kg	EN ISO 11885, mod., ICP-OES	2.9	2.5	2.8	2.9	2.5	2.72

Data information provided by Aker Biomarine.

Analytical Results on Marker PCBs from four representative batches of Superba™ Krill Oil are presented separately (see below)

Levels of Marker PCBs from four representative batches of Superba™ Krill Oil

Marker PCBS	Unit	341 70 A9	A112/011/A10	U194/001/A10	U232/002/A10
PCB 28	pg/g	<54.6	<89.7	<92.8	<90.7
PCB 52	pg/g	<43.1	<46.2	<47.7	56.8
PCB 101	pg/g	<54.6	<66.7	<69.0	<67.4
PCB 118	pg/g	<21.6	<24.1	62.7	36.2
PCB 138	pg/g	<63.2	<79.5	<82.2	<80.3
PCB 153	pg/g	<66.1	<84.6	<87.5	<85.5
PCB 180	pg/g	<26.4	<61.5	<63.7	<62.2
Total 7 indicator PCBs	pg/g	330	452	506	479

9. APPENDIX III

trans-Fatty acid profile from four batches of Superba™ Krill Oil

Fatty acids	Batch 235-24-A8	Batch 234-33-A8	Batch 02925-01	Batch 234-43-A8
trans 16:1	<0.1	<0.1	<0.1	<0.1
trans 18:1	<0.1	<0.1	<0.1	<0.1
trans 18:2	<0.1	<0.1	<0.1	<0.1
trans 18:3	<0.1	<0.1	<0.1	<0.1
trans 20:1	<0.1	<0.1	<0.1	<0.1
trans 20:2	<0.1	<0.1	<0.1	<0.1
trans 20:3	<0.1	<0.1	<0.1	<0.1
trans 20:4	<0.1	<0.1	<0.1	<0.1
trans 20:5	0.1	0.1	0.1	0.1
trans 22:1	<0.1	<0.1	<0.1	<0.1
trans 22:6	<0.1	0.1	0.1	0.1
Total *trans*-fatty acids	0.2	0.2	0.2	0.2

Values are expressed as g/100 g of fatty acids; Method: AOCS Ce 1h-05; Data information provided by Aker Biomarine

10. APPENDIX IV

Novel Food Ingredient approval for Superba™ Krill Oil

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Safety of the Food chain
Food law, nutrition and labelling

SANCO
22. 12. 2009

Brussels,
SANCO/EA/AK/bs (2009) D/540876

Note to the Permanent Representations of

Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

Subject: **Regulation (EC) N° 258/97 concerning novel foods and novel food ingredients**
Notification pursuant to Article 5 of the above mentioned Regulation
Lipid extract from Antarctic Krill

Pursuant to Article 5 of Regulation (EC) N° 258/97, the Commission has received a notification for the placing of the above-mentioned product on the Community market on 17 December 2009.

Notifier: **Aker BioMarine Antartic AS**
Fjordalléen 16
P.O.Box 1423 Vika
NO – 0115 Oslo
Norway.

The Novel Food Board (FIN) has delivered an opinion that the Krill oil to be placed on the market by the company Aker BioMarine Antarctic AS is substantially equivalent to the Krill oil authorised by Commission Decision 2009/752/EC with respect to composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein (Article 3.4 of Regulation (EC) N° 258/97).

Pursuant to Article 5 of Regulation (EC) N° 258/97 you are now receiving a copy of the notification with its enclosures.

(b) (6)

Andreas Klepsch

Enclosures

cc: Competent authorities, EFTA Secretariat, Mr Hogne Vik

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11
Office: FIC1 6/22. Telephone: direct line (32-2) 29532 10. Fax: (32-2) 2961735.

Pages 000042-000129 containing curriculum vitae removed under Freedom of Information exemption 6.

Soni & Associates Inc.

749 46th Square
Vero Beach, FL 32968, USA
Telephone: 772-299-0746

E-mail: msoni@soniassociates.net

January 28, 2011

Dr. Paulette Gaynor
Office of Food Additive Safety (HFS-255)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Subject: GRAS Notification for Kril

Dear Dr. Gaynor:

This has reference to our discussion about Superba™ Krill Oil GRAS notification submitted on behalf of Aker Biomarine Antarctic AS, Norway. As discussed, please find attached three copies of the revised Availability of Information statement (page 3).

If you have any questions or require additional information, please feel free to contact me at 772-299-0746 by phone or at msoni@soniassociates.net by email.

Sincerely,
(b) (6)

Madhu G. Soni, Ph.D.

Enclosure:

determination of high phospholipid krill oil is based on the totality of available scientific evidence that includes human observations and a variety of preclinical and clinical studies. Based on the available safety-related information, the estimated daily intake, if ingested daily over a lifetime, is safe.

F. Availability of Information:

The data and information that forms the basis of Aker Biomarine's Superba™ Krill Oil GRAS determination will be available for the Food and Drug Administration's review and copying at the following address or will be provided to the FDA upon request:

Madhu G. Soni, Ph.D., FACN,
Soni & Associates Inc.,
749 46th Square,
Vero Beach FL, 32968
Phone: (772) 299-0746; E-mail: sonim@bellsouth.net

II. Detailed Information About the Identity of the Notified Substance:

A. Trade Name:

The subject of this notification will be marketed as Superba™ Krill Oil

B. Physical Characteristics

Superba™ Krill Oil is dark red colored viscous oil

C. Chemical Abstract Registry Number:

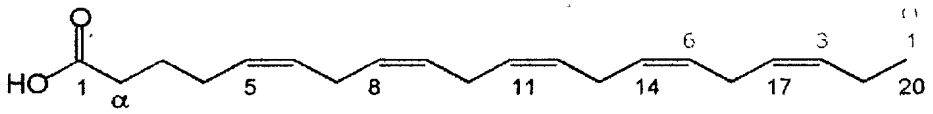
Not available

D. Chemical Formula:

Not applicable

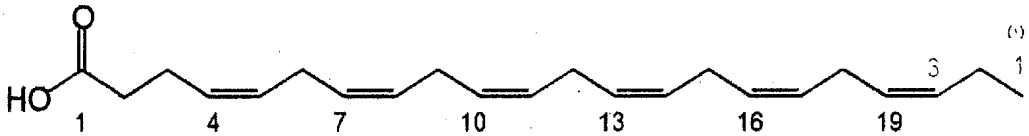
E. Structure:

The important constituents of high phospholipid krill oil are the fatty acids, EPA and DHA. The structures of these two fatty acids presented in Figure 1.



CH_3CH_2**CH=CHCH$_2$CH=CHCH$_2$CH=CHCH$_2$CH=CHCH$_2$CH=CH**$(CH_2)_3COOH$

Eicosapentaenoic acid (EPA)



CH_3CH_2**CH=CHCH$_2$CH=CHCH$_2$CH=CHCH$_2$CH=CHCH$_2$CH=CHCH$_2$CH=CH**$(CH_2)_2COOH$

Docosahexaenoic acid (DHA)

Figure 1. Chemical structures of EPA and DHA

AM

Fus, Andrea

From: Madhu Soni [sonim@bellsouth.net]
Sent: Friday, April 08, 2011 9:28 AM
To: Fus, Andrea *
Subject: RE: FDA Request for Clarification Regarding GRN 371, Krill Oil
Attachments: GRN 371 Krill Oil GRAS FDA Query Response.pdf

Dear Dr. Fus,

Please find attached an electronic file providing a point-by-point response to your queries. I hope the information and clarifications, along with some discussion in the response addresses your queries. If you have any questions or need additional explanation, please let me know. Thank you for the opportunity to provide this explanation.

Best regards

Madhu

From: Fus, Andrea * [mailto:Andrea.Fus@fda.hhs.gov]
Sent: Monday, March 21, 2011 2:31 PM
To: sonim@bellsouth.net
Subject: FDA Request for Clarification Regarding GRN 371, Krill Oil

Dear Dr, Soni,

I am glad we were able to speak on the phone today.

As we discussed, an electronic file describing several points of clarification for GRN 371, krill oil by Aker Biomarine Antarctic AS, is attached. I understand that you estimate it may take two or three weeks to finalize a response from the notifier. Please let me know if there are any significant changes in your time line.

Please do not hesitate to contact me should you have any questions or concerns.

Thanks

Andrea Fus

Andrea F. Fus, Pharm.D
ORISE / Regulatory Team B
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Biotechnology and GRAS Notice Review
5100 Paint Branch Parkway
College Park, MD 20740
(301) 436-1351
Andrea.Fus@fda.hhs.gov

Dear Dr. Fus,

RE: Krill oil GRAS Notice (GRN 371)

This responds to your email of March 21, 2011 regarding additional information and clarifications required for our Krill oil GRAS notice (GRN 000371). We are providing a point-by-point response to your queries along with some relevant discussion.

1. **FDA Query:** Please address methods used by Aker Biomarine Antarctic's to calculate a maximum 2.2 g per person per day total omega-3 (DHA and EPA) exposure for your krill oil and its typical composition (as indicated in Table 1).

   Response: Thank you for bringing this to our attention. By oversight we forgot to include the correct value for total omega-3 exposure. Based on the data provided in Table 1 of our GRN, the maximum omega-3 content (EPA- 14±2 and DHA- 6.5±1) of the krill oil will be 23.5 (EPA- 16.0 and DHA- = 7.5). As the intended use of krill oil will result in an estimated daily maximum (90th percentile) intake of 8.3 g/person/day, the resulting high intake of EPA+DHA is estimated as 1.95 g/person/day. Hence the correct value for total omega-3 (EPA and DHA) exposure should be 1.95 g/person/day.

2. **FDA Query:** Please include specifications for incidental chemicals in Aker Biomarine Antarctic's krill oil, at minimum, for arsenic, mercury, and lead.

   Response: As desired, we are including specification for incidental chemicals below:

Specifications for Incidental Chemicals (Superba™ Krill Oil)

Incidental Chemical	Units	Specifications	Method
Heavy metals			
Arsenic (inorganic)	mg/kg	< 0.05	Extraction/digestion, HPLC-ICP-MS
Mercury	mg/kg	< 0.05	ALC 208:112
Lead	mg/kg	< 0.10	NMKL161 mod;ICP-MS
Cadmium	mg/kg	< 0.10	NMKL161 mod;ICP-MS
Copper	mg/kg	< 10.0	NMKL161 mod;ICP
Iron	mg/kg	< 2.00	NMKL161 mod;ICP
Zinc	mg/kg	< 5.00	NMKL161 mod;ICP
Dioxins, furans and dioxine like PCBs			
PCDDs/PCDFs (WHO98-TEQ)	pg/g	< 0.30	EN 1948 modified, HRGC/HRMS
PCCDs/PCDFs and dioxine like PCBs (WHO98-TEQ)	pg/kg	< 0.50	EN 1948 modified, HRMS/HRMS
2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD)	µg/g	$< 6 \times 10^{-8}$	EN 1948 modified HRGC/HRMS
PCBs (28,52,101,118,138,153,180)	µg/g	$< 6 \times 10^{-4}$	EN 1948 modified HRGC/HRMS
PAHS			
Benzo(a)pyrene	µg/kg	< 2.0	GC-MS
Benzo(a)anthracene	µg/kg	< 2.0	GC-MS

3. **FDA Query:** GRAS notice 243 (D-Ribose) (rather than GRN 242) is referred to twice in section 2.6 in reference to *Trans*-Fatty acids.

   Response: We apologize for the incorrect citation. The correct reference should be GRN 242.

4. **FDA Query:** The Joint FAO/WHO Expert Committee on Food Additives (JECFA) provisional maximum tolerable intake PTWI for inorganic arsenic of 15 μg/kg body weight/week has been withdrawn, and is no longer appropriate.

   Response: Thank you for bringing to our attention the JECFA withdrawal of inorganic arsenic PTWI. We are sorry that we missed this recent JECFA withdrawal. As discussed in our GRAS notice regarding the safety of arsenic, not all forms of arsenic are associated with health concerns and organic arsenic is considered to be relatively non-toxic. As the specifications for inorganic arsenic for Superba® Krill Oil is set at < 0.05 ppm (below detection limits), the resulting intake of inorganic arsenic from the intended maximum exposure of 8.3 g of krill oil will be 0.415 μg/person/day (0.0069 μg/kg bw/day for an individual weighing 60 kg). The Agency for Toxic Substances and Disease Registry (ATSDR, 2007)[1] has derived Minimal Risk Level (MRL)[2] of 0.0003 mg/kg bw/day (0.3 μg/kg bw/day) for inorganic arsenic for chronic oral exposure. Compared to the MRL, the resulting intake of inorganic arsenic from the intended uses of krill oil is very small and is considered as safe.

   In 2008, the Natural Health Products Directorate, Health Canada[3] has suggested a limit of < 0.03 μg/kg bw/day for inorganic arsenic and < 20 μg/kg bw/day for organic arsenic. The batch analysis data of Superba® Krill Oil revealed maximum total arsenic levels of approximately 6 ppm, primarily containing organic arsenic. Based on this, the intended use of Superba™ Krill Oil will result in maximum daily intake of 50 μg/person/day or 0.8 μg/kg bw/day of total arsenic, majority of which is organic arsenic. The total intake of arsenic, including organic and inorganic, from the intended uses of krill oil is 25-fold lower than those set by Health Canada for organic arsenic.

   Additionally, in a 1993 Guidance Document for Arsenic in Shellfish[4], FDA provided guidance on determining permitted levels of contaminant using information on tolerable daily intake of arsenic. In this document the daily tolerable intake of arsenic is considered as 130 μg/person/day. The plausible concentration level of concern for crustacean shellfish at mean and 90th percentile was determined as 140 and 76 μg/person/day, respectively. Compared to this, the resulting intake of inorganic arsenic of 0.415 μg/person/day from the intended uses of krill oil is very small and is considered as safe.

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[1] Report available at the website: http://www.atsdr.cdc.gov/ToxProfiles/tp2.pdf

[2] An MRL is defined as an estimate of daily human exposure to a substance that is likely to be without an appreciable risk of adverse effects (noncarcinogenic) over a specified duration of exposure.

[3] Report available at the website: http://standards.nsf.org/apps/group_public/download.php/1436/4-addendum%20-%20DS-2008-2%20Arsenic%20HC%20-%20summary.pdf

[4] Food and Drug Administration. 1993. Guidance Document for Arsenic in Shellfish. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood (HFS-416), 200 C Street, SW, Washington, DC 20204. 44 pages.

In conclusion, the intake of Superba® Krill Oil from its intended uses does not represent a major increase in the expected total daily arsenic exposure, and especially with regards to inorganic arsenic. Based on the available information, the resulting intake of arsenic from the proposed uses of Superba® Krill Oil is considered as safe.

We hope the above information and clarification addresses your queries. If you have any questions or need additional explanation, please let me know.

Thank you for the opportunity to provide this explanation.

Best regards

Madhu Soni, PhD

Australian Government
IP Australia

P TM D PBR

ABN 38 113 872 755
P 1300 651 010
Int +61 2 6283 2999
www.ipaustralia.gov.au

5 October 2016

Pizzeys Patent and Trade Mark Attorneys Pty Ltd
PO Box 291
WODEN ACT 2606
Australia

Notice of Acceptance

Application Number: 2013227998

Applicant Name(s): Aker BioMarine Antarctic AS

Your Ref: 40741AKE/TMB

I am pleased to advise that there are no objections to the application. The Examiner has incorporated into the complete specification amendments made under Section 104 based on the following:

S104 amendments up to and including item number: 2

The application and complete specification were accepted on 27 September 2016 and a notice of the acceptance will appear in the Supplement to the Australian Official Journal of Patents on 20 October 2016.

A fee for acceptance of an application applies. This fee includes a component determined by the number of claims in excess of 20. If the acceptance has not been paid, an Invitation to Pay (ITP) will issue. If the amount is paid by the due date, your patent will be granted as soon as practicable after the 3 month period for opposition has expired.

The total number of claims at acceptance has been reported as: 8

The attached sheet provides bibliographic details of this application at acceptance and may be displayed on the Certificate of Grant. If you wish to amend any details prior to grant please do so within 3 months of the accepted advertised date.

If you need any further information please contact 1300 651 010. Alternatively, please visit us at www.ipaustralia.gov.au.

Yours faithfully

Patent and Plant Breeder's Rights Administration

Electronic certificates for Patents are now available
IP Australia is pleased to announce the introduction of electronic certificates for patents to our electronic channel customers. Non-electronic channel customers will receive a printed copy of the certificate on plain paper. For more information please visit www.ipaustralia.gov.au

Bibliographic Details at Acceptance

Details for Patent Application: 2013227998

Your Reference: 40741AKE/TMB

Acceptance Date: 27 September 2016

Acceptance to be Advertised: 20 October 2016

Complete Filing Date: 11 September 2013

OPI Date: 26 September 2013

National Phase Entry Date: Not Applicable

Applicant Name and Address *(as it will appear on certificate/s)*:
Aker BioMarine Antarctic AS
Fjordalleen 16, P.O. Box 1423 Vika, Oslo 0115, Norway

Title: BIOEFFECTIVE KRILL OIL COMPOSITIONS

Inventor Name(s): Mancinelli, Daniele
Bruheim, Inge
Tilseth, Snorre
Griinari, Mikko
Banni, Sebastiano
Cohn, Jeffrey

Agent Name: Pizzeys Patent and Trade Mark Attorneys Pty Ltd

Address for Correspondence: PO Box 291
WODEN ACT 2606
Australia

Address for Legal Service: PO Box 291
WODEN ACT 2606
Australia

Prior Art Documents:
JP 4057853 A
US 2004/0241249 A1
YAMAGUCHI K, et al., J. Agric. Food Chem, (1986), Vol 34, pp 904-907
WO 2000/023546 A1
WO 2007/123424 A1
Antarctica Select Wild Krill Oil [retrieved from the internet on 15 November 2015]: <URL:http://web.archive.org/web/20060426175256/http://www.aquasourceproducts.com/store/> published on 26 April 2006 as per Wayback Machine.

Priority Details:
Divisional of: 2011213836

International Classification:
A61K 35/60 (2006.01)

Continuation Fee Due Date: **28 March 2017**

Date of Patent: 28 March 2008

Expiry Date: 28 March 2028

Electronic Patent Application Fee Transmittal

Application Number:	15180439
Filing Date:	13-Jun-2016
Title of Invention:	BIOEFFECTIVE KRILL OIL COMPOSITIONS
First Named Inventor/Applicant Name:	Inge Bruheim
Filer:	John Mitchell Jones
Attorney Docket Number:	AKBM-14409/US-13/CON

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	27191471
Application Number:	15180439
International Application Number:	
Confirmation Number:	4687
Title of Invention:	BIOEFFECTIVE KRILL OIL COMPOSITIONS
First Named Inventor/Applicant Name:	Inge Bruheim
Customer Number:	72960
Filer:	John Mitchell Jones/Mallory Checkett
Filer Authorized By:	John Mitchell Jones
Attorney Docket Number:	AKBM-14409/US-13/CON
Receipt Date:	12-OCT-2016
Filing Date:	13-JUN-2016
Time Stamp:	14:31:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	898
Deposit Account	504302
Authorized User	Jones, J. Mitchell

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		161012ROA1_14409US13.pdf	197491 9f9938817f973fe86596ccf99c8025dfc52f5090	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	10

Warnings:

Information:

2	Information Disclosure Statement (IDS) Form (SB08)	14409US13CON_IDS_10-12-2016_.pdf	1035440 dbbc7c13ca97363ffd01311a48dbed2f9a7eb89d	no	4

Warnings:

Information:

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

3	Other Reference-Patent/App/Search documents	AU_ThirdPartyObservation20144256345_5-23-2016_scanned.pdf	2798563 108c577a4adb1d48106dc9f0f662bb2e2c573174	no	50

Warnings:

Information:

4	Other Reference-Patent/App/Search documents	AU_ThirdPartyObservation_2013227998_7-15-2016.pdf	1160150 39d9cdfbc7a8dcb779b830bd0a9b5340d2a4d825	no	6

Warnings:

Information:

5	Other Reference-Patent/App/Search documents	AU_EvidenceinSupport_20132 27998_9-22-2016.pdf	10659074 d0fba17e2a2f28c3dcba8bb18109da46dd4 0490e	no	58
Warnings:					
Information:					
6	Other Reference-Patent/App/Search documents	AUNoticeofAcceptance_20132 27998_10-5-2016.pdf	164760 1a9ed387828de1ef616004eeae56bb5baa6 e8daf	no	2
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	30585 9c12e446ecaa52dbcfefe2f07e566985bc3a efcc	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	16046063	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed	PTO/SB/25 PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION AND TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	15180439
Filing Date	13-Jun-2016
First Named Inventor	Inge Bruheim
Attorney Docket Number	AKBM-14409/US-13/CON
Title of Invention	BIOEFFECTIVE KRILL OIL COMPOSITIONS

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
AKER BIOMARINE ANTARCTIC AS	100 %

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

14136848 filed on 12/20/2013

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant appl[illegible] date of the full statutory term of prior patent number(s)

9072752

9078905

9320765

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicants claims the following fee status:

○ Small Entity

○ Micro Entity

◉ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 44174

○ A sole inventor

○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application

○ A joint inventor; all of whom are signing this request

Signature	/J. Mitchell Jones/

Name	J. Mitchell Jones

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	15180439
Filing Date:	13-Jun-2016
Title of Invention:	BIOEFFECTIVE KRILL OIL COMPOSITIONS
First Named Inventor/Applicant Name:	Inge Bruheim
Filer:	John Mitchell Jones/Mallory Checkett
Attorney Docket Number:	AKBM-14409/US-13/CON

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	160	160
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**160**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 15180439

Filing Date: 13-Jun-2016

Applicant/Patent under Reexamination: Bruheim et al.

Electronic Terminal Disclaimer filed on October 12, 2016

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	27191306
Application Number:	15180439
International Application Number:	
Confirmation Number:	4687
Title of Invention:	BIOEFFECTIVE KRILL OIL COMPOSITIONS
First Named Inventor/Applicant Name:	Inge Bruheim
Customer Number:	72960
Filer:	John Mitchell Jones/Mallory Checkett
Filer Authorized By:	John Mitchell Jones
Attorney Docket Number:	AKBM-14409/US-13/CON
Receipt Date:	12-OCT-2016
Filing Date:	13-JUN-2016
Time Stamp:	14:32:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$160
RAM confirmation Number	917
Deposit Account	504302
Authorized User	Jones, J. Mitchell

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Electronic Terminal Disclaimer-Filed	eTerminal-Disclaimer.pdf	36998 6faf0eec3947eadb758ad3b1f07ed1e7e15cd532	no	3
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30458 89a4adb2ff507fd76b46f57f5616ec6c57eac223	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	67456		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/180,439	Filing Date 06/13/2016	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **10/12/2016**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $420 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
DORRETTA BROOKS

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/180,439	06/13/2016	Inge Bruheim	AKBM-14409/US-13/CON	4687

72960 7590 10/20/2016

Casimir Jones, S.C.
2275 DEMING WAY, SUITE 310
MIDDLETON, WI 53562

EXAMINER
WARE, DEBORAH K

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
10/20/2016	ELECTRONIC

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

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@casimirjones.com
pto.correspondence@casimirjones.com

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	15/180,439	BRUHEIM ET AL.	
	Examiner	Art Unit	
	DEBBIE K. WARE	1651	

All participants (applicant, applicant's representative, PTO personnel):

(1) *DEBBIE K. WARE*. (3)_____.

(2) *J. MITCHELL JONES*. (4)_____.

Date of Interview: *11 October 2016*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☒112 ☐102 ☒103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *all pending claims*.

Identification of prior art discussed: *Sampalis (US2004/0241249) and all art applied in last office action as necessary*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

First Applicants stated that the ODP with respect to 14/370,324 is not proper because it is not commonly owned. Examiner stated that she will review the issue and reconsider the ODP issue with respect to this pointed argument. Furthermore, with respect to Sampalis the Applicants' Representative argued that the krill oil in Sampalis is made by the Beaudoin (US2005/0234587 and US 6800299). Applicants can show that the ether phospholipid content is only 2.46% which is below the claimed range. See Example 8 and Table 22 of instant specification and parent history files. Therefore, Applicants have shown that the Beaudoin method for production of krill oil cannot be expected to produce krill oil containing the same range of ether phospholipids as a percentage of the total krill oil composition. The Examiner will reconsider the claims on the merits upon their response on the record to the last office action.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/DEBBIE K. WARE/ Primary Examiner, Art Unit 1651	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

72960 7590 12/22/2016

Casimir Jones, S.C.
2275 DEMING WAY, SUITE 310
MIDDLETON, WI 53562

EXAMINER
WARE, DEBORAH K

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/22/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/180,439	06/13/2016	Inge Bruheim	AKBM-14409/US-13/CON	4687

TITLE OF INVENTION: BIOEFFECTIVE KRILL OIL COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	03/22/2017

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

72960 7590 12/22/2016
Casimir Jones, S.C.
2275 DEMING WAY, SUITE 310
MIDDLETON, WI 53562

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/180,439	06/13/2016	Inge Bruheim	AKBM-14409/US-13/CON	4687

TITLE OF INVENTION: BIOEFFECTIVE KRILL OIL COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	03/22/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
WARE, DEBORAH K	1651	424-520000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/180,439	06/13/2016	Inge Bruheim	AKBM-14409/US-13/CON	4687

72960 7590 12/22/2016

Casimir Jones, S.C.
2275 DEMING WAY, SUITE 310
MIDDLETON, WI 53562

EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/22/2016

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violati

Notice of Allowability	Application No. 15/180,439	Applicant(s) BRUHEIM ET AL.	
	Examiner DEBBIE K. WARE	Art Unit 1651	AIA (First Inventor to File) Status No

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *10/12/2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-20*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   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)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Deborah K. Ware/
Deborah K. Ware
Primary Examiner
Art Unit: 1651

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.W./

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15180439
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	1651
Examiner Name	WARE, DEBORAH K.
Attorney Docket Number	AKBM-14409/US-13/CON

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2011/050474	WO		2011-05-05	ACASTI PHARMA INC.		

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.W./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15180439
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	1651
Examiner Name	WARE, DEBORAH K.
Attorney Docket Number	AKBM-14409/US-13/CON

	1	Third Party Observation against corresponding AU Patent Application No. 2014256345, filed May 23, 2016, 50 pages	
	2	Third Party Observation against corresponding AU Patent Application NO. 2013227998, filed July 15, 2016, 6 pages	
	3	Evidence in Support of Opposition, AU Patent Application No. 2013227998, filed September 22, 2016, 22 pages	
	4	Notice of Acceptance of Application, AU Patent Application No. 2013227998, mailed October 5, 2016, 2 pages	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Deborah Ware/	Date Considered	10/31/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.W./

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(Not for submission under 37 CFR 1.99)

Application Number	15180439
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Art Unit	1651
Examiner Name	WARE, DEBORAH K.
Attorney Docket Number	AKBM-14409/US-13/CON

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/J. Mitchell Jones/	Date (YYYY-MM-DD)	2016-10-12
Name/Print	J. Mitchell Jones	Registration Number	44174

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.W./

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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Art Unit	1651
Examiner Name	WARE, DEBORAH K
Attorney Docket Number	AKBM-14409/US-13/CON

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140370115		2014-12-18	HOEM, Nils et al.	
	2	20100226977		2010-09-09	TILSETH SNORRE et al.	
	3	20140274968		2014-09-18	BERGE KJETIL et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2014/013335	WO		2014-01-23	HOEM, Nils et al.		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.W./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
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Examiner Name	WARE, DEBORAH K
Attorney Docket Number	AKBM-14409/US-13/CON

	2	102746941	CN		2014-01-15	UNIV. SHANDONG NORMAL		☒
	3	2909508	JP		1999-06-23	TAIYO FISHERY CO LTD.		☒
	4	2010/097701	WO		2010-09-02	AKER BIOMARINE ASA		☐
	5	2013/102792	WO		2013-07-11	Olympic Seafood AS		☐

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NON-PATENT LITERATURE DOCUMENTS [Remove]

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	International Search Report, International Patent Application No. PCT/IB2016/000208, mailed May 13, 2016, five pages	
	2	Partial International Search Report, International Patent Application No. PCT/IB2016/000326, mailed June 15, 2016, six pages	
	3	Database FSTA [Online} International Food Information Service, Frankfurt-Main; SHIBATA N. "Effect of fishing season on lipid content and composition of Antarctic krill (translated)" Database accession no. FS-1985-04-r-0091, abstract only	
	4	Statement of Grounds and Particulars, Rimfrost AS, filed June 10, 2016, Australian Patent Application No. 2014203179, 21 pages	

If you wish to add additional non-patent literature document citation information please click the Add button [Add]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.W./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15180439
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	1651
Examiner Name	WARE, DEBORAH K
Attorney Docket Number	AKBM-14409/US-13/CON

EXAMINER SIGNATURE

Examiner Signature	/Deborah Ware/	Date Considered	10/31/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.W./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15180439
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	1651
Examiner Name	WARE, DEBORAH K
Attorney Docket Number	AKBM-14409/US-13/CON

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/J. Mitchell Jones/	Date (YYYY-MM-DD)	2016-07-13
Name/Print	J. Mitchell Jones	Registration Number	44174

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.W./

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15180439	BRUHEIM ET AL.
	Examiner	**Art Unit**
	DEBBIE K WARE	1651

CPC						
Symbol					**Type**	**Version**
C11B		3	/	006	F	2013-01-01
A61K		9	/	4858	I	2013-01-01
A61K		31	/	122	I	2013-01-01
A61K		31	/	23	I	2013-01-01
A61K		31	/	683	I	2013-01-01
A61K		31	/	685	I	2013-01-01
A61K		35	/	612	I	2013-01-01
A61K		45	/	06	I	2013-01-01
A61K		31	/	202	I	2013-01-01
A61K		9	/	48	I	2013-01-01
A61K		31	/	20	I	2013-01-01
A61K		31	/	235	I	2013-01-01
A61K		9	/	0053	I	2013-01-01
A61K		9	/	4825	I	2013-01-01
			/			

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K		31	/	23	I	1	1	2013-01-01
A61K		2300	/	00	A	1	2	2013-01-01
A61K		31	/	683	I	2	1	2013-01-01
A61K		2300	/	00	A	2	2	2013-01-01
A61K		31	/	685	I	3	1	2013-01-01
A61K		2300	/	00	A	3	2	2013-01-01
A61K		31	/	122	I	4	1	2013-01-01
A61K		2300	/	00	A	4	2	2013-01-01

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/DEBBIE K WARE/ Primary Examiner.Art Unit 1651 (Primary Examiner)	10/31/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure None

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15180439	BRUHEIM ET AL.
	Examiner	**Art Unit**
	DEBBIE K WARE	1651

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION												
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED							
		C	1	1	B	3 / 00 (2006.01.01)								
CROSS REFERENCE(S)		A	6	1	K	9 / 48 (2006.01.01)								
		A	6	1	K	31 / 20 (2006.01.01)								
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)	A	6	1	K	31 / 122 (2006.01.01)								

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/DEBBIE K WARE/ Primary Examiner.Art Unit 1651	10/31/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	None

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15180439	BRUHEIM ET AL.
	Examiner	**Art Unit**
	DEBBIE K WARE	1651

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/DEBBIE K WARE/ Primary Examiner.Art Unit 1651 (Primary Examiner)	10/31/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure None

WEST Search History for Application 15180439

Creation Date: 2016103114:48

Interference Searches

Query	DB	Hits	Op.	Plur.	Thes.	Date
krill.clm. and oil.clm. and capsule.clm. and Euphausia.clm. and superba.clm.	PGPB, USPT	14	OR	YES		10-31-2016
(krill.clm. and oil.clm. and capsule.clm. and Euphausia.clm. and superba.clm.) and phospholipid.clm.	PGPB, USPT	12	OR	YES		10-31-2016
(krill.clm. and oil.clm. and capsule.clm. and Euphausia.clm. and superba.clm. and phospholipid.clm.) and astaxanthin.clm.	PGPB, USPT	10	OR	YES		10-31-2016

Prior Art Searches

Query	DB	Hits	Op.	Plur.	Thes.	Date
krill.clm. and oil.clm. and superba.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	20	OR	YES		07-09-2016
krill.clm. and oil.clm. and phospholipid.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	140	OR	YES		07-09-2016
krill.clm. and oil.clm. and phospholipids.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	140	OR	YES		07-09-2016

(krill.clm. and oil.clm. and phospholipids.clm.) and trimethyl.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	2	OR	YES		07-09-2016
krill and oil and phospholipid and trimethyl	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	108	OR	YES		07-09-2016
(krill and oil and phospholipid and trimethyl) and astaxanthin	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	57	OR	YES		07-09-2016
(krill and oil and phospholipid and trimethyl and astaxanthin) and ether	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	55	OR	YES		07-09-2016
(krill and oil and phospholipid and trimethyl and astaxanthin and ether) and Euphausia	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	13	OR	YES		07-09-2016
(krill and oil and phospholipid and trimethyl and astaxanthin and ether and Euphausia) and ((A61K2300/00 | A61K35/612 | A61K31/122 | A61K31/685 | A61K31/133 | A61K31/198 | A61K31/202 | A61K31/575 | A61K38/1767 | A61K9/2009 | A61K9/2054 | A61K9/2866 | A23L1/3006 | A23L1/33 |	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD,	13	OR	YES		07-09-2016

A23L1/305 | A23L1/0152 | A23L1/0153 | A23L1/3053 | A23L1/3252 | A23L1/0026 | A23L1/30 | A23L1/3008 | A23L1/326 | A23D9/013 | A23D9/007 | A23D9/02 | A23D7/011 | C11B1/10 | C11B1/025 | C11B1/104 | C11B3/006 | C11B1/06 | A23J1/04 | A23J3/34 | A23J3/04 | A23J7/00 | Y02P20/544 | A23K20/158 | A23K10/22 | A23K20/179 | A23K50/80 | C07K14/43509 | C07K19/00 | C07F9/103 | A23V2002/00).CPC.)	FPRS					
((A61K2300/00 | A61K35/612 | A61K31/122 | A61K31/685 | A61K31/133 | A61K31/198 | A61K31/202 | A61K31/575 | A61K38/1767 | A61K9/2009 | A61K9/2054 | A61K9/2866 | A23L1/3006 | A23L1/33 | A23L1/305 | A23L1/0152 | A23L1/0153 | A23L1/3053 | A23L1/3252 | A23L1/0026 | A23L1/30 | A23L1/3008 | A23L1/326 | A23D9/013 | A23D9/007 | A23D9/02 | A23D7/011 | C11B1/10 | C11B1/025 | C11B1/104 | C11B3/006 | C11B1/06 | A23J1/04 | A23J3/34 | A23J3/04 | A23J7/00 | Y02P20/544 | A23K20/158 | A23K10/22 | A23K20/179 | A23K50/80 | C07K14/43509 | C07K19/00 | C07F9/103 | A23V2002/00).CPC.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	528944	OR	YES		07-09-2016
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(((A61K2300/00 | A61K35/612 | A61K31/122 | A61K31/685 | A61K31/133 | A61K31/198 | A61K31/202 | A61K31/575 | A61K38/1767 | A61K9/2009 | A61K9/2054 | A61K9/2866 | A23L1/3006 | A23L1/33 | A23L1/305 | A23L1/0152 | A23L1/0153 | A23L1/3053 | A23L1/3252 | A23L1/0026 | A23L1/30 | A23L1/3008 | A23L1/326 | A23D9/013 |	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	40	OR	YES		07-09-2016

A23D9/007 | A23D9/02 | A23D7/011 | C11B1/10 | C11B1/025 | C11B1/104 | C11B3/006 | C11B1/06 | A23J1/04 | A23J3/34 | A23J3/04 | A23J7/00 | Y02P20/544 | A23K20/158 | A23K10/22 | A23K20/179 | A23K50/80 | C07K14/43509 | C07K19/00 | C07F9/103 | A23V2002/00).CPC.) and krill and oil and phospholipid) and trimethyl						
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(((A61K2300/00 | A61K35/612 | A61K31/122 | A61K31/685 | A61K31/133 | A61K31/198 | A61K31/202 | A61K31/575 | A61K38/1767 | A61K9/2009 | A61K9/2054 | A61K9/2866 | A23L1/3006 | A23L1/33 | A23L1/305 | A23L1/0152 | A23L1/0153 | A23L1/3053 | A23L1/3252 | A23L1/0026 | A23L1/30 | A23L1/3008 | A23L1/326 | A23D9/013 | A23D9/007 | A23D9/02 | A23D7/011 | C11B1/10 | C11B1/025 | C11B1/104 | C11B3/006 | C11B1/06 | A23J1/04 | A23J3/34 | A23J3/04 | A23J7/00 | Y02P20/544 | A23K20/158 | A23K10/22 | A23K20/179 | A23K50/80 | C07K14/43509 | C07K19/00 | C07F9/103 | A23V2002/00).CPC.) and krill and oil and phospholipid and trimethyl and astaxanthin) and trimethyl.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	3	OR	YES		07-09-2016
(krill.clm. and oil.clm. and superba.clm.) and trimethyl.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	0	OR	YES		07-09-2016

Inge.in. and Bruheim.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	116	OR	YES		07-09-2016
(Inge.in. and Bruheim.in.) and krill.clm. and phospholipid.clm. and trimethyl.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	1	OR	YES		07-09-2016
trimethyl.clm. and astaxanthin.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	19	OR	YES		07-09-2016
(trimethyl.clm. and astaxanthin.clm.) and krill.clm. and oil.clm. and phospholipid.clm.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	2	OR	YES		07-09-2016
20040241249	PGPB	1	OR	YES		07-09-2016
(20040241249) and trimethyl	PGPB	0	OR	YES		07-09-2016
(20040241249) and phospholipid	PGPB	1	OR	YES		07-09-2016
(20040241249 and phospholipid) and methyl	PGPB	0	OR	YES		07-09-2016
Krill and oil and (encapsulated or capsule)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	1182	OR	YES		07-09-2016

(Krill and oil and (encapsulated or capsule)) and methyl and amine	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	328	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule)) and trimethyl and amine	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	86	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule) and trimethyl and amine) and krill and oil	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	86	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule) and trimethyl and amine and krill and oil) and Euphausia	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	12	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule) and methyl and amine) and oil	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	328	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule) and trimethyl and amine and krill and oil) and capsule	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD,	63	OR	YES		07-09-2016

	FPRS					
(Krill and oil and (encapsulated or capsule) and trimethyl and amine and krill and oil and capsule) and encapsulated and krill and oil	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	6	OR	YES		07-09-2016
(Krill and oil and (encapsulated or capsule) and trimethyl and amine and krill and oil and capsule and encapsulated and krill and oil)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	6	OR	YES		07-09-2016
trimethylamine and krill	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	133	OR	YES		07-09-2016
(trimethylamine and krill) and oil	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	122	OR	YES		07-09-2016
(trimethylamine and krill and oil) and astaxanthin	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	64	OR	YES		07-09-2016
(trimethylamine and krill and oil and astaxanthin) and phospholipid	PGPB, USPT, USOC, EPAB, JPAB,	54	OR	YES		07-09-2016

	DWPI, TDBD, FPRS					
9375453.pn.	USPT	1	OR	YES		07-09-2016
9034388.pn.	USPT	1	OR	YES		07-09-2016
(9034388.pn.) and amine.clm.	USPT	0	OR	YES		07-09-2016
(9034388.pn.) and trimethyl.clm.	USPT	0	OR	YES		07-09-2016
(9375453.pn.) and amine.clm.	USPT	0	OR	YES		07-09-2016
(9375453.pn.) and trimethyl.clm.	USPT	0	OR	YES		07-09-2016
(krill.clm. and oil.clm. and capsule.clm. and Euphausia.clm. and superba.clm.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	14	OR	YES		10-31-2016
(krill.clm. and oil.clm. and capsule.clm. and Euphausia.clm. and superba.clm.) and ((A61K2300/00 | A61K31/122 | A61K31/23 | A61K31/683 | A61K31/685 | A61K35/612 | A61K31/202 | A61K31/20 | A61K31/235 | A61K45/06 | A61K9/0053 | A61K9/48 | A61K9/4825 | A61K9/4858 | A61K31/201 | C11B3/006 | C11B1/06 | C11B1/10 | C11B3/12 | A23L33/12 | A23L17/10 | A23L33/10 | A23L33/115 | A23L33/17 | A23D7/011 | A23D9/00 | A23D9/013 | A23J7/00 | A23K10/22 | A23K20/158 | A23K20/179 | A23K50/80 | C07F9/103).CPC.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	13	OR	YES		10-31-2016

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15180439	BRUHEIM ET AL.
	Examiner	Art Unit
	DEBBIE K WARE	1651

CPC- SEARCHED		
Symbol	Date	Examiner
A61K2300/00 | A61K35/612 | A61K31/122 | A61K31/685 | A61K31/133 | A61K31/198 | A61K31/202 | A61K31/575 | A61K38/1767 | A61K9/2009 | A61K9/2054 | A61K9/2866 | A23L1/3006 | A23L1/33 | A23L1/305 | A23L1/	7/2016	dkw
A61K2300/00 | A61K31/122 | A61K31/23 | A61K31/683 | A61K31/685 | A61K35/612 | A61K31/202 | A61K31/20 | A61K31/235 | A61K45/06 | A61K9/0053 | A61K9/48 | A61K9/4825 | A61K9/4858 | A61K31/201 | C11B3/006	10/2016	dkw

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
WEST_CPC_Inventor_Searches and NPL Searches: see search history print out	7/2016	dkw
WEST_CPC_Inventor_Searches and NPL Searches:updated	10/2016	dkw

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	CPC_WEST_Interference_Search: see search history print out	10/2016	dkw

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/180,439	06/13/2016	Inge Bruheim	AKBM-14409/US-13/CON	4687

72960 7590 01/27/2017

Casimir Jones, S.C.
2275 DEMING WAY, SUITE 310
MIDDLETON, WI 53562

EXAMINER
WARE, DEBORAH K

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
01/27/2017	ELECTRONIC

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

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@casimirjones.com
pto.correspondence@casimirjones.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 15180439
Applicant : Bruheim
Filing Date : 06/13/2016
Date Mailed : 01/27/2017

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Stephanie Smart/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 15180439

IDENTIFICATION OF SPECIFICATION/DRAWING INCONSISTENCIES

☐ On Page of the specification there is a brief description of FIG. , but the drawings filed do not include a drawing with that designation. Applicant must respond either by supplying the omitted drawing or by amending the specification to remove all references to that drawing.

☐ The drawings filed include FIG. , but the specification's brief description of the drawings does not describe a drawing with that designation. Applicant must respond either by amending the specification to add a brief description of that drawing or by correcting the drawings to remove the drawing in question.

☐ Drawings are present in the application and are referred to in the detailed description of the invention, but the specification does not contain a brief description of the drawings as required by 37 CFR 1.74 and 37 CFR 1.77(b)(8).

☒ Page page 50 of the specification refers to FIG. 20-25, but no drawing with that designation is described in the brief description of the drawings and no drawing with that designation is present in the application. Applicant must respond either by amending the specification to remove all references to that drawing, or by supplying that drawing and amending the specification to add a brief description of it.

☐ In the reissue application, FIG. , is labeled as "New" but is not described in the reissue specification's brief description of the drawings. Applicant must respond by amending the reissue specification's brief description of the drawings to add a brief description of the new drawing.

☐ OTHER:

☐ COMMENTS:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	15/180,439	Confirmation No.:	4687
Filed:	13-Jun-2016	Art Unit:	1651
First Inventor:	Bruheim et al.	Examiner:	WARE, Deborah
Title:	BIOEFFECTIVE KRILL OIL COMPOSITIONS		

RESPONSE TO THE NOTICE TO FILE CORRECTED APPLICATION PAPERS MAILED JANUARY 27, 2017

EFS Web Filed
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In response to the Notice to File Corrected Application Papers mailed January 27, 2017, Applicant submits the following:

AMENDMENTS TO THE SPECIFICATION

Please amend the specification at page 50, lines 8-20 as follows:

The purpose of this experiment was to investigate the effect of dietary krill oil on metabolic parameters in high-fat fed mice and to compare the effect of dietary krill oil with that of fish oil containing the same amount of omega-3 fatty acids. Four groups of C57BL/6 mice (n = 10 per group) were fed 1) chow (N), 2) high fat diet comprising 21% butter fat and 0.15% cholesterol (HF), 3) high fat diet + krill oil (HFKO) or 4) high fat diet + fish oil (HFFO). Treatment 3 contained 2.25% (w/w) krill oil as prepared in example 5 (except that the astaxanthin content was 500 ppm) which were equivalent to 0.36% omega-3 fatty acids. Treatment 4 also contained 0.36% omega-3 fatty acids obtained from regular 18-12 fish oil. The diets were fed to the mice for 7 weeks with free access to drinking water. Data represented in this example means ± SE. Columns not sharing a common letter are significantly different ($P < 0.05$) by ANOVA followed by Tukey's multiple comparison test. N = normal chow diet (n = 10); HF = high-fat diet (n = 10); HFFO = high-fat diet supplemented with fish oil (n = 9); HFKO = high-fat diet supplemented with krill oil (n = 8). The data are presented in Figures 12-19~~18-25~~.

REMARKS

In response to the Notice to File Corrected Application Papers mailed January 27, 2017, Applicant has amended the specification to correct the figure designations in Example 12. No new matter has been added.

No fees are believed to be due in connection with this filing. Nevertheless, if the Director finds any additional fees to be due in connection with this, or any other filing, authorization is given to charge said fees to Deposit Account No. 50-4302, referencing attorney docket number AKBM-14409/US-13/CON.

Respectfully,

Date: February 7, 2017

/J. Mitchell Jones/

J. Mitchell Jones
Registration No. 44,174
2275 Deming Way
Suite 310
Middleton, WI 53562
Phone: (608) 662-1277
Fax: (608) 662-1276

Electronic Acknowledgement Receipt

EFS ID:	28277518
Application Number:	15180439
International Application Number:	
Confirmation Number:	4687
Title of Invention:	BIOEFFECTIVE KRILL OIL COMPOSITIONS
First Named Inventor/Applicant Name:	Inge Bruheim
Customer Number:	72960
Filer:	John Mitchell Jones/Mallory Checkett
Filer Authorized By:	John Mitchell Jones
Attorney Docket Number:	AKBM-14409/US-13/CON
Receipt Date:	07-FEB-2017
Filing Date:	13-JUN-2016
Time Stamp:	16:32:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		14409US13CON_RNFCAP.pdf	117797 7a2d0abb474203860189422777f1cdc2f9a8ca80e	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment after Notice of Allowance (Rule 312)	1	1
	Specification	2	2
	Applicant Arguments/Remarks Made in an Amendment	3	3
Warnings:			
Information:			
	Total Files Size (in bytes):	117797	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/180,439	06/13/2016	Inge Bruheim	AKBM-14409/US-13/CON	4687

72960 7590 02/14/2017

Casimir Jones, S.C.
2275 DEMING WAY, SUITE 310
MIDDLETON, WI 53562

EXAMINER
WARE, DEBORAH K

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
02/14/2017	ELECTRONIC

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

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@casimirjones.com
pto.correspondence@casimirjones.com

Response to Rule 312 Communication	Application No. 15/180,439	Applicant(s)
	Examiner	Art Unit

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

1. ☒ The amendment filed on *02/07/2017* under 37 CFR 1.312 has been considered, and has been:

a) ☒ entered.

b) ☐ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

Publishing Division

B.Crittenden

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15180439
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	1651
Examiner Name	WARE, DEBORAH K.
Attorney Docket Number	AKBM-14409/US-13/CON

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15180439
	Filing Date	2016-06-13
	First Named Inventor	Inge Bruheim
	Art Unit	1651
	Examiner Name	WARE, DEBORAH K.
	Attorney Docket Number	AKBM-14409/US-13/CON

	1	Petition for Inter Partes Review, U.S. Patent No. 9,078,905, Case No.: IPR2017-00745, filed January 27, 2017
	2	Petition for Inter Partes Review, U.S. Patent No. 9,078,905, Case No.: IPR2017-00747, filed January 27, 2017
	3	Petition for Inter Partes Review, U.S. Patent No. 9,028,877, Case No.: IPR2017-00746, filed February 3, 2017
	4	Petition for Inter Partes Review, U.S. Patent No. 9,028,877, Case No.: IPR2017-00748, filed February 3, 2017
	5	Respondents' Notice of Prior Art, United States International Trade Commission, Investigation No. 337-TA-1019, dated February 1, 2017
	6	Notice of Opposition, Rimfrost AS, AU Patent Application No. 2014256345, filed March 1, 2017
	7	Notice of Opposition, Enzymotec Ltd., AU Patent Application No. 2014256345, filed March 1, 2017
	8	Respondents' Motion for Leave to Amend Their Response to the Complaint and Notice of Investigation, United States International Trade Commission, Investigation No. 337-TA-1019, dated March 14, 2017

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15180439
	Filing Date	2016-06-13
	First Named Inventor	Inge Bruheim
	Art Unit	1651
	Examiner Name	WARE, DEBORAH K.
	Attorney Docket Number	AKBM-14409/US-13/CON

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/J. Mitchell Jones/	Date (YYYY-MM-DD)	2017-03-17
Name/Print	J. Mitchell Jones	Registration Number	44174

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	28633619
Application Number:	15180439
International Application Number:	
Confirmation Number:	4687
Title of Invention:	BIOEFFECTIVE KRILL OIL COMPOSITIONS
First Named Inventor/Applicant Name:	Inge Bruheim
Customer Number:	72960
Filer:	John Mitchell Jones/Mallory Checkett
Filer Authorized By:	John Mitchell Jones
Attorney Docket Number:	AKBM-14409/US-13/CON
Receipt Date:	17-MAR-2017
Filing Date:	13-JUN-2016
Time Stamp:	17:31:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Other Reference-Patent/App/Search documents	IPR2017-00745_PetitionforInterPartesReview.pdf	1904523 e73e2b349d301fba71293a509c8e9400a7fb8c4a	no	82

Warnings:

Information:					
2	Other Reference-Patent/App/Search documents	IPR2017-00747_PetitionforInterPartesReview.pdf	1807020 8019fb462d1e065c45b8788de85f108f76528654	no	80
Warnings:					
Information:					
3	Other Reference-Patent/App/Search documents	2017-00746_877_IPR.pdf	2892891 0138d0266c9f0f0ba94b34e3753fa09a0c62c02c	no	93
Warnings:					
Information:					
4	Other Reference-Patent/App/Search documents	2017-00748_877_IPR.pdf	4355272 65b11f71e2b1f111ace884443e1fcb9a13cc5a6d	no	94
Warnings:					
Information:					
5	Other Reference-Patent/App/Search documents	ITC_337-TA-1019RespondentsNoticeofPriorArt_02_01_2017_uspto.pdf	352309 2469901b244d42b3587a63a591631030b25bf1dd	no	49
Warnings:					
Information:					
6	Other Reference-Patent/App/Search documents	AU2014256345_14409AU13_NoticeofOppositionFiledEnzymotec.pdf	99805 a8133ef4cba8f5534bfdedb1a8e81482d28a6430	no	3
Warnings:					
Information:					
7	Other Reference-Patent/App/Search documents	AU2014256345_14409AU13_NoticeofOppositionFiledRimfrost.pdf	92621 8741a6ce5631a2ddb80721338710b05a6abd3b0a	no	3
Warnings:					
Information:					
8	Other Reference-Patent/App/Search documents	ITC_337-TA-1019MotionforLeavetoAmend_uspto.pdf	308855 f466150cc0196cfdd1b840f454c6799526772c7a	no	66
Warnings:					
Information:					

9	Information Disclosure Statement (IDS) Form (SB08)	14409US13CON_IDS_3-17-17.pdf	1035596 201819dcde2b731b49c2c30395a0a3e3befe2e6a	no	4

Warnings:

Information:

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

Total Files Size (in bytes):	12848892

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS

Petitioner

v.

AKER BIOMARINE ANTARCTIC AS

Patent Owner

Case No.: IPR2017-00745

U.S. Patent 9,078,905

Issue Date: July 14, 2015

Title: Bioeffective Krill Oil Compositions

PETITION FOR *INTER PARTES* REVIEW

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ.*

TABLE OF CONTENTS

APPENDIX OF EXHIBITS

Exhibit Number	Exhibit Description
1001	U.S. Patent No. 9,078,905 B2, filed September 18, 2014 ('905 Patent)
1002	U.S. Provisional Patent Application No. 61/024,072, filed January 28, 2008 ('072 Provisional)
1003	U.S. Provisional Patent Application No. 60/983,446, filed October 29, 2007 ('446 Provisional)
1004	U.S. Provisional Patent Application No. 60/975,058, filed September 25, 2007 ('058 Provisional)
1005	U.S. Provisional Patent Application No. 60/920,483, filed March 28, 2007 ('483 Provisional)
1006	Declaration of Stephen Tallon (Tallon Decl.)
1007	Bottino, N.R.,"The Fatty Acids of Antarctic Phytoplankton and Euphausiids. Fatty Acid Exchange among Trophic Levels of the Ross Sea", Marine Biology, 27, 197-204 (1974) (Bottino)
1008	Budziński, E., P. Bykowski and D. Dutkiewicz, 1985, "Possibilities of processing and marketing of products made from Antarctic krill". FAO Fish.Tech. Pap., (268):46. (Budzinski)
1009	Catchpole and Tallon, WO 2007/123424, published November 1, 2007, "Process for Separating Lipid Materials," (Catchpole)

1010	Fricke et al., "Lipid, Sterol and Fatty Acid Composition of Antactic Krill (Euphausia superba Dana)," LIPIDS 19(11):821-827 (1984) (Fricke)
1011	Randolph, et al., U.S. Patent Application Publication No. US/2005/0058728 A1, "Cytokine Modulators and Related Method of Use"(Randolph)
1012	Sampalis [I] *et al.*, "Evaluation of the Effects of Neptune Krill Oil™ on the Management of Premenstrual Syndrome and Dysmenorrhea," Altern. Med. Rev. 8(2):171-179 (2003) (Sampalis I)
1013	Sampalis [II] *et al.*,WO 2003/011873, published February 13, 2003, "Natural Marine Source Phospholipids Comprising Flavonoids, Polyunsaturated Fatty Acids and Their Applications" (Sampalis II)
1014	Tanaka [I] et al., "Platelet – Activating Factor (PAF) – Like Phospholipids Formed During Peroxidation of Phosphatidylcholines from Different Foodstuffs," Biosci. Biotech. Biochem., 59(8) 1389-1393 (1995) (Tanaka I).
1015	Tanaka [II] et al., "Extraction of Phospholipids from Salmon Roe with Supercritical Carbon Dioxide and an Entrainer", Journal of Oleo Science Vol. 53 (2004) No. 9, p.17-424 (Tanaka II)
1016	Beaudoin et al., "Method of Extracting Lipids From Marine and Aquatic Animal Tissues," U.S. Patent No. 6,800,299 B1 filed July 25, 2001 (Beaudoin).

1017 Folch et al., "A simple method for the isolation and purification of total lipides from animal tissues," J. Biol. Chem. (1957) 226: 497-509 (Folch).

1018 Kochian et al, "Agricultural Approaches to Improving Phytonutrient Content in Plants: An Overview," Nutrition Reviews", Vol. 57, No. 9, September 1999: S13-S18.

1019 Porzio et al., "Encapsulation Compositions and Processes for Preparing the Same," U.S. Patent No. 7,488,503 B1 filed March 31, 2004 (Porzio).

1020 Bunea, et al., "Evaluation of The Effects Of Neptune Krill Oil On The Clinical Course of Hyperlipidemia," Altern Med Rev. 2004; 9:420–428 (Bunea).

1021 Complaint filed in *Aker Biomarine Antarctic AS v. Olympic Holding AS, et al.,* 1:16-CV-00035-LPS-CJB (D. Del).

1022 Affidavits of Service Filed in *Aker Biomarine Antarctic AS v. Olympic Holding AS, et al.,* No. 1:16-CV-00035 LPS-CJB (D. Del).

1023 Federal Register Notice of Institution of Investigation 337-TA-1019 on September 16, 2016 by the ITC (81 Fed. Reg. pages 63805-63806)

1024 File History to U.S. Patent No. 9,034,388 B2, Serial No, 12/057,775 ('388 File History)

1024 Part 1 - Pages 1-450
1024 Part 2 - Pages 451-900
1024 Part 3 - Pages 901-1350

1024 Part 4 - Pages 1351-1800
1024 Part 5 - Pages 1801-2250
1024 Part 6 - Pages 2251-2700
1024 Part 7 - Pages 2701-3083

1025 File History to U.S. Patent No. 9,028,877 B2, Serial No, 14/490,176 ('877 File History)

1025 Part 1 - Pages 1-375
1025 Part 2 - Pages 376-724

1026 File History to U.S. Patent No. 9,078,905 B2, Serial No, 14/490,221 ('905 File History)

1026 Part 1 - Pages 1-450
1026 Part 2 - Pages 451-882

1027 Saether et al., "Lipolysis post mortem in North Atlantic krill", Comp. Biochem. Physiol. Vol. 83B, No. 1, pp. 51-55, 1986 (Saether).

1028 Hawley's Condensed Chemical Dictionary, p. 893, 13th ed.,1997 (Hawley's)

1029 Webster's New Universal Unabridged Dictionary, 2nd ed., p. 732, 1983 (Webster's)

1030 Tehoharides, U.S. Patent Application Publication No. US/2006/0013905 A1, "Anti-Inflammatory Compositions For Treating Multiple Sclerosis" (Tehoharides)

1031 Halliday, Jess, "Neptune-Degussa Deal to Develop Phospholipids, Adapt Krill Oil," http://www.nutraingredients-usa.com/Suppliers2/Neptune-Degussa-deal-to-develop-phospholipids-adapt-krill-oil, December 12, 2005 (Neptune-DeGussa).

1032 Grantham, G.J., "The Utilization Of Krill", UNDP/FAO Southern Ocean Fisheries Survey Programme (1977) (Grantham).

1033 Yoshitomi, U.S. Patent Application Publication No. US/2003/0113432 A1, "Process For Making Dried Powdery and Granular Krill" (Yoshitomi).

I. THE PETITION

Petitioner, real party-in-interest, Rimfrost AS, a Norwegian corporation with its principal place of business at Vågsplassen, 6090, Fosnavåg, Norway, hereby petitions the Patent Trial and Appeal Board (the "Board" or the "PTAB") of the United States Patent and Trademark Office ("PTO"), pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.1 *et seq.*, to institute *inter partes* review and to find unpatentable and cancel Claims 1-20 of U.S. Patent No. 9,078,905, entitled "Bioeffective Krill Oil Compositions," issued July 14, 2015 (Serial No. 14/490,221, filed September 18, 2014) ("the '905 patent"), assigned to Aker Biomarine Antarctic AS. The '905 patent is submitted as Exhibit 1001. There is a reasonable likelihood that Petitioner will prevail with respect to at least one claim challenged in this petition.

II. MANDATORY NOTICES

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this petition.

A. Real parties-in-interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Olympic Holding AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, Bioriginal

Food and Science Corp., and Petitioner, Rimfrost AS, are identified as the real parties-in-interest. Several other entities have a majority ownership interest in the above-identified real parties-in-interest. Based upon those ownership interests, and in an abundance of caution, Petitioner also names Stig Remøy, SRR Invest AS, Rimfrost Holding AS, Pharmachem Laboratories, Inc., and Omega Protein Corporation as real parties-in-interest.

B. **Related matters (37 C.F.R. § 42.8(b)(2))**

Aker has asserted two patents – U.S. Patent Nos. 9,078,905 and 9,028,877 in a lawsuit captioned *Aker Biomarine Antarctic AS v. Olympic Holding AS; Rimfrost AS; Emerald Fisheries AS, Rimfrost USA, LLC; Avoca Inc.;* and *Bioriginal Food & Science Corp.* Case No. 1:16-CV-00035-LPS-CJB (D. Del.). (Complaint, Exhibit 1021). The litigation has been stayed pursuant to 28 U.S.C. § 1659 in view of Investigation No. 337-TA-1019 instituted by the United States International Trade Commission on September 16, 2016 as noticed in the Federal Register. The ITC proceeding, entitled *In the Matter of Certain Krill Oil Products and Krill Meal for Production of Krill Oil Products*, relates to U.S. Patent Nos.

9,028,877; 9,078,905[1]; 9,072,752; 9,320,765; and 9,375,453. The ITC investigation lists as respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited and Bioriginal Food & Science Corp. (Exhibit 1023).

C. **Counsel (37 C.F.R. §§ 42.8(b)(3) and 42.10(a))**

Petitioner designates the following individuals as its lead counsel and back-up lead counsel:

Lead Counsel	Back-up Lead Counsel
James F. Harrington Reg. No. 44,741 Hoffmann & Baron, LLP jfhdocket@hbiplaw.com (516)822-3550	Michael I. Chakansky Reg. No. 31,600 Hoffmann & Baron, LLP micdocket@hbiplaw.com (973)331-1700

[1] Petitioner believes the '905 patent is unenforceable due to the filing of an improper terminal disclaimer. During prosecution applicants filed a terminal disclaimer in an effort to overcome a double patenting rejection based upon copending U.S. Application No. 13/856,642. However, U.S. Application No. 13/856,642 (U.S. Patent No. 9,068,142) was assigned to Rimfrost AS' predecessor-in-interest, Olympic Seafood AS. The application for the '905 patent and U.S. Application No. 13/856,642 were therefore not commonly owned. As a result, Complainants in the ITC proceeding moved for partial termination, based on withdrawal of the '905 claims. The ALJ granted the motion to terminate as to the '905 patent and a determination of unenforceability was deemed moot.

Ronald J. Baron
Reg. No. 29,281
Hoffmann & Baron, LLP
rjbdocket@hbiplaw.com
(516)822-3550

John T. Gallagher
Reg. No. 35,516
Hoffmann & Baron, LLP
jtgdocket@hbiplaw.com
(516)822-3550

D. **Service information (37 C.F.R. §42.8(b)(4))**

Service on Petitioner may be made electronically by using the following email address: 905ipr1@hbiplaw.com and the email addresses above. Service on Petitioner may be made by Postal Mailing or Hand-delivery addressed to Lead and Back-up Lead Counsel at the following address, but electronic service above is requested:

Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset, New York 11791

This document, together with all exhibits referenced herein, has been served on the patent owner at its corporate headquarters, Oskenøyveien 10 No-1327, 1366 Lysaker, Norway, as well as the correspondence address of record for the

'905 patent: Casimir Jones, S.C., 2275 Deming Way, Suite 310, Middleton, Wisconsin 53562, and the address of Patent Owner's litigation counsel: Andrew F. Pratt, Esq., Venable LLP, 575 Seventh Street NW, Washington, DC 20004.

III. PAYMENT OF FEES

Pursuant to 37 C.F.R. §§ 42.103 and 42.15(a), the requisite filing fee of $25,000 (request fee of $9,000, post-institution fee of $14,000 and excess claims fee of $2,000) for a Petition for *Inter Partes* Review is submitted herewith. Claims 1-20 of the '905 patent are being reviewed as part of this Petition. The undersigned further authorizes payment from Deposit Account No. 08-2461 for any additional fees or refund that may be due in connection with the Petition.

IV. ADDITIONAL REQUIREMENTS FOR *INTER PARTES* REVIEW

A. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner hereby certifies that the '905 patent is available for *Inter Partes* Review and that Petitioner is not barred or estopped from requesting *Inter Partes* Review challenging the claims of '905 patent on the grounds identified herein. This Petition is timely filed under 35 U.S.C. §315(b) because it is filed within one year of the service of the Complaint alleging infringement of the '905 patent by Aker. *See, e.g.,* Exhibits 1021-1022.

B. **Level of Ordinary Skill in the Art**

As of the earliest priority date the '905 Patent is entitled to, that is January 28, 2008, a person of ordinary skill in the art ("POSITA") would have held an advanced degree in marine sciences, biochemistry, organic (especially lipid) chemistry, chemical or process engineering, or associated sciences with complementary understanding, either through education or experience, of organic chemistry and in particular lipid chemistry, chemical or process engineering, marine biology, nutrition, or associated sciences; and knowledge of or experience in the field of extraction. In addition, a POSITA would have had at least five years applied experience. (Tallon Decl. ¶27).

C. **Identification of Challenge and Relief Requested (37 C.F.R. § 42.104(b) and 37 C.F.R. § 42.22(a)(1))**

The precise relief requested by Petitioner is that Claims 1-20 are found unpatentable and cancelled from the '905 patent.

1. Claims for which Inter Partes Review is Requested (37 C.F.R. §42.104(b)(2))

Petitioner requests *Inter Partes* Review of Claims 1-20 of the '905 patent.

2. Specific Statutory Grounds on which the Challenge is Based (37 C.F.R. § 42.104(b)(2))

The specific statutory grounds for the challenge are as follows:

Ground	Reference(s)	Basis	Claims Challenged
1	Catchpole and Sampalis I	35 U.S.C. §103(a)	1-4 and 9-10
2	Catchpole, Sampalis I, and Randolph	35 U.S.C. §103(a)	5
3	Catchpole, Sampalis I, and Fricke	35 U.S.C. §103(a)	6, 12, 15-16, and 18
4	Catchpole, Sampalis I, Fricke, and Bottino	35 U.S.C. §103(a)	7-8, 13-14, 17, and 19-20
5	Catchpole, Sampalis I, and Bottino	35 U.S.C. §103(a)	11

Petitioner also relies on the expert declaration of Dr. Stephen Tallon (Exhibit 1006, hereinafter "Tallon Decl.").

3. Earliest Effective Priority Date

The '905 patent claims priority to Provisional Application No. 60/920,483, filed on March 28, 2007, Provisional Application No. 60/975,058, filed on September 25, 2007, Provisional Application No. 60/983,446, filed on October 29, 2007, and Provisional Application No. 61/024,072, filed on January 28, 2008. All of the issued claims in the '905 patent require the element that the recited krill oil comprise from about 3% to about 15% w/w or 3% to about 10% w/w ether phospholipids. Support of the claim element "ether phospholipid" – recited in

each '905 claim – was not introduced until the filing of U.S. Application No. 61/024,072 filed on January 28, 2008. (See Exhibits 1002-1005). Consequently, the earliest effective priority date for the claims of the '905 patent is January 28, 2008. (Tallon Decl. ¶ 34).

Thus, Aker cannot claim a priority date earlier than January 28, 2008.

4. Prior Art References

Other than Catchpole, all prior art references utilized herein were published more than one year prior to the earliest possible priority date of January 28, 2008, and therefore qualify as prior art under 35 U.S.C.§102(b). Catchpole has an international filing date of April 20, 2007 and was published on November 1, 2007 and, therefore, qualifies as a prior art reference under 35 U.S.C. § 102(e).[2]

§ 102(b) Reference	Publication Date	Exhibit No.
Sampalis I	May 2003	1012
Fricke	April 30, 1984	1010
Bottino	June 28, 1974	1007

[2] Catchpole also qualifies as a reference pursuant to 35 U.S.C. § 102(a).

§ 102(b) Reference	Publication Date	Exhibit No.
Randolph	March 17, 2005	1011

§ 102(e) Reference	Publication Date	Exhibit No.
Catchpole	November 1, 2007	1009

D. Claim Construction - Broadest Reasonable Interpretation ("BRI") (37 C.F.R. § 42.104(b)(3))

In an *inter partes* review, claim terms are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48756 and 48766 (Aug. 14, 2012).

The following discussion proposes constructions of terms in the challenged claims under the broadest reasonable construction standard. Any claim terms not included in the following discussion are to be given their broadest reasonable interpretation (BRI) in light of the specification as commonly understood by those of ordinary skill in the art. (M.P.E.P. § 2111.01(I)). Should the patent owner, in order to avoid the prior art, contend that the claims have a construction different

from their BRI, the appropriate course is for the patent owner to seek to amend the claims to expressly correspond to its contentions in this proceeding. *See* 77 Fed. Reg. 48764 (Aug. 14, 2012). Any such amendment would only be permissible if the proposed amended claims comply with 35 U.S.C. § 112.

Also, for the applicants of the '905 patent to act as their own lexicographer, the definition of a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). If a limitation is not necessary to give meaning to what the '905 patent inventors mean by a claim term, it would be "extraneous" and should not be read into the claim. *Renishaw*, 158 F.3d at 1249; *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988). The construction that stays true to the claim language and most naturally aligns with the inventors' description is likely the correct interpretation. *See Renishaw*, 158 F.3d at 1250.

Petitioner's position regarding the scope of the '905 patent claims should not be taken as an admission of the proper claim scope in other adjudicative forums where a different claim interpretation standard may apply, *e.g.*, in a patent infringement action. Moreover, Petitioner reserves all of its rights to further

challenge any claim terms of the '905 patent under 35 U.S.C. § 112, including by arguing that the terms are not definite, not supported by the written description, and/or not enabled. Further, as Petitioner is precluded from presenting challenges under 35 U.S.C. § 112 in an *inter partes* review, Petitioner's arguments in this Petition, or lack of arguments on any of these grounds, should not be interpreted as waiving or conflicting with invalidity arguments in other forums under 35 U.S.C. § 112.

The claim construction in a district court litigation or ITC proceeding can be narrower than in an *inter partes* review because it is performed in view of both the intrinsic and extrinsic record and is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.,* as of the effective filing date of the application. *Phillips v. AWH Corp.,* 415 F.3d 1303, 1313 (Fed. Cir. 2005). This construction may be narrower than the BRI. In addition, if the claim is still ambiguous in view of the relevant evidence during litigation, it should be construed to preserve the validity. *Id.* at 1327.

This standard does not apply to *inter partes* review. For purposes of *inter partes* review, each challenged claim must be given "its broadest reasonable constructions in light of the specification." 37 C.F.R. § 42.100(b); *see also Cuozzo*

Speed Technologies. LLC v. Lee, 136 S. Ct. 2131, 2142 (2016); *see also In re Cuozzo Speed Techs., LLC,* 778 F. 3d 1271, 1279 (Fed. Cir. 2015). The BRI must be consistent with the construction that one of ordinary skill in the art would reach and must take into account any special definition given to a claim term in the specification. *In re Am. Acad. Of Sci. Tech. Ctr.,* 367 F. 3d 1359, 1364 (Fed. Cir. 2004). Thus, solely for this proceeding, Petitioner's proposed constructions are set forth below. *See infra*, pp. 19-26. All other terms, not expressly discussed, should should be given their plain and ordinary meaning. Petitioner reserves the right to address any claim construction issue raised by Patent Owner.

V. SUMMARY OF THE '905 PATENT (EXHIBIT 1001)

A. Background of '905 Patent

The '905 patent relates to extracts from Antarctic krill that includes bioactive fatty acids. (Exhibit 1001, p. 0025, col. 1, lines 19-20). In the Detailed Description of the Invention, the patentees of the '905 patent state, "[t]his invention discloses novel krill oil compositions characterized by containing high levels of astaxanthin, phospholipids, included an enriched qualities of ether phospholipids, and omega-3 fatty acids." (Exhibit 1001, p. 0029, col. 9, lines 28-28-31).

However, as acknowledged in the Background of the Invention, "a krill oil composition has been disclosed comprising a phospholipid and/or a flavonoid. The phospholipid content and the krill lipid extract could be as high as 60% w/w and the EPA/DHA content as high as 35% (w/w). See, e.g., WO 03/011873." (Exhibit 1001, p. 0025, col. 1, lines 53-57). Patentees also acknowledged that krill oil compositions have been described as being effective for decreasing cholesterol, inhibiting platelet adhesion, inhibiting artery plaque formation, preventing hypertension, controlling arthritis symptoms, preventing skin cancer, enhancing transdermal transport, reducing the symptoms of premenstrual symptoms or controlling blood glucose levels in a patient. Citing, *e.g.*, WO 02/102394 (Exhibit 1001, p. 0025 col. 1, lines 46-52). Patentees also admit, "[s]upercritical fluid extraction with solvent modifier has previously been used to extract marine phospholipids from salmon roe, but has not been previously used to extract phospholipids from krill meal. See, *e.g.*, Tanaka *et al.*, *J. Oleo. Sci.* (2004), 53(9), 417-424." (Exhibit 1001, p. 0025, col. 1, line 65 to col. 2, line 2).

The analysis of the krill oil preparation disclosed in the '905 patent is provided in Table 21, which shows the amount of phospholipids, triglycerides, and

omega-3 fatty acids in the extract. Tables 22 and 23 provide the only ether phospholipid data in the entire specification. Example 8 concludes:

> The main polar ether phospholipids of the krill meal are alkylacylphosphatidylcholine (AAPC) at 7-9% of total polar lipids, lysoalkylacylphosphatidylcholine (LAAPC) at 1% of total polar lipids (TPL) and alkylacylphosphatidyl-ethanolamine (AAPE) at <1% of TPL.

(Exhibit 1001, p. 0041, col. 33, lines 9-14). (Tallon Decl. ¶184).

All issued claims recite the ether phospholipid limitation, which is the element that patentees rely upon for novelty. However, as demonstrated herein, it would have been obvious to a POSITA to encapsulate a krill oil having between 3 and 10% w/w of ether phospholipids.

B. Prosecution History of the '905 Patent

The '905 patent issued on July 14, 2015 from U.S. Application No. 14/490,221 filed September 18, 2014. The '905 patent is a continuation of U.S. Application No. 12/057,775 filed on March 28, 2008 and claims the benefit of four U.S. Provisional Applications: 61/024,072 filed on January 28, 2008; 60/983,446 filed on October 29, 2007; 60/975,058 filed on September 25, 2007; and 60/920,483 filed on March 28, 2007.

All of the claims of the '905 patent recite the claim limitation of "about 3% to about 15% w/w ether phospholipids" or "about 3% to about 10% w/w ether phospholipids." Applicants relied on this limitation in asserting patentability of the claims.

In parent U.S. Application no. 12/057,775, which granted as U.S. Patent No. 9,034,388, Applicants amended the claims to add the limitation "about 3% to about 10% ether phospholipid" and argued that the cited references do not teach extraction of a krill oil having the amended limitations. See response to Office Action dated September 7, 2012. (Exhibit 1024, part 2, pp. 0633 - 0650). The claims are directed to "[a] method of producing krill oil....from about 3% to about 10% w/w ether phospholipids." (Exhibit 1024, part 2, p. 0640).

In the '221 application which issued as the '905 patent, a Non-Final Office Action was mailed November 17, 2014 (Exhibit 1026, part 2, pp. 0622 - 0631) that rejected all the as-filed claims. In addition to several non-statutory double patenting rejections, the Examiner asserted two United States Patents as prior art arguing that the disclosures these patents made the as-filed claims obvious: Beaudoin (Exhibit 1016); and Porzio (Exhibit 1019). Beaudoin *et al.* was characterized as disclosing krill oil components including phospholipids and

triglycerides at similar concentrations as presented in the claims. This was combined with Porzio, which teaches how to encapsulate lipid compositions.

A Response to the Non-Final Office Action was filed on December 19, 2014 with no claim amendments. In an effort to distinguish the cited art, applicants maintained that the prior art did not disclose a krill oil comprising "from about 3% - 15% ether phospholipids." It was argued that Beaudoin's '299 patent extraction method was virtually identical to the NKO (Neptune Krill Oil) extraction process and would therefore would purportedly contain less than 3% ether phospholipids.

An analysis was presented of the NKO composition in the '905 patent (Example 8 and Table 22), showing that NKO has 7% AAPC and 1.2% LAAPC, *i.e.*, a total ether phospholipid content of 8.2% of total phospholipids. It was argued that this percentage corresponded to an actual 2.46% value[3] when relative to the krill oil (*e.g.*, based upon a 30% measurement of total NKO phospholipids). It was argued, "[a]pplicant respectfully submits that this demonstrates that krill oil made by the Beaudoin method does not contain the claimed range of 3% to 15%

[3] This is an admission that Beaudoin *et al.* describes krill oil having just below 3% ether phospholipids.

ether phospholipids as a percentage of the total krill oil composition." (Exhibit 1026, part 1 pp. 0242 - 0251).

A Final Rejection was mailed on February 17, 2015 (Exhibit 1026, part 1, pp. 0168 - 0177) where the non-statutory double patenting and obviousness rejections were maintained. The Examiner asserted that the calculated 2.46% ether phospholipid concentration in Beaudoin *et al.* was close enough to the claimed range such that it would be obvious for one of ordinary skill in the art to optimize the extraction process through routine means to increase the ether phospholipid content to the claimed 3% concentration because of the known health benefits of ether phospholipids.

A Response to the Final Office Action was filed on April 16, 2015 (Exhibit 1026, part 1, pp. 0159 - 0164) with no claim amendments. Instead, an argument concerning purported unexpected results was made in which the Applicants directed the examiner's attention to Example 9 and some selected figures referred to therein that allegedly compares the claimed krill oil (designated Superba or PL2) to prior art krill oil (designated (NKO or PL1).

Despite Applicants' assertion that "greater than 3% ether phospholipids have superior activity," there is no evidence in the specification for ether

phospholipid amounts other than that in Table 22 and Table 23. (Tallon Decl., ¶ 184). Moreover, the claims specify "about 3%" – not "greater than 3%." Nevertheless, it appears that this "superior results" assertion convinced the Examiner, since a Notice of Allowance followed on May 20, 2015 (with no written reasons for the allowance).

Accordingly, throughout the prosecution of the '905 patent family, Applicants repeatedly stressed the importance of krill oil compositions with greater than 3% ether phospholipids in gaining allowance of the claims.

C. **Construction of the '905 patent Claim Terms**

As discussed above, a claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." *See* 37 C.F.R. § 42.100(b).

Petitioner sets forth herein its recommended interpretation of certain claim terms, the scope of which are unclear on their face.

1. Claims 1, 12, and 18 - "krill oil"

The term "krill oil" is recited in all of the independent claims, *i.e.,* Claims 1, 12 and 18. The meaning of "krill oil" can be determined from the specification. In particular, the '905 specification states:

> In order to isolate the krill oil from krill, solvent extraction methods have been used. See, e.g., WO 00/23564. Krill lipids have been extracted by placing the material in a ketone solvent (e.g., acetone) in order to extract the lipid soluble fraction. (Exhibit 1001, p. 0025, col. 1, lines 31-34).

Accordingly, patentees equate krill oil with the lipids extracted from krill.

The '905 patent further describes "krill oil" is a lipid-rich extract of krill. This extract can primarily include phospholipids and neutral lipids in varying proportions. The Abstract of the '905 patent describes the "actual krill oils" as the oil extracted using a polar solvent after using a non-polar solvent to remove neutral lipids: "The krill oils are obtained from krill meal using supercritical fluid extraction in a two stage process. Stage 1 removes the neutral lipid by extracting with neat supercritical CO_2 or CO_2 plus approximately 5% of a co-solvent. Stage 2 extracts the *actual krill oils* by using supercritical CO_2 in combination with approximately 20% ethanol" (Exhibit 1001, Abstract, emphasis added) (Tallon Decl., ¶ 40). The '905 patent therefore also describes krill oil as a phospholipid rich extract produced by removing some or much of the triglyceride and other neutral oils. In addition, the '905 patent describes "combining said polar extract and said neutral extract to provide *Euphausia superba* krill oil...." (Exhibit 1001, p. 0027, col. 5, line 55 to col. 6, line 11) (Tallon Decl., ¶¶ 43-47).

Additionally, in the context of the '905 Patent, "krill oil" is a lipid-rich extract of krill that comprises phospholipids, as well as a lipid-rich extract of krill that comprises blends of polar lipids (phospholipids) and neutral lipids in varying proportions. The '905 Patent repeatedly refers to the krill oil composition as comprising blend of lipid fractions. "In some embodiments, krill oil composition comprises a blend of lipid fractions obtained from krill" (Exhibit 1001, col. 3, lines 26-27, Exhibit 1001, p. 0026). "In some embodiments, the blended krill oil product comprises a blend of lipid fractions obtained from *Euphausia superba*" (Exhibit 1001, col. 5, lines 43-45, col. 6, lines 50-52, col. 7, lines 18-20. (See Tallon Decl., ¶¶ 35-48).

Thus, the broadest reasonable construction of "krill oil" is "lipids extracted from krill." (Tallon Decl., ¶ 48).

2. Claims 1, 12, and 18 – "an effective amount of krill oil"

The claim limitation of "an *effective amount* of krill oil" is found in all of the independent claims. *See* Claims 1, 12, 18 (Exhibit 1001, p. 0042). In the only only two separate places of the specification where the term "effective amount" is disclosed, Patentees state, "effective amount" is stated by Patentees as follows: "[i]n some preferred embodiments, the effective amount of a krill oil composition

is from 0.2 grams to 10 grams of said krill oil composition." (Exhibit 1001, p. 0027, col. 6 lines 45-46; and p. 0028, col. 7, lines 12 - 14.) This range is also disclosed in the '446 Provisional Application, *e.g.,* Claim 4. (Exhibit 1003, p. 0029) (Tallon Decl., ¶¶ 49, 50, and 52).

The range of 0.2 to 10 grams of oil in the capsule is consistent with the beneficial effective range of krill oil taught in the prior art. *See e.g.*, Randolph: "[t]ypically, a composition contains between about 300 mg and about 3000 mg of a krill oil ingredient." (Exhibit 1011, p. 0006, [0040]) This effective amount is also consistent with the disclosure of Sampalis I wherein they state "[e]ach patient was asked to take two 1-gram soft gels of…NKO…." (Sampalis I, Exhibit 1012, p. 0004, 2nd col.) (Tallon Decl., ¶¶ 54-55).

Thus, the proper BRI of "effective amount of krill oil" as recited in the claims of the '905 patent is "at least the range of between 0.2 and 10 grams of krill oil." (Tallon Decl., ¶ 56).

3. Claim 4 - "polar solvent extract"

The element of "polar solvent extract" as recited in Claim 4 is not explicitly defined in the specification, but is described. In the Krill Processing section of the the Detailed Description, patentees disclose methods of making a *Euphausia*

superba krill oil by contacting a *Euphausia superba* preparation, such as *Euphausia superba* krill meal, with a polar solvent, such as ethanol to extract lipids. (Exhibit 1001, p. 0030, col. 12, lines 24-36). Patentees also disclose, "In some embodiments, krill oil is extracted from denatured krill meal. In some embodiments, the krill oil is extracted by contacting the krill meal with ethanol." (Exhibit 1001, p. 0030, col. 11, lines 3-5) (Tallon Decl. ¶ 57).

In the Background of the Invention, patentees admit:

> In order to isolate the krill oil from the krill, solvent extraction methods have been used. See, e.g., WO 00/23546. Krill lipids have been extracted by placing the material in a ketone solvent (e.g., acetone) in order to extract the lipid soluble fraction. This method involves separating the liquid and solid contents and recovering a lipid rich fraction from the liquid fraction by evaporation. Further processing steps include extracting and recovering by evaporation the remaining soluble lipid fraction from the contents by using a solvent such as ethanol. See, e.g., WO 00/23546.

(Exhibit 1001, p. 0025, col. 1, lines 31-40).

In the Detailed Description, patentees further state:

> In some embodiments, krill oil is extracted from the denatured krill meal. In some embodiments, the krill oil is extracted by contacting the krill meal with ethanol. In some embodiments, krill is then extracted with a ketone solvent such as acetone. In other embodiments, the krill oil is extracted by one or two step supercritical fluid extraction. In some embodiments, the

> supercritical fluid extraction uses carbon dioxide and neutral krill oil is produced. In some embodiments, the supercritical fluid extraction uses carbon dioxide with the addition of a polar entrainer, such as ethanol, to produce a polar krill oil. In In some embodiments, the krill oil meal is first extracted with carbon dioxide followed by carbon dioxide with a polar entrainer, or vice versa. In some embodiments, the krill meal is first extracted with CO_2 supplemented with a low amount of a polar co-solvent (e.g., from about 1% to about 10%, preferably about 5%) such a C_1-C_3 monohydric alcohol, preferably ethanol, followed by extraction with CO_2 supplemented with a high amount of a polar co-solvent (from about 10% to about 30%, preferably about 23%) such as such a C_1-C_3 monohydric alcohol, preferably ethanol, or vice versa. Surprisingly, it has been found that use of a low amount of polar solvent in the CO_2 as an entrainer facilitates the extraction of neutral lipid components and astaxanthin in a single step. Use of the high of polar solvent as an entrainer in the other step facilitates extraction of ether phospholipids, as well as non-ether phospholipids.

(Exhibit 1001, p. 0030, col. 11, lines 3-29).

Thus, patentees contemplated extraction with either a polar solvent or a mixture of a polar solvent and supercritical CO_2. (Tallon Decl., ¶¶ 58-60).

The solvent used must also be capable of extracting lipids that include phospholipids. The '905 patent explains, "In some embodiments, the present invention provides a method of making a *Euphausia superba* krill oil composition comprising contacting *Euphausia superba* with a polar solvent to provide an polar

extract comprising phospholipids…." (Exhibit 1001, p. 0030, col. 12, lines 12-12-16). Typical polar organic solvents (pure or mixtures) used in conventional industrial practice that satisfy these criteria include alcohols (*e.g.*, methanol, ethanol, and isopropyl alcohol), ketones (particularly acetone), and esters (*e.g.*, ethyl acetate) (Tallon Decl., ¶ 61).

Thus, the broadest reasonable construction of "polar solvent extract" is "material extracted in the presence of a solvent or mixtures of solvents capable of extracting polar lipids comprising phospholipids." (Tallon Decl., ¶ 62).

4. Claim 5 - "phytonutrient"

The specification does not expressly define the term "phytonutrient." However, the specification states:

> In still further embodiments, the compositions comprise at least one phytonutrient (e.g., soy isoflavonoids, oligomeric proanthcyanidins, inodol 3 carbinol, sulforaphone, fibrous ligands, plant phytosterols, ferulic acid, anthocyanocides, triterpenes, omega 3/6 fatty acids, conjugated fatty acids such as conjugated linoleic acid and conjugated linolenic acid, polyacetylene, quinones, terpenes, cathechins, gallates, and querctin). Sources of plant phytonutrients include but are not limited to, soy lecithin, soy isoflavones, brown rice germ, royal jelly, bee propolis, acerola berry juice powder, Japanese green tea, grape seed extract, grape skin extract, carrot juice, bilberry, flaxseed meal, bee pollen, ginkgo biloba, primrose (evening primrose oil), red clover, burdock root, dandelion,

> parsley, rose hips, milk thistle, ginger, Siberian ginseng, rosemary, curcumin, garlic, lycopene, grapefruit seed extract spinach and broccoli.

(Exhibit 1001, p. 0032, col. 15, lines 52-67). (Tallon Decl., ¶¶ 64-65).

The examples provided in the '905 patent are consistent with the extrinsic evidence.

For example, Kochian (1999) (Exhibit 1018), provides an overview of various agricultural approaches to improving phytonutrient content in plants. Kochian defines the literal definition of the term "phytonutrient" as "a nutrient derived from plants," and further explains that "we would be talking about a plant-based substance essential for proper metabolism and function in humans.... These compounds could play an important role in improving human health by reducing the impact of certain chronic diseases (e.g. heart disease, cancer) and the effects of aging." (Kochian, Exhibit 1018, pp. 0001-0002) (Tallon Decl., ¶ 63).

Thus, the broadest reasonable construction of the term "phytonutrient" is "a plant-derived compound that has a positive impact on human health or nutrition." (Tallon Decl., ¶ 66).

VI. EACH GROUND PROVIDES MORE THAN A REASONABLE LIKELIHOOD THAT EACH CLAIM OF THE '905 PATENT IS UNPATENTABLE

A detailed discussion of each ground for claim invalidation, *i.e.*, Grounds 1-5, is detailed below. In support of the invalidity arguments, Petitioner relies upon the accompanying Declaration of Dr. Stephen Tallon ("Tallon Decl.") (Exhibit 1006).

Petitioner notes that all the prior art cited herein may be combined with each other, and should not be limited by the way Petitioner has organized the grounds and prior art citations herein. Thus, absence of an entry in any claim chart is not an admission that the particular prior art does not disclose, teach and/or possess that element. Petitioner expressly reserves the right to present arguments, if applicable, that the particular prior art does disclose, teach and/or possess same.

A. Ground 1: §103(a) – Catchpole and Sampalis I [Claims 1-4 and 9-10]

Claim 1 of the '905 patent relates to an encapsulated krill oil and is set forth below:

> 1. Encapsulated krill oil comprising:
> a capsule containing an effective amount of krill oil,
> said krill oil comprising from about 3% to about 15 %
> w/w ether phospholipids.

Claim 1 of the '905 patent recites krill oil having from about 3% to about 15% w/w ether phospholipids. Catchpole is an international patent publication relating to phospholipids and methods for separating lipid materials from various natural feedstock material. (Exhibit 1009) (See Tallon Decl., ¶¶ 83-92). Catchpole describes that phospholipids have been implicated in conferring a number of health benefits including brain health, skin health, eczema treatment, anti-infection, wound healing, gut microbiota modifications, anti-cancer activity, alleviation of arthritis, improvement of cardiovascular health, and treatment of metabolic syndromes. Phospholipids can also be utilized in sports nutrition. (Exhibit 1009, p. 0001, line 11 - p. 0002, line 2). Catchpole also describes that an object of the invention is to provide a process for producing a product that contains desirable levels of particular phospholipids. (Exhibit 1009, p. 0003, lines 28-29) (Tallon Decl., ¶ 84). Catchpole further teaches that the described compositions and methods may be employed in a number of applications including infant formulas, brain health, sports nutrition and dermatological compositions. (Exhibit 1009, p. 0025, lines 9-13) (Tallon Decl., ¶¶ 85-86).

Catchpole also expressly describes that one of the feedstock materials that can be used to obtain phospholipids include marine animals such as krill. (Exhibit

(Exhibit 1009, p. 0007, lines 5-6, p. 0024, lines 1-19.) (Tallon Decl., ¶¶ 87, 88). In particular, Example 18 of Catchpole shows the fractionation of krill lipids from krill powder. The corresponding phospholipid concentrations are reported in Table 16. (Exhibit 1009, p. 0024, lines 1-19.) (Tallon Decl., ¶¶ 88-91). Extract and residue fractions were analyzed for phospholipid content and profiled by ^{31}P-^{31}P-NMR. The phospholipid fractions analyzed were phosphatidylchoine (PC), phosphatidylinositol (PI), phosphatidylethanolamine (PE), plasmalogens (PL), phosphonolipids (PP), alkylacylphospholipids (ALP), sphingomyelin (SM), ceramide aminoethylphosphonate (CAEP), phosphatidylserine (PS), and cardiolipin (CL). Of these, AAPC and AAPE are well known ether phospholipids. phospholipids. (Exhibit 1009, p. 0014, lines 7-11) (Tallon Decl., ¶ 90, 91).

In particular, Extract 2 from Table 16 describes krill oil having 4.6% AAPC (alkylacylphosphatidylcholine) and 0.2% AAPE (alkylacylphosphatidylethanolamine).

Table 16

	Yield % of feed	Composition, %							
		PC	PI	PS	PE	CL	AAPC	AAPE	Other compounds
Feed		6.6	0.0	0.0	0.4	0.1	0.6	0.1	78.6
Extract 2	4.3	39.8	0.0	0.0	0.3	0.2	4.6	0.2	53.7
Residue	79.2	3.6	0.0	0.0	0.3	0.2	0.5	0.1	93.4

(Exhibit 1009, Tallon Decl. ¶¶ 91 and 193). Thus, the analysis of Extract 2 expressly describes a krill extract having 4.8% ether phospholipids, which is within the 3% of 15% range recited in Claim 1. (Tallon Decl., ¶¶ 91, 92, 193).

Sampalis I (Exhibit 1012) describes administration of an effective amount of encapsulated krill oil in the form of a soft gel. Sampalis I teaches the beneficial health effects achieved by the administration of a commercial krill oil product, *e.g.,* Neptune Krill Oil™. The authors describe, "Neptune Krill Oil™ (NKO™) [as] a natural health product extracted from Antarctic krill also known as *Euphausia superba*. *Euphausia superba*, a zooplankton crustacean, is rich in phospholipids and triglycerides carrying long-chain omega-3 polyunsaturated fatty acids, mainly EPA and DHA, and in various potent antioxidants…." (Exhibit 1012, p. 0004). (Tallon Decl., ¶¶ 68-69). Sampalis I further describes the administration of "two 1-gram soft gels of either NKO or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial." (Exhibit 1012, p. 0004). Sampalis I also teaches that the the NKO krill oil product is rich in phospholipids and triglycerides carrying long chain omega-3 polyunsaturated fatty acids such as EPA and DHA and is rich in various potent antioxidants including vitamins A and E, astaxanthin, and a novel

flavonoid. (Exhibit 1012, p. 0004). (Tallon Decl., ¶¶ 68-71). Accordingly, Sampalis I expressly describes an encapsulated krill oil that includes a capsule containing an effective amount of krill oil. (Tallon Decl., ¶¶ 71, 193).

Thus, it would be obvious to a POSITA to take the krill oil disclosed in Catchpole and encapsulate the krill oil as disclosed in Sampalis I. (Tallon Decl., ¶¶ 193-195, 201).

Dependent Claim 2 requires the additional element wherein said krill oil comprises at least 30% total phospholipids w/w. Table 16 of Example 18 of Catchpole expressly discloses the krill Extract 2 contains 45.1% total phospholipids (PC+PI+PS+PE+CL+AAPC+AAPE).

Table 16

	Yield % of feed	Composition, %							
		PC	PI	PS	PE	CL	AAPC	AAPE	Other compounds
Feed		6.6	0.0	0.0	0.4	0.1	0.6	0.1	78.6
Extract 2	4.3	39.8	0.0	0.0	0.3	0.2	4.6	0.2	53.7
Residue	79.2	3.6	0.0	0.0	0.3	0.2	0.5	0.1	93.4

(Exhibit 1009, p. 0024). Thus, krill oil containing at least 30% phospholipids w/w would have been obvious in view of the teachings of Catchpole and Sampalis I. (Tallon Decl., ¶¶ 91, 92, 196, 201).

Dependent Claim 3 further requires the element of the krill oil comprise at least 30% phosphatidylcholine w/w. Table 16 of Example 18 in Catchpole expressly discloses that the krill Extract 2 has a phosphatidylcholine (PC) level of 39.8%.

Table 16

	Yield % of feed	Composition, %							
		PC	PI	PS	PE	CL	AAPC	AAPE	Other compounds
Feed		6.6	0.0	0.0	0.4	0.1	0.6	0.1	78.6
Extract 2	4.3	39.8	0.0	0.0	0.3	0.2	4.6	0.2	53.7
Residue	79.2	3.6	0.0	0.0	0.3	0.2	0.5	0.1	93.4

(Exhibit 1009, p. 0024). Thus, Claim 3 would have been obvious to one skill in the art based upon the combination of Catchpole and Sampalis I. (Tallon Decl., ¶¶ 91, 92, 197, 201).

Dependent Claim 4 further recites that the krill oil is a polar solvent extract of krill. Example 18 of Catchpole expressly describes extraction of krill lipids using CO_2 and absolute ethanol using a mass ratio of ethanol to CO_2 of 11%. (Exhibit 1009, p. 0024, lines 8-9) (Tallon Decl., ¶¶ 87, 88). As described above, applicants readily acknowledged in the specification that ethanol is a polar solvent, and therefore Claim 4 would have been obvious over Catchpole and Sampalis I. (Tallon Decl., ¶¶ 87,88,198, 201).

Dependent Claim 9 relates to the encapsulated krill oil of Claim 1, wherein the krill oil is *Euphausia superba*. Sampalis I explains that the commercial Neptune Krill Oil™ product (NKO) administered is extracted from Antarctic krill, also known as *Euphausia superba*. Sampalis I also confirms it was known that *Euphausia superba* is rich in phospholipids and triglycerides carrying long chain omega-3 polyunsaturated fatty acids, such as EPA and DHA. (Exhibit 1012, p. 0004). Thus, Claim 9 would have been obvious based upon the teaching of Catchpole and Sampalis I. (Tallon Decl., ¶¶ 68, 69,199, 201).

Dependent Claim 10 recites encapsulated krill oil of Claim 1, wherein the capsule is a soft gel capsule. In Sampalis I, each patient took two 1-gram soft gel capsules of the commercially available NKO product. (Exhibit 1012, p. 0004). Thus, as of the earliest effective priority date for the '905 patent, it was well known to administer krill oil in a soft gel capsule. Thus, Claim 10 is obvious over Catchpole and Sampalis I. (Tallon Decl., ¶¶ 71, 200, 201).

Reason to combine

A person of ordinary skill in the art ("POSITA") seeking to achieve the various health benefits described in Catchpole, as well as Sampalis I would have been motivated to combine the krill oil composition expressly recited in Example

18 of Catchpole with the mode of administration taught by Sampalis I (*i.e.*, encapsulated gel caps) to obtain the subject matter recited in Claim 1. As discussed above, Catchpole details a host of health benefits obtained from the administration of phospholipids, including ether phospholipid compositions extracted from krill. (Tallon Decl., ¶¶ 85-86). Further, Sampalis I teaches that krill oil extracted from *Euphausia superba* can be administered in an encapsulated dosage form, as evidenced by the commerical Neptune Krill Oil™ (NKO™) product, for the management of premenstrual syndrome and dysmenorrhea. (Exhibit 1012, p. 0004) (Tallon Decl., ¶¶ 70-71).

Catchpole teaches that supercritical fluid extraction processes using CO_2 are popular because of processing and consumer benefits. For example, CO_2 can be easily removed from the final product by reducing the pressure, whereupon CO_2 reverts to a gaseous state. The extract is considered to be more "natural" than extracts produced using other solvents. (Exhibit 1009, p. 0002, lines 18-25) (Tallon Decl., ¶ 83). Also, Catchpole discloses that it is an object of the invention described therein to provide a process for producing a product that contains desirable levels of particular phospholipids. (Exhibit 1009, p. 0003, lines 27-29) (Tallon Decl., ¶ 84). Therefore, a POSITA would have been motivated to include

the extract of Catchpole, which extract it describes as being "more 'natural' than extracts using other solvents" in the soft gel krill oil capsule taught by Sampalis I. (Tallon Decl., ¶¶ 28-32, 200, 201).

B. Ground 2: §103(a) – Catchpole, Sampalis I and Randolph [Claim 5]

Claim 5 relates to the encapsulated krill oil of Claim 1, wherein the capsule contains a phytonutrient derived from a source other than krill. The discussion regarding the obviousness of claim 1 in Ground 1 is incorporated herein.

Randolph discloses compositions for modulating cytokines to regulate an inflammatory or immunomodulatory response. The compositions can include at least one of rosehips, grape seed extract, resveratrol [grape skin extract], krill oil, at least one type of xanthophyll (*e.g.,* astaxanthin) and ferulic acid. "Based on the the cytokine modulation and cytokine response inhibition of the composition, it can be used to regulate an immunomodulatory and/or inflammatory response, and subsequently treat diseases and/or abnormal conditions associated with inflammatory response, for example, cardiovascular conditions, arthritis, osteoporosis and Alzheimer's disease." (Exhibit 1011, Abstract, p. 0001, *see also* p. 0004, [0021]). Randolph notes that "treatments have been developed to

regulate the release of inflammatory cytokines, or the signaling of inflammatory cytokines, specifically the interleukin-1 (IL-1) cytokine from macrophages." (Exhibit 1011, p. 0004, [0007]) (Tallon Decl. ¶¶ 119, 120, 121).

In the Summary of Invention, Randolph discloses "[t]he present invention… provides a composition that regulates interleukin cytokines and/or regulates a physiological response caused by interleukin cytokines. This regulation is effective in controlling an immune response and/or an inflammatory condition. In one aspect, the composition can comprise rosehips and at least one of blackberry, blueberry and elderberry. *In another aspect, the composition can comprise rosehips and krill oil.* In yet another aspect, *the composition can comprise rosehips, blackberry, blueberry, elderberry and krill oil.*" (Exhibit 1011, p. 0004, [0008] (emphasis added)). (Tallon Decl., ¶¶ 121-122).

Randolph further discloses, "[e]xamples of rosehip ingredients include, without limitation, dried rosehips, rosehip oil, and rosehip extracts." (Exhibit 1011, p. 0005, [0024]). Randolph also teaches that "[a] composition of the invention can include krill oil. Krill oil can be obtained from any member of the *Euphausia* family, for example *Euphausia superba*. Conventional oil producing

techniques can be used to obtain the krill oil. In addition, krill oil can be obtained commercially from Neptune Technologies and Bioresources of Quebec, Canada." (Exhibit 1011, p. 0006, [0039]). In addition, Randolph explains, "[a] composition can contain any amount of krill oil. For example, at least about 1 percent (e.g., at least about 2, 3, 4, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, or 90 percent) of a dietary supplement can be a krill oil. Typically, a composition contains between about 300 mg and about 3000 mg of a krill oil ingredient." (Exhibit 1011, p. 0006, [0040], see also Table III, pp. 0009-0010). Randolph further discloses, "[w]here the composition includes resveratrol, *the resveratrol can be obtained from an extract of grape skin* or other grape components. Resveratrol can be present in the composition in one or more different forms, for example, extract form and powder form." (Exhibit 1011, p. 0006, [0041], (emphasis added)) (Tallon Decl., ¶¶ 123-126).

With regard to the dosage form, Randolph teaches that, "[t]he ingredients of the composition can be processed into forms having varying delivery systems. For For example, *the ingredients can be processed and included in capsules*, tablets, gel tabs, lozenges, strips, granules, powders, concentrates, solutions, lotions, creams or suspensions." (Exhibit 1011, p. 0007, [0046] (emphasis added), see

also p. 0007 [0049], (rosehips in capsule form)). They further disclose, "[a] soft gel capsule of the composition can be manufactured to include krill oil. This capsule can be manufactured using conventional capsule manufacturing techniques. The amount of krill oil in each capsule is about 300 mg." (Exhibit 1011, p. 0007, [0052]) (Tallon Decl., ¶¶ 127, 128).

As explained above, the '905 patent expressly identifies grape skin extract and rose hips as sources of plant phytonutrients. Thus, it would have been obvious to a POSITA to include a phytonutrient (in fact, the exact same ones as in the '905 patent) in an encapsulated krill oil as set forth in Claim 5. (Tallon Decl., ¶¶ 202-211).

Reason to combine

A POSITA would have possessed reasons to combine the teaching of Randolph with the references discussed in Ground I because Randolph discloses the health benefits of the composition that includes both krill oil and phytonutrients. As mentioned above, Sampalis I evaluated the effectiveness of Neptune Krill Oil™ for the management of premenstrual syndrome and dysmenorrhea. (Exhibit 1012, p. 0004). Sampalis I also described previous studies that reinforced the theory that one of the main causes of PMS is

inflammation. Sampalis I, explained that omega-3 acids in krill oil promote the production of anti-inflammatory prostaglandins. (See also, Exhibit 1020, p. 0006). (Tallon Decl., ¶¶ 70, 209-211).

Catchpole, as discussed above, teaches processes for extracting phospholipids from krill (Exhibit 1009, p. 0024) and that such phospholipids can confer health benefits including improving cardiovascular health and treatment of metabolic syndromes. (Exhibit 1009, p. 0001, line 29 - p. 0002, line 2) (Tallon Decl., ¶¶ 85-86). Catchpole also describes that the recited process produces a more natural extract. (Exhibit 1009, p. 0002, lines 18-25) (Tallon Decl., ¶ 83).

Accordingly, a POSITA would have been motivated to include the lipid extract extracted by the process in Catchpole, in combination with a phytonutrient as taught by Randolph in the krill oil composition described in Sampalis I. (Tallon Decl., ¶¶ 28-32, 202-211).

C. Ground 3: §103(a) to Catchpole, Sampalis I and Fricke [Claims 6, 12, 15-16, and 18]

Claim 6 relates to the encapsulated krill oil of Claim 1 wherein the krill oil further includes from about 3% to about 10% ether phospholipids. The discussion regarding obviousness in Ground 1 is incorporated herein.

As detailed above, Catchpole teaches the fractionation of krill lipids extracted from krill. Table 16 in Example 18 of Catchpole expressly discloses that krill Extract 2 includes 4.6% AAPC and 0.2% AAPE. Both AAPC and AAPE are ether phospholipids. (Exhibit 1009, p. 0024, lines 1-19.). Accordingly, Catchpole discloses a lipid extract totaling 4.8% ether phospholipid which is between 3 and 10%. (Tallon Decl., ¶¶ 88, 91, 92, 214).

Claim 6 also requires from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the krill oil is from about 30% to 60% w/w. Table 16 of Example 18 of Catchpole shows krill Extract 2 includes 45.1% total phospholipids, which is within the range required by Claim 6. (Exhibit 1009, p. 0024) (Tallon Decl., ¶¶ 91, 92, 214). In addition, as described above, the ether phospholipids in Catchpole, AAPC and AAPE, total 4.8%. Therefore, the non-ether phospholipids described in Catchpole are 40.3%, which is between 30% and 60% in Claim 6. (Tallon Decl., ¶ 91, 92, 214).

Claim 6 also requires from about 20% to 50% w/w triglycerides. Fricke (Exhibit 1010) expressly discloses this element. In particular, Table 1 of Fricke provides the lipid composition of the Antarctic krill for both samples. (Exhibit 1010, p. 0002). Both the 1977 sample and 1981 sample show levels of

triacylglycerols (triglycerides) of 33.3% +/- 0.5 and 40.4% +/- 0.1 for both the 1977 and 1981 samples, respectively. (Tallon Decl., ¶ 97).

TABLE 1

Lipid Composition of Antarctic Krill
(*Euphausia superba* Dana)

Sample	12/1977	3/1981
Total lipid content (% wet weight)	2.7 ± 0.2	6.2 ± 0.3
Phospholipids		
Phosphatidylcholine	35.6 ± 0.1	33.3 ± 0.5
Phosphatidylethanolamine	6.1 ± 0.4	5.2 ± 0.5
Lysophosphatidylcholine	1.5 ± 0.2	2.8 ± 0.4
Phosphatidylinositol	0.9 ± 0.1	1.1 ± 0.4
Cardiolipin	1.0 ± 0.4	1.6 ± 0.2
Phosphatidic acid	0.6 ± 0.4	
Neutral lipids		
Triacylglycerols	33.3 ± 0.5	40.4 ± 0.1
Free fatty acids[a]	16.1 ± 1.3	8.5 ± 1.0
Diacylglycerols	1.3 ± 0.1	3.6 ± 0.1
Sterols	1.7 ± 0.1	1.4 ± 0.1
Monoacylglycerols	0.4 ± 0.2	0.9 ± 0.1
Others[b]	0.9 ± 0.1	0.5 ± 0.1
Total	98.9	99.3

Accordingly, even as far back as 1984, it was well known that krill contained triglyceride levels within 20% - 50% the limitation of Claim 6 using conventional solvent extraction techniques. (Tallon Decl., ¶¶ 97, 215).

Thus, Claim 6 would have been obvious in view of the teachings found in Catchpole, Sampalis I, and Fricke. (Tallon Decl., ¶ 216).

Claim 12 merely repeats Claim 6 in independent form. Accordingly, Claim 12 is invalid for the same reasons as those set forth in connection with Claim 6. (Tallon Decl., ¶ 217).

Claim 15 further defines Claim 12 wherein the krill is *Euphausia superba.* As discussed above in connection with Claim 9, Sampalis I explains that the Neptune Krill Oil™ is extracted from Antarctic krill known as *Euphausia superba*. (Tallon Decl. ¶ 68). Fricke also discloses extraction from *Euphausia superba*. (Tallon Decl. ¶¶ 93, 95). Sampalis I confirms that it was known prior to the earliest effective filing date that *Euphausia superba* is rich in phospholipids and triglycerides carrying long omega-3 polyunsaturated fatty acids, such as EPA and DHA. (Exhibit 1012, p. 0004). (Tallon Decl., ¶ 68). Thus, Claim 15 would have been obvious to a POSITA. (Tallon Decl., ¶ 218).

Claim 16 further defines Claim 12 wherein the capsule is a soft gel capsule. As discussed above in connection with Claim 10, Sampalis I teaches the administration of two 1-gram soft gel capsules of the commercial NKO krill oil product. (Exhibit 1012, p. 0004). Thus, as of the earliest effective priority date for the '905 patent, it was well known to administer krill in a soft gel capsule form such that Claim 16 would have been obvious to a POSITA. (Tallon Decl., ¶¶ 71, 219).

Claim 18 is the same as Claim 12 except that the preamble recites encapsulated Antarctic krill oil. In addition, Claim 18 further specifies the capsule capsule containing the effective amount of krill oil as being a soft gel capsule. As discussed above, in connection with Claim 15, both Sampalis I and Fricke confirm it was well known as of the date of earliest effective priority date to extract krill oil from the Antarctic species *Euphausia superba*. Also, as explained in connection with Claim 16, it was well known as of the earliest effective priority date to encapsulate krill oil in a soft gel capsule as taught by Sampalis I. Accordingly, Claim 18 is invalid for the same reasons as discussed above in connection with Claims 15 and 16, respectively. (Tallon Decl., ¶¶ 68, 93, 220-220-221).

Thus, Claims 6, 12, 15-16 and 18 of the '905 Patent are rendered obvious in view of the teachings of Catchpole, Sampalis I and Fricke. (Tallon Decl., ¶ 222).

Reason to combine

In addition, a POSITA would have reason to combine Fricke with Sampalis I and Catchpole as described above in connection with Claim 1 because it was well known to extract lipids from krill and utilize the resulting oil as a dietary supplement as taught by Catchpole and Sampalis I, respectively. For example, Fricke analyzed the lipid, sterol and fatty acid composition of Antarctic krill and, more specifically, the lipid composition of Antarctic krill. As of the earliest effective filing date of the '905 patent it was demonstrated that phospholipids and, phosphatidlycholine in particular, were associated with beneficial health effects. (*See, e.g.*, Sampalis II, 1013, pp. 0017-0022). (Tallon Decl., ¶ 151). Sampalis II also disclosed that krill oil phospholipids "a. achieve a superior profile; b. have the highest quantities of polyunsaturated fatty acids; c. have the highest quantities of DHA; d. are the only phospholipids that contain EPA; and e. are the only phospholipids that contain a combination of EPA and DHA on the same molecule." (Exhibit 1013, 29: 8-16). (Tallon Decl., ¶ 151). The health benefits of omega-3 fatty acids, particularly in connection with cardiovascular disease, was

also well established. (*See, e.g.*, Bunea, Exhibit 1020, pp. 0001-0002). (Tallon Decl., ¶ 30). Moreover, it was well known that "[k]rill oil has a unique biomolecular profile of phospholipids naturally rich in omega-3 fatty acids and diverse antioxidants significantly different than fish oil" and that "[t]he association between phospholipids and long-chain omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing bioavailability...." (Bunea, Exhibit 1020, p. 0002). (Tallon Decl., ¶ 30). Accordingly, a POSITA developing an encapsulated krill oil supplement as disclosed in Sampalis I would be motivated to look to other references such as Catchpole and Fricke to ascertain the components of the krill oil and their amounts as obtained by standard extraction methods. (Tallon Decl., ¶ 28-32, 222).

D. Ground 4: §103(a) to Catchpole, Sampalis I, Fricke and Bottino [Claims 7-8, 13-14, 17, and 19-20]

Claims 7, 13[4] and 19 further define the encapsulated krill oil of Claims 1, 12, and 18, respectively. The discussion regarding the obviousness of claims 1, 12 12 and 18 are incorporated herein.

[4] Even if one assumes a 1% FFA content disclosed as the low end of Fricke or 4% FFA as disclosed in Budzinski, the values of omega-3 fatty acids attached to

Claim 13 asserts antecedent basis from Claim 6, but Petitioner believes it was meant to further define Claim 12. Otherwise, Claim 13 would be identical to Claim 7 and therefore be unenforceable.

Claims 7, 13, and 19 further define the encapsulated krill oil, wherein the krill oil further includes from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in the composition. Bottino expressly teaches this element.

Bottino (Exhibit 1007) analyzed the fatty acid content of Antarctic phytoplankton and Euphausiids, in particular *Euphausia superba* and *Euphausia crystllorophias*. *E. superba* is the better known species found in the Southern Oceans and has been considered almost a synonym for krill. (Bottino, Exhibit 1007, p. 0001). The *E. superba* samples were collected from various locations (stations) and lipids were extracted "immediately after capture" using a chloroform:methanol 2:1 v/v mixture as described in Folch *et al* (1957). (Tallon

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phospholipids as calculated all fall between the 70%-95%. (Tallon Decl. ¶¶ 111-114).

Decl., ¶ 115). The fatty acids were analyzed using chromatography. (Exhibit 1007, pp. 0001-0002) (Tallon Decl., ¶ 116).

Table 1 of Bottino reproduced below details the fatty acid content in *E. superba* from 3 different stations as a weight percent of total fatty acids. The percentage of omega-3 fatty acids are circled in the chart and add up to 30.5%, 26.8%, and 25.0%, respectively. (Exhibit 1007, p. 0002), (Tallon Decl., ¶ 116). Thus, all three samples had an omega-3 fatty acid content of between 20% to 35% omega-3 fatty acids as a percentage of total fatty acids, as required by Claims 7, 13, and 19. (Tallon Decl., ¶¶ 117, 224).

Table 1. *Euphausia superba*. Fatty acids (as weight per cent of total acids)

Fatty acid[a]	Station 8		Station 9	Station 11		
	Whole krill	HP+S[b]	Whole krill	Whole krill	HP+S	Remaining carcass
14:0	14.9	10.7	12.9	14.3	12.9	13.5
16:0	21.2	21.2	20.9	24.7	22.3	23.4
18:0	0.7	1.2	0.9	1.4	1.3	1.4
16:1(n-7)	9.0	6.7	10.7	8.9	8.2	8.0
18:1(n-9)	18.2	17.1	22.8	21.7	21.8	21.5
20:1(n-9)	0.6	0.9	1.1	0.9	1.2	1.1
18:2(n-3)	2.6	2.5	2.7	2.0	2.1	1.9
18:3(n-3)	1.1	1.2	1.4	1.0	1.0	1.1
18:4(n-3)	2.2	1.9	2.6	3.3	3.6	3.8
20:5(n-3)	16.0	22.2	11.8	11.4	13.9	11.6
22:6(n-3)	8.6	9.4	8.3	7.3	8.1	9.4
Minor fatty acids[c]	4.9	5.0	3.9	3.1	3.6	3.3

Footnote c of Table 1 indicates "[o]nly those fatty acids present at a level of 1% or more are included." Table 3 from Bottino further identifies all of the fatty acids identified from the various species tested as a weight percent of total fatty acids. The fatty acid content from *E. superba* is provided as an average of the 3 stations. The omega-3 fatty acid content from *E. superba* in Table 3 are circled below.

Table 3. Fatty acids of Antarctic phytoplankton and euphausiids (as weight per cent of total acids)

Fatty acid													*Euphausia superba* (average of 3 stations)	
18:2(n-3)	3.7	3.3	2.4	3.1	3.3	3.0	2.7	2.1	7.1	12.0	1.2	1.7	2.4	2.1
22:2(n-6)	-	-	-	-	-	0.8	0.9	1.6	2.0	-	-	-	-	-
22:2(n-9)	-	0.6	0.7	1.4	1.4	-	-	-	-	-	-	-	-	-
18:3(n-6)	0.3	0.3	0.3	0.2	0.2	-	-	-	0.2	0.3	0.2	0.3	0.2	0.1
18:3(n-3)	0.9	0.7	0.6	0.7	0.7	0.7	0.3	0.2	0.1	0.2	0.2	0.3	1.2	0.9
20:3(n-6)	0.4	0.2	-	trace	0.9	trace	-	0.3	2.6	0.1	-	0.1	-	-
20:3(n-3)	0.2	0.2	0.3	-	-	-	-	trace	0.9	1.0	-	0.2	0.5	0.3
16:4(n-1)	-	-	0.5	-	-	-	-	-	-	6.3	-	-	-	-
18:4(n-3)	2.0	3.1	3.5	5.2	6.0	3.0	2.7	3.2	6.2	0.9	2.2	2.5	2.7	1.2
20:4(n-6)	-	-	-	0.4	-	-	-	-	-	4.7	-	-	0.4	0.4
20:4(n-3)	0.2	-	0.3	0.2	-	-	-	0.1	trace	-	-	0.2	0.4	0.1
22:4(n-6)	-	-	-	-	-	-	-	-	-	trace	-	-	0.2	-
22:4(n-3)	1.3	-	trace	-	-	-	-	trace	-	trace	-	-	-	-
20:5(n-3)	11.4	4.8	9.2	7.0	6.4	1.7	2.1	5.3	6.0	2.1	18.4	23.4	13.1	14.4
22:5(n-6)	1.1	-	-	-	-	-	-	-	-	-	-	-	-	-
22:5(n-3)	0.3	0.3	-	-	-	-	-	0.1	-	2.1	-	-	0.2	-
22:6(n-3)	6.1	4.9	7.9	8.4	5.5	0.9	0.8	7.1	7.8	16.5	5.5	11.0	8.1	7.5
Minor fatty acids[b]	3.3	1.5	4.3	4.6	1.0	3.2	0.6	4.0	2.8	1.8	0.5	0.9	0.8	0.4

When all of the omega-3 fatty acids are calculated, including those not appearing in Table 1, the total is 28.6%. (Tallon Decl., ¶ 116, 117).

Therefore, it would have been obvious to a POSITA that oil extract from krill included from about 20% to 35% omega-3 fatty acids as a percentage of total fatty as in Claims 7, 13 and 19. (Tallon Decl., ¶ 224).

Claims 8, 14, and 20 further define the encapsulated krill oil of Claims 7, 13, and 19, respectively. In particular, Claims 8, 14, and 20 further recite the

encapsulated krill oil, about 70% - 95% of said omega-3 fatty acids attached to the phospholipids.

In Fricke, the lipids classes, fatty acids of total and individual lipids and sterols of *Euphausia superba* from two areas of the Antarctic Ocean were analyzed by thin layer chromatography and gas liquid chromatography and gas liquid chromatography/mass spectrometry. Krill samples of 5 kg were quick frozen and stored at -35 °C until analyzed. Liquid extraction was performed according to Folch *et al.*, *J. Biol. Chem.* 226:497-509 (1957) (Exhibit 1017), which uses a polar solvent, chloroform:methanol, and a ratio of 2:1 v/v. (Exhibit 1010, p. 0001, 2nd col.). Krill samples were taken from the Scotia Sea (caught in December 1977) and from the Gerlache Strait (caught in March 1981). Fricke noted that, in the 1977 sample, the free fatty acid (FFA) content is about twice that of the 1981 sample. They hypothesize that the high value could be caused by the longer storage time of the 1977 sample. (Exhibit 1010, p. 0002, 2nd col.) (Tallon Decl. ¶¶ 93-96).

To confirm this hypothesis, samples of the same haul were cooked on board immediately after hauling and stored under the same conditions and showed a FFA content which was much lower, ranging from 1% - 3% of total lipids. Fricke *et al.*

al. note that this low FFA content of freshly caught krill also was confirmed by Ellingsen, Ph.D. *thesis, University of Trondheim,* 239-316 (1982). (Exhibit 1010, p. 0002, 2nd col. to p. 0003, 1st col.) (Tallon Decl., ¶ 96).

Table 1 in Fricke provides the amount of each lipid class in the total lipid composition. (Exhibit 1010, p. 0002) (Tallon Decl., ¶¶ 97, 98). Tables 4 and 5 set forth the omega-3 fatty acid composition of each phospholipid class. In particular, the omega-3 fatty acids in Tables 4 and 5 are identified as 18:3(n-3), 18:4(n-3), 20:5(n-3), 21:5(n-3), 22:5(n-3), and 22:6(n-3). (Exhibit 1010, pp. 0004-0005) (Tallon Decl., ¶ 102).

TABLE 4

Fatty Acid Analysis of Polar Lipid Classes of *Euphausia superba* Dana

Polar lipid	PC		PE		LPC		PI		PA + Cl	
Sample	12/1977	3/1981	12/1977	3/1981*	12/1977	3/1981*	12/1977	3/1981*	12/1977	3/1981*
14:0	4.5 ± 1.1	2.8 ± 1.1	2.9 ± 1.1	–	9.1 ± 5.4	4.2	3.5 ± 0.3	3.2	6.0 ± 1.4	–
15:0	–	–	–	–	–	–	–	1.6	–	–
16:0	43.7 ± 7.2	25.7 ± 1.4	42.7 ± 9.3	24.2	40.5 ± 8.9	18.7	33.9 ± 5.9	24.9	39.3 ± 6.3	23.7
16:1(n-7)	3.7 ± 0.4	2.2 ± 0.3	2.0 ± 1.0	1.9	4.4 ± 2.3	2.8	2.2 ± 0.9	1.2	3.6 ± 0.8	4.3
18:0	1.8 ± 0.5	1.5 ± 0.2	3.2 ± 1.0	2.9	2.1 ± 0.3	1.5	6.1 ± 1.0	7.3	2.5 ± 0.1	2.6
18:1(n-7)	7.7 ± 0.8	6.1 ± 0.8	15.0 ± 3.9	16.3	9.7 ± 3.7	4.0	11.6 ± 3.3	10.9	12.3 ± 0.6	14.7
18:1(n-9)	9.2 ± 1.7	5.4 ± 1.1	5.4 ± 2.1	6.8	10.3 ± 3.3	7.3	6.5 ± 0.4	7.9	4.9 ± 1.5	8.7
18:2(n-6)	1.6 ± 0.1	1.1 ± 0.1	1.0 ± 0.6	1.0	1.1 ± 0.8	1.6	1.7 ± 0.7	1.7	1.4 ± 0.1	1.5
18:3(n-3)	–	0.8 ± 0.2	–	–	–	1.1	–	0.6	–	1.6
18:3(n-6)	–	2.7 ± 0.4	–	0.7	–	3.8	–	–	–	1.7
18:4(n-3)	–	–	–	–	–	–	–	–	–	0.8
20:1(n-7)	–	–	–	–	–	–	–	–	–	–
20:1(n-9)	0.6 ± 0.1	0.9 ± 1.1	–	0.8	–	0.8	–	1.1	–	1.1
20:5(n-3)	10.7 ± 0.6	29.9 ± 2.2	10.5 ± 4.9	21.1	2.6 ± 0.1	31.2	8.1 ± 0.1	20.1	1.9 ± 1.0	19.7
21:5(n-3)	1.0 ± 0.7	1.1 ± 0.0	–	0.7	–	1.6	–	1.9	–	0.8
22:1(n-7)	–	0.9 ± 0.1	–	–	–	1.0	–	–	–	–
22:1(n-9)	–	1.7 ± 0.2	–	–	–	1.5	–	1.4	–	–
22:5(n-3)	0.9 ± 0.6	0.6 ± 0.2	–	0.9	–	1.1	–	1.8	–	–
22:6(n-3)	6.2 ± 0.6	11.5 ± 1.0	7.6 ± 2.3	19.2	1.2 ± 0.2	12.2	1.8 ± 0.7	10.1	1.1 ± 0.3	15.5
Phytanic acid	0.7 0.6	–	–	–	–	–	–	–	–	–

TABLE 5

Fatty Acid Analysis of Neutral Lipid Classes of *Euphausia superba* Dana

Neutral lipid	TAG		FFA		DG		MG		WE + SE	
Sample	12/1977	3/1981	12/1977	3/1981	12/1977*	3/1981*	12/1977*	3/1981*	12/1977*	3/1981*
12:0	0.5 ± 0.1	–	–	0.8 ± 0.2	–	–	–	–	3.7	–
14:0	23.3 ± 0.2	21.8 ± 2.0	7.9 ± 1.0	5.1 ± 0.7	4.5	6.1	2.1	3.8	14.8	8.8
15:0	0.5 ± 0.1	–	–	–	–	0.5	–	1.2	–	–
16:0	29.9 ± 1.6	21.8 ± 1.8	32.5 ± 1.1	12.1 ± 2.2	19.4	16.9	9.6	10.3	25.1	37.8
16:1(n-7)	8.9 ± 1.9	13.1 ± 0.3	4.8 ± 1.0	4.9 ± 0.5	5.6	7.1	2.0	6.6	10.8	8.8
18:0	1.5 ± 0.2	1.8 ± 0.3	1.5 ± 0.2	0.7 ± 0.1	2.1	2.0	–	2.1	2.2	2.6
18:1(n-7)	5.9 ± 1.1	6.6 ± 3.1	12.9 ± 2.7	8.5 ± 2.2	14.7	7.5	73.7	10.9	15.8	17.5
18:1(n-9)	11.9 ± 3.6	12.1 ± 2.5	7.1 ± 0.6	4.7 ± 1.3	6.5	10.4	2.3	14.5	14.3	11.9
18:2(n-6)	0.7 ± 0.5	1.0 ± 0.2	1.5 ± 0.3	0.8 ± 0.7	3.1	1.3	0.8	1.3	1.9	–
18:3(n-3)	–	–	–	0.7 ± 0.2	–	0.8	–	–	–	–
18:3(n-6)	–	4.1 ± 1.0	–	1.5 ± 0.7	0.7	3.0	–	1.8	–	–
18:4(n-3)	–	–	0.6 ± 0.2	3.5 ± 1.2	–	–	–	–	–	–
20:1(n-7)	0.5 ± 0.1	–	–	–	0.5	–	–	–	–	–
20:1(n-9)	0.8 ± 0.2	1.3 ± 0.0	0.5 ± 0.1	1.0 ± 0.3	0.8	0.8	–	0.6	–	–
20:5(n-3)	1.0 ± 0.1	3.3 ± 0.5	11.8 ± 2.2	30.0 ± 2.1	15.8	28.8	2.9	26.8	5.1	11.9
21:5(n-3)	–	–	0.5 ± 0.4	0.9 ± 0.2	–	0.7	–	1.4	–	–
22:1(n-7)	–	–	0.8 ± 0.3	–	2.0	–	–	–	–	–
22:1(n-9)	–	0.5 ± 0.2		0.9 ± 0.4	1.5	1.3	–	0.8	–	–
22:5(n-3)	–	–	0.5 ± 0.3	0.5 ± 0.1	2.5	–	–	1.0	–	–
22:6(n-3)	–	0.7 ± 0.2	6.3 ± 2.4	12.1 ± 1.5	7.0	8.2	1.7	12.8	–	–
Phytanic acid	5.6 ± 0.8	4.1 ± 0.6	1.5 ± 0.6	1.3 ± 0.7	1.5	1.6	1.4	1.3	0.8	0.7

Therefore, the amount of omega-3 and each lipid class relative to the total lipid can be easily calculated by multiplying the amount of omega-3 fatty acids for each lipid class by the amount of the particular lipid class in the total lipid composition. This provides the amount of omega-3 associated for each lipid class. The total amount of omega-3 fatty acids associated with the lipid classes that constitute phospholipids can then be added. The total amount of omega-3 associated with phospholipids can then divided by the amount of omega-3 in the total lipid from all lipid classes to provide the percentage of omega-3 fatty acid attached to phospholipid. For the March 1981 sample, 74.81% of the omega-3 fatty acids are attached to phospholipids assuming the 3% free fatty acid content disclosed in

Fricke. The calculation for the December 1977 sample is 82.03%. (Tallon Decl., ¶102-114).[5]

Accordingly, it would have been obvious to a POSITA to obtain krill oil having a range of omega-3 fatty acids attached to phospholipids between the 70%-95% as recited in Claims 8, 14, and 20. (See Tallon Decl., ¶¶ 225-228).

Claim 17 further defines the encapsulated krill oil of Claim 12, wherein the krill oil includes less than 0.45% w/w arachadonic acid. Table 3 in Bottino, represented again below, reports the fatty acids of the Antarctic krill as a weight percentage of total fatty acids. (Exhibit 1007, p. 0004). As highlighted, Table 3 shows arachadonic acid [20:4 (n-6)] constitutes 0.4% of fatty acids. (Exhibit 1007, p. 0005, Table 3) (Tallon Decl., ¶ 116).

[5] Even if one assumes a 1% FFA content disclosed as the low end of Fricke or 4% FFA as disclosed in Budzinski, the values of omega 3 fatty acids attached to phospholipids as calculated all fall between the 70%-95%. (Tallon Decl. ¶¶ 111-114).

Table 3. Fatty acids of Antarctic phytoplankton and euphausiids (as weight per cent of total acids)

Fatty acid													*Euphausia superba* (average of 3 stations)	
18:2(n-3)	3.7	3.3	2.4	3.1	3.3	3.0	2.7	2.1	7.1	12.0	1.2	1.7	2.4	2.1
22:2(n-6)	–	–	–	–	–	0.8	0.9	1.6	2.0	–	–	–	–	–
22:2(n-3)	–	0.6	0.7	1.4	1.4	–	–	–	–	–	–	–	–	–
18:3(n-6)	0.3	0.3	0.3	0.2	0.2	–	–	–	0.2	0.3	0.2	0.3	0.2	0.1
18:3(n-3)	0.9	0.7	0.6	0.7	0.7	0.7	0.3	0.2	0.1	0.2	0.2	0.3	1.2	0.9
20:3(n-6)	0.4	0.2	–	trace	0.9	trace	–	0.3	2.6	0.1	–	0.1	–	–
20:3(n-3)	0.2	0.2	0.3	–	–	–	–	trace	0.9	1.0	–	0.2	0.5	0.3
16:4(n-1)	–	–	0.5	–	–	–	–	–	–	6.3	–	–	–	–
18:4(n-3)	2.0	3.1	3.5	5.2	6.0	3.0	2.7	3.2	6.2	0.9	2.2	2.5	2.7	1.2
20:4(n-6)	–	–	–	0.4	–	–	–	–	–	4.7	–	–	0.4	0.4
20:4(n-3)	0.2	–	0.3	0.2	–	–	–	0.1	trace	–	–	0.2	0.4	0.1
22:4(n-6)	–	–	–	–	–	–	–	–	–	trace	–	–	0.2	–
22:4(n-3)	1.3	–	trace	–	–	–	–	trace	–	trace	–	–	–	–
20:5(n-3)	11.4	4.8	9.2	7.0	6.4	1.7	2.1	5.3	6.0	2.1	18.4	23.4	13.1	14.4
22:5(n-6)	1.1	–	–	–	–	–	–	–	–	–	–	–	–	–
22:5(n-3)	0.3	0.3	–	–	–	–	–	0.1	–	2.1	–	–	0.2	–
22:6(n-3)	6.1	4.9	7.9	8.4	5.5	0.9	0.8	7.1	7.8	16.5	5.5	11.0	8.1	7.5
Minor fatty acids[b]	3.3	1.5	4.3	4.6	1.0	3.2	0.6	4.0	2.8	1.8	0.3	0.9	0.8	0.4

The 0.4% is less than the 0.45% required by the claims. Furthermore, the 0.4% in Table 3 is a percentage of fatty acids. However, the claims require the total krill oil to contain less than 0.45% arachadonic acid. Since fatty acids constitute only a limited percentage of total lipids, the amounts of arachadonic acid recorded by Bottino would be significantly less than 0.45% total lipids. (Tallon Decl., ¶¶ 116-118; Exhibit 1007, p. 0005, Table 3.). Accordingly, it would have been obvious to a POSITA for the krill oil to have less than 0.45% arachadonic acid. (Tallon Decl., ¶ 229).

Reason to combine

A POSITA would have possessed reasons to combine the teachings of Bottino with the references set forth in Grounds 1 and 3 because Bottino disclosed the fatty acid levels of a lipid extract of *Euphausia superba*. Bottino explained that the study of krill at the time of the article (1974) had become intensive as a result of its potential importance as food. (Exhibit 1007, p. 0001). Moreover, it was known that "[k]rill oil has a unique biomolecular profile of phospholipids naturally rich in omega-3 fatty acids and diverse antioxidants significantly different than fish oil" and that "[t]he association between phospholipids and long-chain omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing bioavailability...." (Bunea, Exhibit 1020, p. 0002). (Tallon Decl., ¶ 30). Accordingly, a POSITA would have been motivated to include the omega-3 fatty acid levels disclosed in Bottino naturally found in krill oil using conventional extraction techniques with the encapsulated krill oil disclosed in the combination of Sampalis I, Catchpole, and Fricke. (Tallon Decl., ¶ 230).

E. Ground 5: §103(a) to Catchpole, Sampalis I, and Bottino [Claim 11]

Claim 11 further defines the encapsulated krill oil of Claim 1, wherein the krill oil includes less than 0.45% w/w arachadonic acid. The discussion regarding the obviousness of claim 1 in Ground 1 is incorporated herein.

As discussed above, Table 3 in Bottino shows arachadonic acid [20:4 (n-6)] constitutes 0.4% of fatty acids. (Exhibit 1007, p. 0005). The 0.4% is less than the 0.45% required by the claims. Furthermore, the 0.4% in Table 3 is a percentage of fatty acids. The claims require the total krill oil to contain less than 0.45% arachadonic acid. Since fatty acids constitute only a limited percentage of total lipids, the amounts of arachadonic acid recorded by Bottino would be significantly less than 0.45% total lipids. (Tallon Decl., ¶ 116-118; Exhibit 1007, p. 0005, Table 3.). Therefore, Claim 11 would have been obvious in view of Catchpole, Sampalis I and Bottino. (Tallon Decl., ¶¶ 232).

Reason to combine

A POSITA would have been motivated to combine the disclosure of Bottino with the teachings of other references set forth in Ground 1 because of the heightened interest and analysis and reporting fatty acid levels *Euphausia*

superba. Bottino explains that the study of krill at the time of the article (1974) had become intensive as a result of its potential importance as food. (Exhibit 1007, p. 0001). The health benefits of omega-3 fatty acids, particularly in connection with cardiovascular disease, was also well established. (*See, e.g.*, Bunea, Exhibit 1020, pp. 0001-0002). Moreover, it was well known that "[k]rill oil has a unique biomolecular profile of phospholipids naturally rich in omega-3 fatty acids and diverse antioxidants significantly different than fish oil" and that "[t]he association between phospholipids and long-chain omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing bioavailability...." (Bunea, Exhibit 1020, p. 0002). (Tallon Decl., ¶ 30). Accordingly, a POSITA would have considered Bottino to ascertain the various fatty acid levels, including arachadonic acid, when determining the fatty acid levels in the krill oil. (Tallon Decl., ¶ 232).

F. **CLAIM CHART**

CLAIMS	**REFERENCES**
1. Encapsulated krill oil comprising:	**<u>Sampalis I (Exhibit 1012)</u>** P. 0004, 2nd col. "Each patient was asked to take two 1-1-gram soft **gels of** either

	NKO[Neptune Krill Oil] or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
1(a). a capsule containing an effective amount of krill oil,	**Sampalis I (Exhibit 1012)** P. 0004, 2nd col. "Each patient was asked to take two **1-gram soft gels of** either **NKO** or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
1(b). said krill oil comprising from about 3% to about 15% w/w ether phospholipids.	**Catchpole (Exhibit 1009)**
	P. 0024,lines 1-19, Example 18, Table 16. "This example shows the fractionation of krill lipids from krill powder and demonstrates concentration of AAPC in the extract, and AAPE in the residue." Extract 2, Table 16, includes 4.6% AAPC and 0.2% AAPE, totaling **4.8% ether phospholipid**.[6]

[6] AAPC-alkylacylphosphatidylcholine, AAPE-alkylacylphosphatidylcholine, both are ether-phospholipids.

2. The encapsulated krill oil of claim 1, wherein said krill oil comprises at least 30% total phospholipids w/w.	**Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. **Total phospholipids include 45.1% of the extract**.
3. The encapsulated krill oil of claim 1, wherein said krill oil comprises at least 30% phosphatidylcholine w/w.	**Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. Extract 2 includes **39.8% phosphatidylcholine (PC)**.
4. The encapsulated krill oil of claim 1, wherein said krill oil is a polar solvent extract of krill.	**Catchpole (Exhibit 1009)** P. 0024, lines 8-9. "The residual powder was then extracted with **CO_2 and absolute ethanol, using a mass ratio of ethanol to CO_2 of 11%**."
5. The encapsulated krill oil of claim 1, wherein said capsule contains a phytonutrient derived from a source other than krill.	**Randolph (Exhibit 1011)** P. 0004, ¶[0008]. "In another aspect, the composition can comprise rosehips and krill oil. In yet another aspect, the composition can comprise **rosehips**, blackberry, blueberry, elderberry and krill oil."
6. The encapsulated krill oil of claim	

1, wherein said krill oil further comprises	
6(a). from about 3% to about 10% w/w ether phospholipids;	**Catchpole (Exhibit 1009)** P. 0024, lines 1-19, Example 18, Table 16. "This example shows the fractionation of krill lipids from krill powder and demonstrates concentration of AAPC in the extract, and AAPE in the residue." Extract 2 of Table 16, includes 4.6% AAPC and 0.2% AAPE, totaling **4.8% ether phospholipid**.
6(b). from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w;	**Catchpole (Exhibit 1009)** P. 0024, lines 1-19, Example 18, Table 16. **Total phospholipids include 45.1%** of the extract, and ether phospholipids include 4.8%. Therefore, **non-ether phospholipids include 40.3%**.
6(c). and from about 20% to 50% w/w triglycerides.	**Fricke (Exhibit 1010)** P. 0002, Table 1. Lipid Composition of Antarctic Krill (*Euphausia superba*) Triacylglycerols **33.3 % +/- 0.5** 12/1977 **40.4 % +/- 0.1** 3/1981

7. The encapsulated krill oil of claim 6, wherein said krill oil further comprises	
7(a). from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.	**Bottino (Exhibit 1007)** P. 0002, Table 1. Omega-3 fatty acids[7] (as weight percent of total acids of Euphausia superba) of whole krill: Station 8--**30.5%** Station 9--**26.8%** Station 11--**25.0%** Pp. 0004-0005, Table 3 Omega-3 fatty acids[8] as weight percent of total acids of Euphausia superba: **28.6%**
8. The encapsulated krill oil of claim 7, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said phospholipids.	**Fricke (Exhibit 1010)** Pp. 0002, 0004-0005, Tables 1, 4, and 5. Table 1 provides the amount of each lipid class in the total lipid. Tables 4

[7] Omega-3 fatty acids include 18:2(n-3), 18:3(n-3), 18:4(n-3), 20:5(n-3), and 22:6(n-3).

[8] Omega-3 fatty acids include 18:2(n-3), 22:2(n-3), 18:3(n-3), 20:3(n-3), 18:4(n-3), 20:4(n-3), 22:4(n-3), 22:5(n-3), and 22:6(n-3).

	and 5 provide the omega-3 fatty acid composition of each phospholipid class. Therefore, the amount of omega-3 in each lipid class relative to the total lipid can be calculated by multiplying the amount of omega-3 fatty acid for each lipid class by the amount of the particular lipid class in the total lipid composition. This is done for each lipid class. The amount of omega-3 associated with phospholipid is then divided by the total amount of omega-3 in the total lipid to provide the percentage of omega-3 fatty acid attached to phospholipid. Using this calculation, **74.81%** (3/1981 sample) and **82.03%** (12/1977 sample) of the omega-3 fatty acids are attached to phospholipids. (Tallon Decl., Appendix B).
9. The encapsulated krill oil of claim 1, wherein said krill is Euphausia superba.	**Sampalis I (Exhibit 1012)** P. 0004, 1st col. "Neptune Krill Oil™ (NKO™) is a natural health product extracted from Antarctic krill also known as ***Euphausia superba.*** *Euphausia superba*, a zooplankton crustacean, is rich in phospholipids and triglycerides carrying long-chain omega-3

	polyunsaturated fatty acids, mainly EPA and DHA,"
10. The encapsulated krill oil of claim 1, wherein said capsule is a soft gel capsule.	**Sampalis I (Exhibit 1012)** P. 0004, 2nd col. "Each patient was asked to take two 1-gram **soft gels** of either NKO or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
11. The encapsulated krill oil of claim 1, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.	**Bottino (Exhibit 1007)** Pp.0004- 0005, Table 3. **Arachidonic acid** [20:4(n-6)] include **0.4% of total fatty acids**.
12. Encapsulated krill oil comprising:	**Sampalis I (Exhibit 1012)** P. 0004, 2nd col. "Each patient was asked to take two 1-gram **soft gels** of either **NKO** or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
12(a). a capsule containing an effective	**Sampalis I (Exhibit 1012)**

amount of krill oil,	P. 0004, 2nd col. "Each patient was asked to take two **1-gram soft gels of** either **NKO** or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
12(b). said krill oil comprising from about 3% to about 10% w/w ether phospholipids;	**Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. "This example shows the fractionation of krill lipids from krill powder and demonstrates concentration of AAPC in the extract, and AAPE in the residue." P. 0024, Example 18, Table 16. Extract 2 includes 4.6% AAPC and 0.2% AAPE, totaling **4.8% ether phospholipid**.
12(c). from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and	**Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. **Total phospholipids include 45.1%** of the extract, and ether phospholipids include 4.8%. Therefore, **non-ether phospholipids include 40.3%**.
12(d). from about 20% to 50% w/w triglycerides.	**Fricke (Exhibit 1010)** P.0002, Table 1. Lipid Composition of Antarctic Krill

	(*Euphausia superba*) Triacylglycerols **33.3 % +/- 0.5** 12/1977 **40.4 % +/- 0.1** 3/1981
13. The encapsulated krill oil of claim 6, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.	**Bottino (Exhibit 1007)** P. 0002, Table 1. Omega-3 fatty acids (as weight percent of total acids of Euphausia superba) of whole krill: Station 8--**30.5%** Station 9--**26.8%** Station 11--**25.0%** Pp. 0004-0005, Table 3. Omega-3 fatty acids as weight percent of total acids of Euphausia superba: **28.6%**

14. The encapsulated krill oil of claim 13, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said phospholipids.	**Fricke (Exhibit 1010)** Pp. 0002, 0004-0005, Tables 1, 4, and 5. Table 1 provides the amount of each lipid class in the total lipid. Tables 4 and 5 provide the amount of omega-3 fatty acid composition of each phospholipid class. Therefore, the amount of omega-3 in each lipid class relative to the total lipid can be calculated by multiplying the amount of omega-3 fatty acid for each lipid class by the amount of the particular lipid class in the total lipid composition. This is done for each lipid class. The amount of omega-3 associated with phospholipid is then divided by the total amount of omega-3 in the total lipid to provide the percentage of omega-3 fatty acid attached to phospholipid. Using this calculation, **74.81%** (3/1981 sample) and **82.03%** (12/1977 sample) of the omega-3 fatty acids are attached to phospholipids. (Tallon Decl., Appendix B).
15. The encapsulated krill oil of claim 12, wherein said krill is Euphausia superba.	**Sampalis I (Exhibit 1012)** P. 0004, 1st col.

	"Neptune Krill Oil™ (NKO™) is a natural health product extracted from Antarctic krill also known as ***Euphausia superba***. *Euphausia superba*, a zooplankton crustacean, is rich in phospholipids and triglycerides carrying long-chain omega-3 polyunsaturated fatty acids, mainly EPA and DHA," **Fricke (Exhibit 1010)** P. 0001, Abstract. "The lipid classes, fatty acids of total and individual lipids and sterols of **Antarctic krill** *(Euphausia superba* Dana) from two areas of the Antarctic Ocean …"
16. The encapsulated krill oil of claim 12, wherein said capsule is a soft gel capsule.	**Sampalis I (Exhibit 1012)** P. 0004. "Each patient was asked to take two 1-gram **soft gels** of either NKO or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
17. The encapsulated krill oil of claim 12, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.	**Bottino (Exhibit 1007)** P. 0005, Table 3. **Arachidonic acid** [20:4(n-6)] include

	0.4% of total fatty acids.
18. Encapsulated Antarctic krill oil comprising:	**Sampalis I (Exhibit 1012)** P. 0004, 1st col. "**Neptune Krill Oil**™ (NKO™) is a natural health product extracted from **Antarctic krill** also known as *Euphausia superba. Euphausia superba*, a zooplankton crustacean, is rich in phospholipids and triglycerides carrying long-chain omega-3 polyunsaturated fatty acids, mainly EPA and DHA," P. 0004, 2nd col. "Each patient was asked to take two 1-gram **soft gels** of either NKO or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
18(a). a soft gel capsule containing an effective amount of krill oil,	**Sampalis I (Exhibit 1012)** P. 0004. "Each patient was asked to take two **1-gram soft gels of** either **NKO** or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."

18(b). said krill oil comprising from about 3% to about 10% w/w ether phospholipids,	**Catchpole (Exhibit 1009)** P. 0024, lines 1-19, Example 18, Table 16. Extract 2 includes 4.6% AAPC and 0.2% AAPE, totaling **4.8% ether phospholipid**.
18(c). from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w;	**Catchpole (Exhibit 1009)** P. 0024, lines 1-19, Example 18, Table 16. **Total phospholipids include 45.1%** of the extract, and **ether phospholipids include 4.8%**. Therefore, non-ether phospholipids include 40.3%.
18(d). and from about 20% to 50% w/w triglycerides.	**Fricke (Exhibit1010)** P. 0002, Table 1. Lipid Composition of Antarctic Krill (*Euphausia superba*) Triacylglycerols **33.3 %** +/- 0.5 12/1977 **40.4 %** +/- 0.1 3/1981
19. The encapsulated krill oil of claim 18, wherein said krill oil further comprises	
19(a). from about 20% to 35% omega-3 omega-3 fatty acids as a percentage of	**Bottino (Exhibit 1007)**

total fatty acids in said composition.	P. 0002, Table 1. Omega-3 fatty acids (as weight percent of total acids of Euphausia superba) of whole krill: Station 8--**30.5%** Station 9--**26.8%** Station 11--**25.0%** Pp. 0004-0005, Table 3. Omega-3 fatty acids as weight percent of total acids of Euphausia superba: **28.6%**
20. The encapsulated krill oil of claim 19, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said phospholipids.	**Fricke (Exhibit 1010)** Pp. 0002, 0004-0005, Tables 1, 4, and 5. Table 1 provides the amount of each lipid class in the total lipid. Tables 4 and 5 provide the amount of omega-3 fatty acid composition of each phospholipid class. Therefore, the amount of omega-3 in each lipid class relative to the total lipid can be calculated by multiplying the amount of omega-3 fatty acid for each lipid class by the amount of the particular lipid class in the total lipid composition. This is done for each lipid class. The amount of omega-3 associated with

	phospholipid is then divided by the total amount of omega-3 in the total lipid to provide the percentage of omega-3 fatty acid attached to phospholipid. Using this calculation, **74.81%** (3/1981 sample) and **82.03%** (12/1977 sample) of the omega-3 fatty acids are attached to phospholipids. (Tallon Decl., Appendix B).

VII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *Inter Partes* Review of Claims 1-20 of U.S. 9,078,905, followed by a grant of this Petition cancelling Claims 1-20 of the '905 patent.

Dated: January 27, 2017

Respectfully submitted,

/James F. Harrington/
James F. Harrington
jfhdocket@hbiplaw.com
Registration No. 44,741

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(516) 822-3550

Attorney for Petitioner
Rimfrost AS

VIII. CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of to 37 C.F.R. §42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 13,419 words, including the parts of the brief exempted by to 37 C.F.R. §42.24(a) (that is, the word count does not include the table of contents, the exhibit list, mandatory notices under §42.8, the certificate of service or the certificate of compliance).

Dated: January 27, 2017

Respectfully,

/James F. Harrington/
James F. Harrington
jfhdocket@hbiplaw.com
Registration No. 44,741

CERTIFICATE OF SERVICE

I hereby certify that on this 27th th day of January 27, 2017, the foregoing PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ.*, including all Exhibits and the Power of Attorney, were served pursuant to 37 C.F.R. §§ 42.6 and 42.105, via Federal Express®, (Domestic - next day delivery, International – priority) on the following:

[Patent Owner Correspondence Address of Record (37 C.F.R. § 42.105(a)]

John Jones, Esq.
Casimir Jones, S.C.,
2275 Deming Way, Suite 310
Middleton, Wisconsin 53562
and

[Patent Owner (37 C.F.R. §§ 42.6(e)(2) and 42.105(a))]

Aker BioMarine Antarctic AS
Oksenøyveien 10, N-1327
1366 Lysaker, Norway
and

[Patent Owner's Litigation Counsel]

Andrew F. Pratt, Esq.
Venable LLP
575 Seventh Street, NW
Washington, DC 20004

By: /James F. Harrington/
James F. Harrington (Reg. No. 44,741)
Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset, NY 11791
jharrington@hbiplaw.com
Tel: (516) 822-3550

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS

Petitioner

v.

AKER BIOMARINE ANTARCTIC AS

Patent Owner

Case No.: IPR2017-00747

U.S. Patent 9,078,905

Issue Date: July 14, 2015

Title: Bioeffective Krill Oil Compositions

PETITION FOR *INTER PARTES* REVIEW

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ.*

TABLE OF CONTENTS

APPENDIX OF EXHIBITS

Exhibit Number	Exhibit Description
1001	U.S. Patent No. 9,078,905 B2, filed September 18, 2014 ('905 Patent)
1002	U.S. Provisional Patent Application No. 61/024,072, filed January 28, 2008 ('072 Provisional)
1003	U.S. Provisional Patent Application No. 60/983,446, filed October 29, 2007 ('446 Provisional)
1004	U.S. Provisional Patent Application No. 60/975,058, filed September 25, 2007 ('058 Provisional)
1005	U.S. Provisional Patent Application No. 60/920,483, filed March 28, 2007 ('483 Provisional)
1006	Declaration of Stephen Tallon (Tallon Decl.)
1007	Bottino, N.R., "The Fatty Acids of Antarctic Phytoplankton and Euphausiids. Fatty Acid Exchange among Trophic Levels of the Ross Sea", Marine Biology, 27, 197-204 (1974) (Bottino)
1008	Budziński, E., P. Bykowski and D. Dutkiewicz, 1985, "Possibilities of processing and marketing of products made from Antarctic krill," FAO Fish.Tech. Pap., (268):46. (Budzinski)
1009	Catchpole and Tallon, WO 2007/123424, published November 1, 2007, "Process for Separating Lipid Materials," (Catchpole)
1010	Fricke et al., "Lipid, Sterol and Fatty Acid Composition of Antactic Krill (Euphausia superba Dana)," LIPIDS 19(11):821-827 (1984) (Fricke)

1011 Randolph, et al., U.S. Patent Application Publication No. US/2005/0058728 A1, "Cytokine Modulators and Related Method of Use"(Randolph)

1012 Sampalis [I] *et al.*, "Evaluation of the Effects of Neptune Krill Oil™ on the Management of Premenstrual Syndrome and Dysmenorrhea," Altern. Med. Rev. 8(2):171-179 (2003) (Sampalis I)

1013 Sampalis [II] *et al.*,WO 2003/011873, published February 13, 2003, "Natural Marine Source Phospholipids Comprising Flavonoids, Polyunsaturated Fatty Acids and Their Applications" (Sampalis II)

1014 Tanaka [I] et al., "Platelet – Activating Factor (PAF) – Like Phospholipids Formed During Peroxidation of Phosphatidylcholines from Different Foodstuffs," Biosci. Biotech. Biochem., 59(8) 1389-1393 (1995) (Tanaka I).

1015 Tanaka [II] et al., "Extraction of Phospholipids from Salmon Roe with Supercritical Carbon Dioxide and an Entrainer," Journal of Oleo Science Vol. 53 (2004) No. 9, p.17-424 (Tanaka II)

1016 Beaudoin et al., "Method of Extracting Lipids From Marine and Aquatic Animal Tissues," U. S. Patent No. 6,800,299 B1 filed July 25, 2001 (Beaudoin).

1017 Folch et al., "A simple method for the isolation and purification of total lipides from animal tissues," J. Biol. Chem. (1957) 226: 497-509 (Folch).

1018 Kochian et al, "Agricultural Approaches to Improving Phytonutrient Content in Plants: An Overview," Nutrition Reviews", Vol. 57, No. 9, September 1999: S13-S18.

1019	Porzio et al., "Encapsulation Compositions and Processes for Preparing the Same," U.S. Patent No. 7,488,503 B1 filed March 31, 2004 (Porzio).
1020	Bunea, et al., "Evaluation Of The Effects Of Neptune Krill Oil On The Clinical Course Of Hyperlipidemia," Altern Med Rev. 2004; 9:420–428 (Bunea).
1021	Complaint filed in *Aker Biomarine Antarctic AS v. Olympic Holding AS, et al.,* 1:16-CV-00035-LPS-CJB- (D. Del.).
1022	Affidavits of Service Filed in *Aker Biomarine Antarctic AS v. Olympic Holding AS, et al.,* 1:16-CV-00035-LPS-CJB- (D. Del.).
1023	Federal Register Notice of Institution of Investigation 337-TA-1019 on September 16, 2016 by the ITC (81 Fed. Reg. pages 63805-63806)
1024	File History to U.S. Patent No. 9,034,388 B2, Serial No, 12/057,775 ('388 File History) 1024 Part 1 - Pages 1-450 1024 Part 2 - Pages 451-900 1024 Part 3 - Pages 901-1350 1024 Part 4 - Pages 1351-1800 1024 Part 5 - Pages 1801-2250 1024 Part 6 - Pages 2251-2700 1024 Part 7 - Pages 2701-3083
1025	File History to U.S. Patent No. 9,028,877 B2, Serial No, 14/490,176 ('877 File History) 1025 Part 1 - Pages 1-375 1025 Part 2 - Pages 376-724

1026	File History to U.S. Patent No. 9,078,905 B2, Serial No, 14/490,221 ('905 File History) 1026 Part 1 - Pages 1-450 1026 Part 2 - Pages 451-882
1027	Saether et al., "Lipolysis post mortem in North Atlantic krill," Comp. Biochem. Physiol. Vol. 83B, No. 1, pp. 51-55, 1986 (Saether).
1028	Hawley's Condensed Chemical Dictionary, p. 893, 13th ed.,1997 (Hawley's)
1029	Webster's New Universal Unabridged Dictionary, 2nd ed., p. 732, 1983 (Webster's)
1030	Tehoharides, U.S. Patent Application Publication No. US/2006/0013905 A1, "Anti-Inflammatory Compositions For Treating Multiple Sclerosis" (Tehoharides)
1031	Halliday, Jess, "Neptune-Degussa Deal to Develop Phospholipids, Adapt Krill Oil," http://www.nutraingredients-usa.com/Suppliers2/Neptune-Degussa-deal-to-develop-phospholipids-adapt-krill-oil, December 12, 2005 (Neptune-DeGussa).
1032	Grantham, G.J., "The Utilization Of Krill", UNDP/FAO Southern Ocean Fisheries Survey Programme (1977) (Grantham).
1033	Yoshitomi, U.S. Patent Application Publication No. US/2003/0113432 A1, "Process For Making Dried Powdery and Granular Krill" (Yoshitomi).

I. THE PETITION

Petitioner, real party-in-interest, Rimfrost AS, a Norwegian corporation with its principal place of business at Vågsplassen, 6090, Fosnavåg, Norway, hereby petitions the Patent Trial and Appeal Board (the "Board" or the "PTAB") of the United States Patent and Trademark Office ("PTO"), pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.1 *et seq.*, to institute *inter partes* review and to find unpatentable and cancel Claims 1-20 of U.S. Patent No. 9,078,905, entitled "Bioeffective Krill Oil Compositions," issued July 14, 2015 (Serial No. 14/490,221, filed September 18, 2014) ("the '905 patent"), assigned to Aker Biomarine Antarctic AS. The '905 patent is submitted as Exhibit 1001. There is a reasonable likelihood that Petitioner will prevail with respect to at least one claim challenged in this petition.

II. MANDATORY NOTICES

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this petition.

A. Real parties-in-interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Olympic Holding AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, Bioriginal

Food and Science Corp., and Petitioner, Rimfrost AS, are identified as the real parties-in-interest. Several other entities have a majority ownership interest in the above-identified real parties-in-interest. Based upon those ownership interests, and in an abundance of caution, Petitioner also names Stig Remøy, SRR Invest AS, Rimfrost Holding AS, Pharmachem Laboratories, Inc., and Omega Protein Corporation as real parties-in-interest.

B. **Related matters (37 C.F.R. § 42.8(b)(2))**

Aker has asserted two patents – U.S. Patent Nos. 9,078,905 and 9,028,877 in a lawsuit captioned *Aker Biomarine Antarctic AS v. Olympic Holding AS; Rimfrost AS; Emerald Fisheries AS, Rimfrost USA, LLC; Avoca Inc.;* and *Bioriginal Food & Science Corp.* Case No. 1:16-CV-00035-LPS-CJB (D. Del.). (Complaint, Exhibit 1022). The litigation has been stayed pursuant to 28 U.S.C. § 1659 in view of Investigation No. 337-TA-1019 instituted by the United States International Trade Commission on September 16, 2016 as noticed in the Federal Register. The ITC proceeding, entitled *In the Matter of Certain Krill Oil Products and Krill Meal for Production of Krill Oil Products*, relates to U.S. Patent Nos.

9,028,877; 9,078,905[1]; 9,072,752; 9,320,765; and 9,375,453. The ITC investigation lists as respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited and Bioriginal Food & Science Corp. (ITC Exhibit 1023).

C. Counsel (37 C.F.R. §§ 42.8(b)(3) and 42.10(a))

Petitioner designates the following individuals as its lead counsel and back-up lead counsel:

Lead Counsel	Back-up Lead Counsel
James F. Harrington Reg. No. 44,741 Hoffmann & Baron, LLP jfhdocket@hbiplaw.com (516)822-3550	Michael I. Chakansky Reg. No. 31,600 Hoffmann & Baron, LLP micdocket@hbiplaw.com (973)331-1700

[1] Petitioner believes the '905 patent is unenforceable due to the filing of an improper terminal disclaimer. During prosecution applicants filed a terminal disclaimer in an effort to overcome a double patenting rejection based upon copending U.S. Application No. 13/856,642. However, U.S. Application No. 13/856,642 (U.S. Patent No. 9,068,142) was assigned to Rimfrost AS' predecessor-in-interest, Olympic Seafood AS. The application for the '905 patent and U.S. Application No. 13/856,642 were therefore not commonly owned. As a result, Complainants in the ITC proceeding moved for partial termination, based on withdrawal of the '905 claims. The ALJ granted the motion to terminate as to the '905 patent and a determination of unenforceability was deemed moot.

Ronald J. Baron
Reg. No. 29,281
Hoffmann & Baron, LLP
rjbdocket@hbiplaw.com
(516)822-3550

John T. Gallagher
Reg. No. 35,516
Hoffmann & Baron, LLP
jtgdocket@hbiplaw.com
(516)822-3550

D. **Service information (37 C.F.R. §42.8(b)(4))**

Service on Petitioner may be made electronically by using the following email address: 905ipr2@hbiplaw.com and the email addresses above. Service on Petitioner may be made by Postal Mailing or Hand-delivery addressed to Lead and Back-up Lead Counsel at the following address, but electronic service above is requested:

Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset, New York 11791

This document, together with all exhibits referenced herein, has been served on the patent owner at its corporate headquarters, Oskenøyveien 10 No-1327, 1366 Lysaker, Norway, as well as the correspondence address of record for the

'905 patent: Casimir Jones, S.C., 2275 Deming Way, Suite 310, Middleton, Wisconsin 53562, and the address of Patent Owner's litigation counsel: Andrew F. Pratt, Esq., Venable LLP, 575 Seventh Street NW, Washington, DC 20004.

III. PAYMENT OF FEES

Pursuant to 37 C.F.R. §§ 42.103 and 42.15(a), the requisite filing fee of $25,000 (request fee of $9,000, post-institution fee of $14,000 and excess claims fee of $2,000) for a Petition for *Inter Partes* Review is submitted herewith. Claims 1-20 of the '905 patent are being reviewed as part of this Petition. The undersigned further authorizes payment from Deposit Account No. 08-2461 for any additional fees or refund that may be due in connection with the Petition.

IV. ADDITIONAL REQUIREMENTS FOR *INTER PARTES* REVIEW

A. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner hereby certifies that the '905 patent is available for *Inter Partes* Review and that Petitioner is not barred or estopped from requesting *Inter Partes* Review challenging the claims of '905 patent on the grounds identified herein. This Petition is timely filed under 35 U.S.C. §315(b) because it is filed within one year of the service of the Complaint alleging infringement of the '905 patent by Aker. *See* Exhibits. 1021-1022.

B. **Level of Ordinary Skill in the Art**

As of the earliest priority date the '905 Patent is entitled to, that is January 28, 2008, a person of ordinary skill in the art ("POSITA") would have held an advanced degree in marine sciences, biochemistry, organic (especially lipid) chemistry, chemical or process engineering, or associated sciences with complementary understanding, either through education or experience, of organic chemistry and in particular lipid chemistry, chemical or process engineering, marine biology, nutrition, or associated sciences; and knowledge of or experience in the field of extraction. In addition, a POSITA would have had at least five years applied experience. (Tallon Decl., ¶27).

C. **Identification of Challenge and Relief Requested (37 C.F.R. § 42.104(b) and 37 C.F.R. § 42.22(a)(1))**

The precise relief requested by Petitioner is that Claims 1-20 are found unpatentable and cancelled from the '905 patent.

1. Claims for which Inter Partes Review is Requested (37 C.F.R. §42.104(b)(2))

Petitioner requests *Inter Partes* Review of Claims 1-20 of the '905 patent.

2. Specific Statutory Grounds on which the Challenge is Based (37 C.F.R. § 42.104(b)(2))

The specific statutory grounds for the challenge are as follows:

Ground	Reference(s)	Basis	Claims Challenged
1	Sampalis I, Tanaka I, and Fricke	35 U.S.C. §103(a)	1-4, 6, 9-10, 12, 15-16, and 18
2	Sampalis I, Tanaka I, Fricke, and Randolph	35 U.S.C. §103(a)	5
3	Sampalis I, Tanaka I, Fricke and Bottino	35 U.S.C. §103(a)	7, 8, 11, 13-14, 17, 19, and 20

Petitioner also relies on the expert declaration of Dr. Stephen Tallon (Exhibit 1006, hereinafter "Tallon Decl.").

3. Earliest Effective Priority Date

The '905 patent claims priority to Provisional Application No. 60/920,483, filed on March 28, 2007, Provisional Application No. 60/975,058, filed on September 25, 2007, Provisional Application No. 60/983,446, filed on October 29, 2007, and Provisional Application No. 61/024,072, filed on January 28, 2008. All of the issued claims in the '905 patent require the element that the recited krill oil comprise from about 3% to about 15% w/w or 3% to about 10% w/w ether phospholipids. Support of the claim element "ether phospholipid" – recited in each '905 claim – was not introduced until the filing of U.S. Application No.

61/024,072 filed on January 28, 2008. (See Exhibits 1002-1005). Consequently, the earliest effective priority date for the claims of the '905 patent is January 28, 2008. (Tallon Decl., ¶ 34).

Thus, Aker cannot claim a priority date earlier than January 28, 2008.

4. Prior Art References

All prior art references utilized herein were published more than one year prior to the earliest possible priority date of January 28, 2008, and therefore qualify as prior art under 35 U.S.C.§102(b).

§ 102(b) Reference	Publication Date	Exhibit No.
Sampalis I	2003	1012
Tanaka I	1995	1014
Fricke	April 30, 1984	1010
Bottino	June 28, 1974	1007
Randolph	March 17, 2005	1011

D. Claim Construction - Broadest Reasonable Interpretation ("BRI") (37 C.F.R. § 42.104(b)(3))

In an *inter partes* review, claim terms are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48756 and 48766 (Aug. 14, 2012).

The following discussion proposes constructions of terms in the challenged claims under the broadest reasonable construction standard. Any claim terms not included in the following discussion are to be given their broadest reasonable interpretation (BRI) in light of the specification as commonly understood by those of ordinary skill in the art. (M.P.E.P. § 2111.01(I)). Should the patent owner, in order to avoid the prior art, contend that the claims have a construction different from their BRI, the appropriate course is for the patent owner to seek to amend the claims to expressly correspond to its contentions in this proceeding. *See* 77 Fed. Reg. 48764 (Aug. 14, 2012). Any such amendment would only be permissible if the proposed amended claims comply with 35 U.S.C. § 112.

Also, for the applicants of the '905 patent inventors to act as their own lexicographer, the definition of a claim term must be set forth in the specification

with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). If a limitation is not necessary to give meaning to what the '905 patent inventors mean by a claim term, it would be "extraneous" and should not be read into the claim. *Renishaw*, 158 F.3d at 1249; *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988). The construction that stays true to the claim language and most naturally aligns with the inventors' description is likely the correct interpretation. *See Renishaw*, 158 F.3d at 1250.

Petitioner's position regarding the scope of the '905 patent claims should not be taken as an admission of the proper claim scope in other adjudicative forums where a different claim interpretation standard may apply, *e.g.*, in a patent infringement action. Moreover, Petitioner reserves all of its rights to further challenge any claim terms of the '905 patent under 35 U.S.C. § 112, including by arguing that the terms are not definite, not supported by the written description, and/or not enabled. Further, as Petitioner is precluded from presenting challenges under 35 U.S.C. § 112 in an *inter partes* review, Petitioner's arguments in this Petition, or lack of arguments on any of these grounds, should not be interpreted

as waiving or conflicting with invalidity arguments in other forums under 35 U.S.C. § 112.

The claim construction in a district court litigation or ITC proceeding can be narrower than in an *inter partes* review because it is performed in view of both the intrinsic and extrinsic record and is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the application. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). This construction may be narrower than the BRI. In addition, if the claim is still ambiguous in view of the relevant evidence during litigation, it should be construed to preserve the validity. *Id.* at 1327.

This standard does not apply to *inter partes* review. For purposes of *inter partes* review, each challenged claim must be given "its broadest reasonable constructions in light of the specification." 37 C.F.R.§ 42.100(b); *see also Cuozzo Speed Technologies. LLC v. Lee,* 136 S. Ct. 2131, 2142 (2016); *see also In re Cuozzo Speed Techs., LLC,* 778 F. 3d 1271, 1279 (Fed. Cir. 2015). The BRI must be consistent with the construction that one of ordinary skill in the art would reach and must take into account any special definition given to a claim term in the specification. *In re Am. Acad. Of Sci. Tech. Ctr.,* 367 F. 3d 1359, 1364 (Fed. Cir.

2004). Thus, solely for this proceeding, Petitioner's proposed constructions are set forth below. *See infra*, pp 19-26. All other terms, not expressly discussed, should should be given their plain and ordinary meaning. Petitioner reserves the right to address any claim construction issue raised by Patent Owner.

V. SUMMARY OF THE '905 PATENT (EXHIBIT 1001)

A. Background of '905 Patent

The '905 patent relates to extracts from Antarctic krill that includes bioactive fatty acids. (Exhibit 1001, p. 0025, col. 1, lines 19-20). In the Detailed Description of the Invention, the patentees of the '905 patent state, "[t]his invention discloses novel krill oil compositions characterized by containing high levels of astaxanthin, phospholipids, included an enriched qualities of ether phospholipids, and omega-3 fatty acids." (Exhibit 1001, p. 0029, col. 9, lines 28-31).

However, as acknowledged in the Background of the Invention, "a krill oil composition has been disclosed comprising a phospholipid and/or a flavonoid. The phospholipid content and the krill lipid extract could be as high as 60% w/w and the EPA/DHA content as high as 35% (w/w). See, e.g., WO 03/011873." (Exhibit 1001, p. 0025, col. 1, lines 53-57). Patentees also acknowledged that krill

krill oil compositions have been described as being effective for decreasing cholesterol, inhibiting platelet adhesion, inhibiting artery plaque formation, preventing hypertension, controlling arthritis symptoms, preventing skin cancer, enhancing transdermal transport, reducing the symptoms of premenstrual symptoms or controlling blood glucose levels in a patient. Citing, *e.g.,* WO 02/10234. (Exhibit 1001, p. 0025 col. 1, lines 46-52). Patentees also admit, "[s]upercritical fluid extraction with solvent modifier has previously been used to extract marine phospholipids from salmon roe, but has not been previously used to extract phospholipids from krill meal. See, *e.g.,* Tanaka *et al., J. Oleo. Sci.* (2004), (2004), 53(9), 417-424." (Exhibit 1001, p. 0025, col. 1, line 65 to col. 2, line 2).

The analysis of the krill oil preparation disclosed in the '905 patent is provided in Table 21, which shows the amount of phospholipids, triglycerides and omega-3 fatty acids in the extract. Tables 22 and 23 provide the only ether phospholipid data in the entire specification. Example 8 concludes:

> The main polar ether phospholipids of the krill meal are alkylacylphosphatidylcholine (AAPC) at 7-9% of total polar lipids, lysoalkylacylphosphatidylcholine (LAAPC) at 1% of total polar lipids (TPL) and alkylacylphosphatidyl-ethanolamine (AAPE) at <1% of TPL. (Exhibit 1001, p. 0041, col. 33, lines 9-14).

(Tallon Decl., ¶184).

All issued claims recite the ether phospholipid limitation, which is the element that patentees rely upon for novelty. However, as demonstrated herein, it would have been obvious to a POSITA to encapsulate a krill oil having between 3 and 10% w/w of ether phospholipids.

B. **Prosecution History of the '905 Patent**

The '905 patent issued on July 14, 2015 from U.S. Application No. 14/490,221 filed September 18, 2014. The '905 patent is a continuation of U.S. Patent Application No. 12/057,775 filed on March 28, 2008 and claims the benefit of four U.S. Provisional Applications: 61/024,072 filed on January 28, 2008; 60/983,446 filed on October 29, 2007; 60/975,058 filed on September 25, 2007; and 60/920,483 filed on March 28, 2007.

All of the claims of the '905 patent recite the claim limitation of "about 3% to about 15% w/w ether phospholipids" or "about 3% to about 10% w/w ether phospholipids." Applicants relied on this limitation in asserting patentability of the claims.

In parent U.S. Application No. 12/057,775, which granted as U.S. Patent No. 9,034,388, Applicants amended the claims to add the limitation "about 3% to

about 10% ether phospholipid" and argued that the cited references do not teach extraction of a krill oil having the amended limitations. See response to Office Action dated September 7, 2012 (Exhibit 1024, part 2, pp. 0633 - 0650). The claims are directed to "[a] method of producing krill oil....from about 3% to about 10% w/w ether phospholipids." (Exhibit 1024, part 2, p. 0640).

In the '221 application which issued as the '905 patent, a Non-Final Office Action was mailed November 17, 2014 (Exhibit 1026, part 2, pp. 622-631) that rejected all the as-filed claims. In addition to several non-statutory double patenting rejections, the Examiner asserted two United States Patents as prior art arguing that the disclosures of these patents made the as-filed claims obvious: Beaudoin *et al.* (Exhibit 1016); and Porzio *et al.* (Exhibit 1019). Beaudoin *et al.* was characterized as disclosing krill oil components including phospholipids and triglycerides at similar concentrations as presented in the claims. This was combined with Porzio *et al.*, which teaches how to encapsulate lipid compositions.

A Response to the Non-Final Office Action was filed on December 19, 2014 (Exhibit 1026, part 1, pp. 0242 - 0251) with no claim amendments. In an effort to distinguish the cited art, applicants maintained that the prior art did not disclose a krill oil comprising "from about 3% - 15% ether phospholipids." It was argued

that Beaudoin's '299 patent extraction method was virtually identical to the NKO (Neptune Krill Oil) extraction process and would therefore would purportedly contain less than 3% either phospholipids.

An analysis is presented of the NKO composition in the '905 patent (Example 8 and Table 22), showing that NKO has 7% AAPC and 1.2% LAAPC, i.e., a total ether phospholipid content of 8.2% of total phospholipids. It was argued that this percentage corresponded to an actual 2.46% value[2] when relative to the krill oil (*e.g.,* based upon a 30% measurement of total NKO phospholipids). It was argued, "Applicant respectfully submits that this demonstrates that krill oil made by the Beaudoin method does not contain the claimed range of 3% to 15% ether phospholipids as a percentage of the total krill oil composition." (Exhibit 1026, part 1, pp. 0242 - 0251).

A Final Rejection was mailed on February 17, 2015 (Exhibit 1026, part 1, pp. 0168 - 0177) where the non-statutory double patenting and obviousness rejections were maintained. The Examiner asserted that the calculated 2.46%

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[2] This is an admission that Beaudoin et al. describes krill oil having just below 3% ether phospholipids.

ether phospholipid concentration in Beaudoin *et al.* was close enough to the claimed range such that it would be obvious for one of ordinary skill in the art to optimize the extraction process through routine means to increase the ether phospholipid content to the claimed 3% concentration because of the known health benefits of ether phospholipids.

A Response to the Final Office Action was filed on April 16, 2015 (Exhibit 1026, part 1, pp. 0159 - 0164) with no claim amendments. Instead, an argument concerning purported unexpected results was made in which the Applicants directed the examiner's attention to Example 9 and some selected figures referred to therein that allegedly compares the claimed krill oil (designated Superba or PL2) to prior art krill oil (designated NKO or PL1).

Despite Applicants' assertion that "greater than 3% ether phospholipids have superior activity," there is no evidence in the specification for ether phospholipid amounts other than that in Table 22 and Table 23. (Tallon Decl.,¶ 184). Moreover, the claims specify "about 3%" – not "greater than 3%." Nevertheless, it appears that this "superior results" assertion convinced the Examiner, since a Notice of Allowance followed on May 20, 2015 (with no written reasons for the allowance).

Accordingly, throughout the prosecution of the '905 patent family, Applicants repeatedly stressed the importance of krill oil compositions with greater than 3% ether phospholipids in gaining allowance of the claims.

C. **Construction of the '905 patent Claim Terms**

As discussed above, a claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." *See* 37 C.F.R. § 42.100(b).

Petitioner sets forth herein its recommended interpretation of certain claim terms, the scope of which are unclear on their face.

1. Claims 1, 12, and 18 - "krill oil"

The term "krill oil" is recited in all of the independent claims, i.e., Claims 1, 12 and 18. The meaning of "krill oil" can be determined from the specification. In particular, the '905 specification states:

> In order to isolate the krill oil from krill, solvent extraction methods have been used. See, e.g., WO 00/23564. Krill lipids have been extracted by placing the material in a ketone solvent (e.g., acetone) in order to extract the lipid soluble fraction. (Exhibit 1001, p. 0025, col. 1, lines 31-34).

Accordingly, patentees equate krill oil with the lipids obtained from krill.

The '905 Patent further describes "krill oil" is a lipid-rich extract of krill. This extract can primarily include phospholipids and neutral lipids in varying

proportions. The Abstract of the '905 Patent describes the "actual krill oils" as the the oil extracted using a polar solvent after using a non-polar solvent to remove neutral lipids: "[t]he krill oils are obtained from krill meal using supercritical fluid extraction in a two stage process. Stage 1 removes the neutral lipid by extracting with neat supercritical CO_2 or CO_2 plus approximately 5% of a co-solvent. Stage 2 extracts the *actual krill oils* by using supercritical CO_2 in combination with approximately 20% ethanol" (Exhibit 1001, Abstract, emphasis added) (Tallon Decl., ¶ 40). The '905 patent therefore also describes krill oil as a phospholipid rich extract produced by removing some or much of the triglyceride and other neutral oils. In addition, the '905 Patent describes "combining said polar extract and said neutral extract to provide *Euphausia superba* krill oil...." (Exhibit 1001, p. 0027, col. 5, line 55 to col. 6, line 11) (Tallon Decl., ¶¶ 43-45).

Additionally, in the context of the '905 Patent, "krill oil" is a lipid-rich extract of krill that comprises phospholipids, as well as a lipid-rich extract of krill that comprises blends of polar lipids (phospholipids) and neutral lipids in varying proportions. The '905 Patent repeatedly refers to the krill oil composition as comprising blend of lipid fractions. "In some embodiments, krill oil composition comprises a blend of lipid fractions obtained from krill" (Exhibit 1001, col. 3,

lines 26-27, Exhibit 1001, p. 0026). "In some embodiments, the blended krill oil product comprises a blend of lipid fractions obtained from *Euphausia superba*" (Exhibit 1001, col. 5, lines 43-45, col. 6, lines 50-52; col. 7, lines 18-20). (See Tallon Decl., ¶¶ 35, 36, 43, 44, 45).

Thus, the broadest reasonable construction of "krill oil" is "lipids extracted from krill." (Tallon Decl., ¶ 48).

2. Claims 1, 12, and 18 – "an effective amount of krill oil"

The claim limitation of "an *effective amount* of krill oil" is found in all of the independent claims. *See* Claims 1, 12, 18 (Exhibit 1001, p. 0042) . In the only two separate places of the specification where the term "effective amount" is disclosed, Patentees state, "[i]n some preferred embodiments, the effective amount of a krill oil composition is from 0.2 grams to 10 grams of said krill oil composition." (Exhibit 1001, p. 0027, col. 6 lines 45-46; and p. 0028, col. 7, lines 12 - 14). This range is also disclosed in the '446 Provisional Application, *e.g.*, Claim 4. (Exhibit 1003, p. 0029) (Tallon Decl., ¶¶ 49, 50, 52, 52).

The range of 0.2 to 10 grams of oil in the capsule is consistent with the beneficial effective range of krill oil taught in the prior art. *See e.g.*, Randolph: "[t]ypically, a composition contains between about 300 mg and about 3000 mg of

a krill oil ingredient." (Exhibit 1011, p. 0006, [0040]) This effective amount is also consistent with the disclosure of Sampalis I wherein they state "[e]ach patient was asked to take two 1-gram soft gels of…NKO…." (Sampalis I, Exhibit 1012, p. 0004, 2nd col.) (Tallon Decl., ¶¶ 54, 55).

Thus, the proper BRI of "an effective amount of krill oil" as recited in the claims of the '905 patent is "at least the range of between 0.2 and 10 grams of krill oil." (Tallon Decl., ¶ 56).

3. Claim 4 - "polar solvent extract"

The element of "polar solvent extract" as set forth in Claim 4 is not explicitly defined in the specification, but is described. In the Krill Processing section of the Detailed Description, patentees disclose methods of making a *Euphausia superba* krill oil by contacting a *Euphausia superba* preparation, such as *Euphausia superba* krill meal, with a polar solvent, such as ethanol to extract lipids. (Exhibit 1001, p. 0030, col. 12, lines 24-36). Patentees also disclose, "In some embodiments, krill oil is extracted from denatured krill meal. In some embodiments, the krill oil is extracted by contacting the krill meal with ethanol." (Exhibit 1001, p. 0030, col. 11, lines 3-5) (Tallon Decl. ¶ 57).

In the Background of the Invention, patentees admit:

> In order to isolate the krill oil from the krill, solvent extraction methods have been used. See, e.g., WO 00/23546. Krill lipids have been extracted by placing the material in a ketone solvent (e.g., acetone) in order to extract the lipid soluble fraction. This method involves separating the liquid and solid contents and recovering a lipid rich fraction from the liquid fraction by evaporation. Further processing steps include extracting and recovering by evaporation the remaining soluble lipid fraction from the contents by using a solvent such as ethanol. See, e.g., WO 00/23546.

(Exhibit 1001, p. 0025, col. l, lines 31-40).

In the Detailed Description, patentees further state:

> In some embodiments, krill oil is extracted from the denatured krill meal. In some embodiments, the krill oil is extracted by contacting the krill meal with ethanol. In some embodiments, krill is then extracted with a ketone solvent such as acetone. In other embodiments, the krill oil is extracted by one or two step supercritical fluid extraction. In some embodiments, the supercritical fluid extraction uses carbon dioxide and neutral krill oil is produced. In some embodiments, the supercritical fluid extraction uses carbon dioxide with the addition of a polar entrainer, such as ethanol, to produce a polar krill oil. In some embodiments, the krill oil meal is first extracted with carbon dioxide followed by carbon dioxide with a polar entrainer, or vice versa. In some embodiments, the krill meal is first extracted with CO_2 supplemented with a low amount of a polar co-solvent (e.g., from about 1% to about 10%, preferably about 5%) such a C_1-C_3 monohydric alcohol, preferably ethanol, followed by extraction with CO_2 supplemented with a high amount of a polar co-solvent (from about 10% to about 30%, preferably about 23%) such as such a C_1-C_3 monohydric alcohol, preferably ethanol, or vice versa.

> Surprisingly, it has been found that use of a low amount of polar solvent in the CO_2 as an entrainer facilitates the extraction of neutral lipid components and astaxanthin in a single step. Use of the high of polar solvent as an entrainer in the other step facilitates extraction of ether phospholipids, as well as non-ether phospholipids.

(Exhibit 1001, p. 0030, col. 11, lines 3-29).

Thus, patentees contemplated extraction with either a polar solvent or a mixture of a polar solvent and supercritical CO_2. (Tallon Decl., ¶¶ 57-60).

The solvent used must also be capable of extracting lipids that include phospholipids. The '905 patent explains, "In some embodiments, the present invention provides a method of making a *Euphausia superba* krill oil composition comprising contacting *Euphausia superba* with a polar solvent to provide an polar extract comprising phospholipids...." (Exhibit 1001, p. 0030, col. 12, lines 12-16). Typical polar organic solvents (pure or mixtures) used in conventional industrial practice that satisfy these criteria include alcohols (*e.g.,* methanol, ethanol, and isopropyl alcohol), ketones (particularly acetone), and esters (*e.g.,* ethyl acetate) (Tallon Decl., ¶ 61.)

Thus, the broadest reasonable construction of "polar solvent extract" is "material extracted in the presence of a solvent or mixtures of solvents capable of extracting polar lipids comprising phospholipids." (Tallon Decl., ¶ 62).

4. Claim 5 - "phytonutrient"

The specification does not expressly define the term "phytonutrient." However, the specification states:

> In still further embodiments, the compositions comprise at least one phytonutrient (e.g., soy isoflavonoids, oligomeric proanthcyanidins, inodol 3 carbinol, sulforaphone, fibrous ligands, plant phytosterols, ferulic acid, anthocyanocides, triterpenes, omega 3/6 fatty acids, conjugated fatty acids such as conjugated linoleic acid and conjugated linolenic acid, polyacetylene, quinones, terpenes, cathechins, gallates, and querctin). Sources of plant phytonutrients include but are not limited to, soy lecithin, soy isoflavones, brown rice germ, royal jelly, bee propolis, acerola berry juice powder, Japanese green tea, grape seed extract, grape skin extract, carrot juice, bilberry, flaxseed meal, bee pollen, ginkgo biloba, primrose (evening primrose oil), red clover, burdock root, dandelion, parsley, rose hips, milk thistle, ginger, Siberian ginseng, rosemary, curcumin, garlic, lycopene, grapefruit seed extract spinach and broccoli.

(Exhibit 1001, p. 0032, col. 15, lines 52-67) (Tallon Decl., ¶¶ 65).

These examples provided in the '905 patent are consistent with the extrinsic evidence. For example, Kochian (1999) (Exhibit 1018), provides an overview of various agricultural approaches to improving phytonutrient content in plants."

Kochian defines the literal definition of the term "phytonutrient" as "a nutrient derived from plants, and further explains that "we would be talking about a plant-plant-based substance essential for proper metabolism and function in humans.... These compounds could play an important role in improving human health by reducing the impact of certain chronic diseases (e.g. heart disease, cancer) and the effects of aging." (Kochian, Exhibit 1018, pp. 0001-0002) (Tallon Decl., ¶ 63).

Thus, the broadest reasonable construction of the term "phytonutrient" is "a plant-derived compound that has a positive impact on human health or nutrition." (Tallon Decl., ¶ 66).

VI. EACH GROUND PROVIDES MORE THAN A REASONABLE LIKELIHOOD THAT EACH CLAIM OF THE '905 PATENT IS UNPATENTABLE

A detailed discussion of each ground for claim invalidation, *i.e.*, Grounds 1-3, is set forth below. In support of the invalidity arguments, Petitioner relies upon the Declaration of Dr. Stephen Tallon (Exhibit 1006 / ("Tallon Decl.")

Petitioner notes that all the prior art cited herein may be combined with each other, and should not be limited by the way Petitioner has organized the grounds and prior art citations. Thus, absence of an entry in any claim chart is not an admission that the particular prior art does not disclose, teach and/or possess that

element. Petitioner expressly reserves the right to present arguments, if applicable, that the particular prior art does disclose, teach and/or possess same.

A. Ground 1: §103(a) – Sampalis I, Tanaka, and Fricke [Claims 1-4, 6, 9-10, 12, 15-16, and 18]

Claim 1 of the '905 patent relates to an encapsulated krill oil and is set forth below:

> 1. Encapsulated krill oil comprising:
> a capsule containing an effective amount of krill oil,
> said krill oil comprising from about 3% to about 15 %
> w/w ether phospholipids.

Sampalis I (Exhibit 1012) describes an encapsulated krill oil composition in the form of a soft gel that includes an effective amount of krill oil. Sampalis I is an evaluation of the effects of Neptune Krill Oil™ on the management of premenstrual syndrome and dysmenorrhea. The authors explain, the "Neptune Krill Oil™ (NKO™) product is a natural health product extracted from Antarctic krill also known as *Euphausia superba*. *Euphausia superba*, a zooplankton crustacean, is rich in phospholipids and triglycerides carrying long-chain omega-3 polyunsaturated fatty acids, mainly EPA and DHA, and in various potent antioxidants…." (Exhibit 1012, p. 0004, 1st col.) (Tallon Decl.,¶¶ 67-68). Sample I explains, that "each patient was asked to take two 1-gram soft gels of

either NKO or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial." (Exhibit 1012, p. 0004, 2nd col.). The study was designed to demonstrate that NKO would significantly reduce the physical and emotional symptoms of premenstrual syndrome and be significantly more effective for managing PMS symptoms than fish oil. (Exhibit 1012, p. 0004, 2nd col.). Thus, Sampalis I expressly discloses an an encapsulated krill oil composition that includes a capsule containing an effective amount of krill oil. (Tallon Decl. ¶¶ 69-71).

Claim 1 of the '905 patent further includes the krill oil comprising from about 3% to about 15% w/w ether phospholipids. The work and analyses disclosed by Tanaka I and Fricke show the presence of 3%-15% w/w ether phospholipids. (Tallon Decl., ¶¶ 98-99, 196).

First, Tanaka I (Exhibit 1014) determined the phosphatidylcholine (PC) content of krill. Tanaka extracted lipids from krill and determined that the resulting PC composition contained 23.0 +/- 1.2% of the ether phospholipid alkylacylphosphatidylcholine (AAPC) as reported in Table 1. (Exhibit 1014, p. 0003).

Table I. Subclass Composition of PCs from Food Stuffs

PC	Diacyl	Alkylacyl	Alkenylacyl
		%	
Hen egg yolk	99.2±0.2	0.8±0.1	<0.1
Salmon roe	98.8±0.2	1.2±0.2	<0.1
Sea urchin egg	57.5±1.1	41.5±0.3	1.0±0.8
Krill	77.0±1.2	23.0±1.2	<0.1

Values are means±SE for four experiments.

(Tallon Decl. ¶¶ 130-131).

Fricke (Exhibit 1010), studied the lipid classes, fatty acids of total and individual lipids and sterols of *Euphausia superba* from two areas of the Antarctic Ocean. Samples were analyzed by thin layer chromatography and gas liquid chromatography and gas liquid chromatography/mass spectrometry. Krill samples of 5 kg were quick frozen and stored at -35 °C until analyzed. Liquid extraction was performed according to Folch *et al.*, *J. Biol. Chem.* 226:497-509 (1957) (Exhibit 1017), which uses a polar solvent, choroform:methanol, in a ratio of 2:1 (v/v). (Exhibit 1010, p. 0001, 2nd col.) (Tallon, Decl. ¶¶ 93-95).

Table 1 of Fricke shows the lipid composition of the Antarctic krill for both samples. Table 1 shows the phosphatidylcholine (PC) level for both samples as

approximately 34% (35.6 +/- 0.1 for 1977 sample and 33.3 +/- 0.5 for 1981 sample. (Exhibit 1010, p. 0002, 2nd col.) (Tallon Decl. ¶ 98).

TABLE 1

Lipid Composition of Antarctic Krill (*Euphausia superba* Dana)

Sample	12/1977	3/1981
Total lipid content (% wet weight)	2.7 ± 0.2	6.2 ± 0.3
Phospholipids		
Phosphatidylcholine	35.6 ± 0.1	33.3 ± 0.5
Phosphatidylethanolamine	6.1 ± 0.4	5.2 ± 0.5
Lysophosphatidylcholine	1.5 ± 0.2	2.8 ± 0.4
Phosphatidylinositol	0.9 ± 0.1	1.1 ± 0.4
Cardiolipin	1.0 ± 0.4	1.6 ± 0.2
Phosphatidic acid	0.6 ± 0.4	
Neutral lipids		
Triacylglycerols	33.3 ± 0.5	40.4 ± 0.1
Free fatty acids[a]	16.1 ± 1.3	8.5 ± 1.0
Diacylglycerols	1.3 ± 0.1	3.6 ± 0.1
Sterols	1.7 ± 0.1	1.4 ± 0.1
Monoacylglycerols	0.4 ± 0.2	0.9 ± 0.1
Others[b]	0.9 ± 0.1	0.5 ± 0.1
Total	98.9	99.3

Since Tanaka demonstrates that AAPC is 23.0 +/- 1.2% of krill phosphatidylcholine and Fricke discloses that PC is approximately 34% of krill

lipids, a POSITA would have understood that AAPC, an ether phospholipid, is present at approximately 8% of krill oil (34% x .23 = 7.8%), which is within the range of 3% and 15% recited by Claim 1. (Tallon Decl., ¶¶ 98-99).

Thus, the combination of Sampalis I, Tanaka and Fricke render Claim 1 obvious. (Tallon Decl., ¶¶ 194-197, 218, 219).

Claim 2 requires the additional element wherein said krill oil comprises at least 30% total phospholipids w/w. Table I in Fricke discloses a total phospholipid level for two krill samples - - 44.0 +/- 2.0 for the 1981 sample and 45.7 +/- 1.6 for the 1977 sample. (Tallon Decl., ¶ 100). Thus, a krill oil containing at least 30% phospholipids w/w would have been obvious. (Tallon Decl., ¶¶ 198, 218-219).

Claim 3 includes the element of the krill oil comprising at least 30% phosphatidylcholine w/w. Table I in Fricke discloses phosphatidylcholine at a level of 33.3 +/- 0.5% for the 1981 sample and 35.6 +/- 0.1 for the 1977 sample. (Tallon Decl., ¶ 98). Thus, it would have been obvious to a POSITA to enapsulate a krill oil including at least 30% PC. (Tallon Decl., ¶¶ 199, 218-219).

Claim 4 includes the element that the krill oil is polar solvent extract of krill. Fricke states that lipid extraction was performed according to Folch *et al.*

(1957) where lipids were extracted using the polar solvent, chloroform:methanol in a 2:1 ratio (v/v). (Tallon Decl., ¶ 95). Thus, it was well known as of the time of of the earliest effective priority date to extract lipids from krill using polar solvent extraction. This fact is also acknowledged by the patent holder in the Background Background of the Invention of the '905 patent at column 1, lines 31-40. (Tallon Decl., ¶ 58). Thus, it would have been obvious to a POSITA to produce a krill oil composition from the polar solvent extract of krill as set forth in Claim 4. (Tallon Decl., ¶ 200).

Claim 6 relates to the encapsulated krill oil of Claim 1 wherein the krill oil further includes from about 3% to about 10% ether phospholipids. As discussed above, the combination of Tanaka I and Fricke teach a krill oil having ether phospholipids of approximately 8%, and therefore render obvious a krill oil having an ether phospholipid range of 3% - 10%. (Tallon Decl., ¶¶ 98, 100, 196 and 203).

Claim 6 also requires from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w. Table 1 of Fricke, reproduced below, discloses total phospholipids of

44.0 +/- 2.0% (1981 sample) and 45.7 +/- 1.6 (1977 sample). (Tallon Decl., ¶¶ 100, 204).

TABLE I

Lipid Composition of Antarctic Krill
(*Euphausia superba* Dana)

Sample	12/1977	3/1981
Total lipid content (% wet weight)	2.7 ± 0.2	6.2 ± 0.3
Phospholipids		
Phosphatidylcholine	35.6 ± 0.1	33.3 ± 0.5
Phosphatidylethanolamine	6.1 ± 0.4	5.2 ± 0.5
Lysophosphatidylcholine	1.5 ± 0.2	2.8 ± 0.4
Phosphatidylinositol	0.9 ± 0.1	1.1 ± 0.4
Cardiolipin	1.0 ± 0.4	1.6 ± 0.2
Phosphatidic acid	0.6 ± 0.4	
Neutral lipids		
Triacylglycerols	33.3 ± 0.5	40.4 ± 0.1
Free fatty acids[a]	16.1 ± 1.3	8.5 ± 1.0
Diacylglycerols	1.3 ± 0.1	3.6 ± 0.1
Sterols	1.7 ± 0.1	1.4 ± 0.1
Monoacylglycerols	0.4 ± 0.2	0.9 ± 0.1
Others[b]	0.9 ± 0.1	0.5 ± 0.1
Total	98.9	99.3

As discussed above, the combination of Tanaka I and Fricke also disclose ether phospholipid levels of approximately 8%. (Tallon Decl., ¶¶ 98-100, 196, 203). Therefore, the combination of Tanaka I and Fricke disclose a krill oil containing

non-ether phospholipids of approximately 36-38%, which would render obvious the range of 27% and 50% required by Claim 6. (Tallon Decl., ¶¶ 100 and 205).

Claim 6 also requires from about 20% to 50% w/w triglycerides. Table I of Fricke describes triacylglycerols (also known as tryglycerides) at a level of 40.4 +/- 0.1% (1981 sample) and 33.3 +/- 0.5% (1977 sample). Thus, it would have been obvious to a POSITA to enacaspsulate a krill oil having triglycerides between 20% to 50% w/w. (Tallon Decl.,¶¶ 97, and 205).

TABLE 1

Lipid Composition of Antarctic Krill
(*Euphausia superba* Dana)

Sample	12/1977	3/1981
Total lipid content (% wet weight)	2.7 ± 0.2	6.2 ± 0.3
Phospholipids		
Phosphatidylcholine	35.6 ± 0.1	33.3 ± 0.5
Phosphatidylethanolamine	6.1 ± 0.4	5.2 ± 0.5
Lysophosphatidylcholine	1.5 ± 0.2	2.8 ± 0.4
Phosphatidylinositol	0.9 ± 0.1	1.1 ± 0.4
Cardiolipin	1.0 ± 0.4	1.6 ± 0.2
Phosphatidic acid	0.6 ± 0.4	
Neutral lipids		
Triacylglycerols	33.3 ± 0.5	40.4 ± 0.1
Free fatty acids[a]	16.1 ± 1.3	8.5 ± 1.0
Diacylglycerols	1.3 ± 0.1	3.6 ± 0.1
Sterols	1.7 ± 0.1	1.4 ± 0.1
Monoacylglycerols	0.4 ± 0.2	0.9 ± 0.1
Others[b]	0.9 ± 0.1	0.5 ± 0.1
Total	98.9	99.3

Claim 9 relates to the encapsulated krill oil of Claim 1, wherein the krill oil is *Euphausia superba*. As of the earliest effective priority date, it was well known known to extract krill oil from *Euphausia superba*. For example, Tanaka I, discloses that the lipid extract of krill utilized for the study was a lipid extract of *Euphausia superba* and was gift from Itano Refrigerated Food Co. (Tokushima,

Japan). (Tanaka I, Exhibit 1014, p. 0002, 1st col.) (Tallon Decl., ¶ 130). Similarly, Similarly, Fricke discloses that their lipid composition studies were performed on *Euphausia superba*, which "is extremely rich in phospholipids (≥ 40% of total lipids) and TG [triglycerides] (33 and 40% respectively of total lipids)." (Fricke Exhibit 1010, p. 0002, 2nd col.) (Tallon Decl., ¶ 93). Sampalis I also discloses a soft gel that includes Neptune Krill Oil ™ (NKO™) which is extracted from *Euphausia superba*. (Exhibit 1012, p. 0004, 1st col.) (Tallon Decl., ¶ 68). Thus, Thus, as of the earliest effective priority date for the '905 patent, it was obvious to a POSITA to extract lipids from *Euphausia superba*. (Tallon Decl., ¶¶ 206-209).

Claim 10 relates to the encapsulated krill oil of Claim 1, wherein the capsule is a soft gel capsule. Sampalis I, describes the administration of two 1-gram soft gels of either Neptune's commercial NKO krill oil product or omega-3 fish oil. (Exhibit 1012, p. 0004, 2nd col.) (Tallon Decl., ¶ 71). Thus, as of the earliest effective priority date for the '905 patent, it would have been obvious to encapsulate krill oil in a soft gel capsule. (Tallon Decl., ¶ 210-211).

Claim 12 is merely a repeat of Claim 6 in independent form. Accordingly, Claim 12 is invalid as being obvious for the same reasons as those set forth in connection with Claim 6. (Tallon Decl., ¶ 213).

Claim 15 further defines Claim 12 wherein the krill is *Euphausia superba.* As discussed above in connection with Claim 9, both Tanaka I and Fricke disclose the extraction of lipids from Antarctic krill known as *Euphausia superba.* Thus, Claim 15 is invalid as being obvious for the same reasons described above in connection with Claim 15. (Tallon Decl., ¶ 213).

Claim 16 further defines Claim 12 wherein the capsule is a soft gel capsule. This is the same element added by Claim 10. As discussed above in connection with Claim 10, the disclosure of Sampalis I demonstrates that, as of the earliest effective priority date for the '905 patent, it was well known to administer krill in a soft gel capsule. (Tallon Decl., ¶ 215).

Claim 18 is the same as Claim 12 except that the preamble refers to encapsulated Antarctic krill oil. In addition, Claim 18 further specifies the capsule capsule containing the effective amount of krill oil as being a soft gel capsule. As discussed above, in connection with Claims 9 and 15, Sampalis I and Fricke confirm it was well known as of the date of earliest effective priority date to extract krill oil from the Antarctic species *Euphausia superba.* Also, as explained in connection with Claims 10 and 16, it was well known as of the earliest effective priority date to encapsulate krill oil in a soft gel capsule as described in Sampalis

I. (Tallon Decl. ¶¶ 68-69, 71). Accordingly, Claim 18 is invalid for the same reasons as discussed above in connection with Claims 9/15 and 10/16, respectively. (Tallon Decl., ¶¶ 216-17).

Reason to combine

A POSITA would have strong reason to combine Tanaka I with Sampalis I and Fricke because Sampalis I demonstrates that it was known as of the earliest effective priority date to extract lipids from krill and utilize the resulting oil as a dietary supplement. As discussed above, Sampalis I described Neptune Krill Oil™ (NKO™) as a natural health product extracted from Antarctic krill (*Euphausia superba)* which is rich in phospholipids and triglycerides carrying long chain omega-3 polyunsaturated fatty acids such as EPA and DHA and is rich in various potent antioxidants including vitamins A and E, astaxanthin, and a novel flavonoid. (Exhibit 1012, p. 0004, 1st col.). Sampalis I also evaluated the effectiveness of Neptune Krill Oil™ for the management of premenstrual syndrome and dysmenorrhea. (Exhibit 1012, p. 0004, 2nd col.). As of the earliest effective filing date of the `905 patent it was demonstrated that phospholipids and, phosphatidlycholine in particular, were associated with beneficial health effects. (*See, e.g.*, Sampalis II, Exhibit 1013, pp. 0017-0022). Sampalis II also disclosed

that krill oil phospholipids "a. achieve a superior profile; b. have the highest quantities of polyunsaturated fatty acids; c. have the highest quantities of DHA; d. are the only phospholipids that contain EPA; and e. are the only phospholipids that contain a combination of EPA and DHA on the same molecule." (Exhibit 1013, p. 0029). (Tallon Decl., ¶ 151). The health benefits of omega-3 fatty acids, particularly in connection with cardiovascular disease, was also well established. (*See, e.g.*, Bunea, Exhibit 1020, pp. 0001-0002). Moreover, it was known that "[k]rill oil has a unique biomolecular profile of phospholipids naturally rich in omega-3 fatty acids and diverse antioxidants significantly different than fish oil" and that "[t]he association between phospholipids and long-chain omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing bioavailability...." (Bunea, Exhibit 1020, p. 0002, col. 1-1-2.) (Tallon Decl., ¶ 30). Accordingly, a POSITA developing an encapsulated krill oil supplement as disclosed in Sampalis I would be motivated to look to other references such as Tanaka I and Fricke to ascertain the components of the krill oil and their amounts as obtained by standard extraction methods. (Tallon Decl., ¶¶ 216-218).

B. Ground 2: §103(a) – Sampalis I, Tanaka I, Fricke, and Randolph [Claim 5]

Claim 5 relates to the encapsulated krill oil of Claim 1, wherein the capsule contains a phytonutrient derived from a source other than krill. The discussion regarding the obviousness of claim 1 in Ground 1 is incorporated herein.

Randolph discloses compositions for modulating cytokines to regulate an inflammatory or immunomodulatory response. The compositions can include at least one of rosehips, grape seed extract, resveratrol [grape skin extract], krill oil, at least one type of xanthophyll (*e.g.,* astaxanthin) and ferulic acid. "Based on the cytokine modulation and cytokine response inhibition of the composition, it can be used to regulate an immunomodulatory and/or inflammatory response, and subsequently treat diseases and/or abnormal conditions associated with inflammatory response, for example, cardiovascular conditions, arthritis, osteoporosis and Alzheimer's disease." (Exhibit 1011, p. 0001, Abstract, *see also* p. 0005, 1st col. [0021]). Randolph notes that "treatments have been developed to regulate the release of inflammatory cytokines, or the signaling of inflammatory cytokines, specifically the interleukin-1 (IL-1) cytokine from macrophages." (Exhibit 1011, p. 0004, [0007]) (Tallon Decl., ¶¶ 119-121).

In the Summary of Invention, Randolph discloses "[t]he present invention…provides a composition that regulates interleukin cytokines and/or regulates a physiological response caused by interleukin cytokines. This regulation is effective in controlling an immune response and/or an inflammatory condition. In one aspect, the composition can comprise rosehips and at least one of blackberry, blueberry and elderberry. *In another aspect, the composition can comprise rosehips and krill oil.* In yet another aspect, *the composition can comprise rosehips, blackberry, blueberry, elderberry and krill oil.*" (Exhibit 1011, p. 0004, [0008] (emphasis added).) (Tallon Decl., ¶ 122).

In the Detailed Description of the Invention, Randolph discloses, "[e]xamples of rosehip ingredients include, without limitation, dried rosehips, rosehip oil, and rosehip extracts." (Exhibit 1011, p. 0005, [0024]) (Tallon Decl. ¶ ¶ 123). Randolph further states, "A composition of the invention can include krill oil. Krill oil can be obtained from any member of the *Euphausia* family, for example *Euphausia superba*. Conventional oil producing techniques can be used to obtain the krill oil. In addition, krill oil can be obtained commercially from Neptune Technologies and Bioresources of Quebec, Canada." (Exhibit 1011, p. 0006, [0039]) (Tallon Decl., ¶ 124). In addition, Randolph teaches "[a]

composition can contain any amount of krill oil. For example, at least about 1 percent (e.g., at least about 2, 3, 4, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, or 90 percent) of a dietary supplement can be a krill oil. Typically, a composition contains between about 300 mg and about 3000 mg of a krill oil ingredient." (Exhibit 1011, p. 0006, [0040], see also pp. 0009-0010, Table III.) (Tallon Decl. ¶ ¶ 125). Randolph further discloses, "[w]here the composition includes resveratrol, resveratrol, *the resveratrol can be obtained from an extract of grape skin* or other grape components. Resveratrol can be present in the composition in one or more different forms, for example, extract form and powder form." (Exhibit 1011, p. 0006, [0041], (emphasis added)) (Tallon Decl., ¶ 126).

With regard to the dosage form, Randolph discloses, "[t]he ingredients of the composition can be processed into forms having varying delivery systems. For example, *the ingredients can be processed and included in capsules*, tablets, gel tabs, lozenges, strips, granules, powders, concentrates, solutions, lotions, creams or suspensions." (Exhibit 1011, p. 0007, [0046] (emphasis added), see also p. 0007, [0049] (rosehips in capsule form)) (Tallon Decl., ¶ 127). Randolph also described that "[a] soft gel capsule of the composition can be manufactured to include krill oil. This capsule can be manufactured using conventional capsule

manufacturing techniques. The amount of krill oil in each capsule is about 300 mg." (Exhibit 1011, p. 0007, [0052]) (Tallon Decl., ¶ 128).

As explained above, the '905 patent expressly identifies grape skin extract and rose hips as sources of plant phytonutrients. Thus, it would be obvious to a POSITA to include a phytonutrient (in fact, the exact same ones as in the '905 patent) in an encapsulated krill oil as set forth in Claim 5. (Tallon Decl. ¶¶ 219-225).

Reason to combine

A POSITA would have a compelling reason to combine Randolph with the references set forth in Ground I because Randolph discloses the health benefits of the composition that includes both krill oil and phytonutrients. As discussed above, Sampalis I discloses the use of encapsulated krill oil in the management of premenstrual syndrome. Sampalis I teaches, "[t]he results of the present study indicates that Neptune Krill Oil has statistically significant and clinically marked benefits against the inflammatory dysmenorrhea symptom complex as well as the emotional symptomology that characterizes premenstrual syndrome." (Sampalis I, Exhibit 1012, p. 0007, 2nd col.). Sampalis I explains that omega-3 fatty acids, mainly EPA and DHA, compete with the omega-6 species for the enzyme

prostaglandin synthetase, which triggers less inflammation. (Exhibit 1012, p. 0003, 2nd col.). Sampalis I, explains, that omega-3 fatty acids in krill oil promote the production of anti-inflammatory prostaglandins. (Exhibit 1012, p. 0003, 2nd col.), (See also Exhibit 1020, p. 0006, 1st col.). Furthermore, both Fricke and Tanaka I analyze the lipid composition of Antarctic kill obtained by standard extraction methods. Randolph discloses the anti-inflammatory effects of combining krill oil with various phytonutrients. Thus, a POSITA would have been been motivated to combine a phytonutrient and krill oil as disclosed by Randolph with the krill oil components disclosed by Fricke and Tanaka and administered as taught by Sampalis I. (Tallon Decl., ¶ 225).

C. Ground 3: §103(a) – Sampalis I, Tanaka I, Fricke, and Bottino [Claims 7-8, 11, 13-14, 17, and 19-20]

Claims 7, 13[3] and 19 further define the encapsulated krill oil of Claims 6, 12, and 18, respectively, wherein the krill oil further includes from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in the composition.

[3] Claim 13 asserts antecedent basis from Claim 6, but Petitioner believes it was meant to further define Claim 12. Otherwise, Claim 13 would be identical to Claim 7 and therefore be unenforceable.

The discussion regarding the obviousness of claim 1, 6, 12, and 18 in Ground 1 is incorporated herein.

Bottino (Exhibit 1007) analyzes the fatty acid content of Antarctic phytoplankton and Euphausiids, in particular *Euphausia superba* and *Euphausia crystllorophias*. *E. superba* is the better known species found in the Southern Oceans and has been considered almost a synonym for krill. (Exhibit 1007, p. 0001, 1st col.) (Tallon Decl., ¶ 115). The *E. superba* samples were collected from various locations (stations) and lipids were extracted "immediately after capture" using a chloroform:methanol 2:1 v/v mixture as described in Folch (1957) (Exhibit 1017). The fatty acids were analyzed using chromatography. (Exhibit 1007, pp. 0001-0002, 2nd col.) (Tallon Decl., ¶ 115).

Table 1 of Bottino set forth below shows the fatty acid content in *E. superba* from 3 different stations as a weight percent of total fatty acids. The percentage of omega-3 fatty acids are circled in the chart and add up to 30.5%, 26.8%, and 25.0%, respectively. Thus, all three samples had an omega-3 fatty acid content of between 20% to 35% omega-3 fatty acids as a percentage of total fatty acids, as

required by Claims 7, 13, and 19. (Exhibit 1007, p. 0002), (Tallon Decl., ¶¶ 116, 117, 228).

Table 1. *Euphausia superba*. Fatty acids (as weight per cent of total acids)

Fatty acid[a]	Station 8		Station 9	Station 11		
	Whole krill	HP+S[b]	Whole krill	Whole krill	HP+S	Remaining carcass
14:0	14.9	10.7	12.9	14.3	12.9	13.5
16:0	21.2	21.2	20.9	24.7	22.3	23.4
18:0	0.7	1.2	0.9	1.4	1.3	1.4
16:1(n-7)	9.0	6.7	10.7	8.9	8.2	8.0
18:1(n-9)	18.2	17.1	22.8	21.7	21.8	21.5
20:1(n-9)	0.6	0.9	1.1	0.9	1.2	1.1
18:2(n-3)	2.6	2.5	2.7	2.0	2.1	1.9
18:3(n-3)	1.1	1.2	1.4	1.0	1.0	1.1
18:4(n-3)	2.2	1.9	2.6	3.3	3.6	3.8
20:5(n-3)	16.0	22.2	11.8	11.4	13.9	11.6
22:6(n-3)	8.6	9.4	8.3	7.3	8.1	9.4
Minor fatty acids[c]	4.9	5.0	3.9	3.1	3.6	3.3

Footnote c of Table 1 indicates "[o]nly those fatty acids present at a level of 1% or more are included." Table 3 from Bottino identifies all of the fatty acids identified from the various species tested as a weight percent of total fatty acids. The fatty acid content from *E. superba* is provided as an average of the 3 stations. The omega-3 fatty acid content from *E. superba* in Table 3 are circled below.

Table 3. Fatty acids of Antarctic phytoplankton and euphausiids (as weight per cent of total acids)

Fatty acid													*Euphausia superba* (average of 3 stations)	
18:2(n-3)	3.7	3.3	2.4	3.1	3.3	3.0	2.7	2.1	7.1	12.0	1.2	1.7	2.4	2.1
22:2(n-6)	–	–	–	–	–	0.8	0.9	1.6	2.0	–	–	–	–	–
22:2(n-3)	–	0.6	0.7	1.4	1.4	–	–	–	–	–	–	–	–	–
18:3(n-6)	0.3	0.3	0.3	0.2	0.2	–	–	–	0.2	0.3	0.2	0.3	0.2	0.1
18:3(n-3)	0.9	0.7	0.6	0.7	0.7	0.7	0.3	0.2	0.1	0.2	0.2	0.3	1.2	0.9
20:3(n-6)	0.4	0.2	–	trace	0.9	trace	–	0.3	2.6	0.1	–	0.1	–	–
20:3(n-3)	0.2	0.2	0.3	–	–	–	–	trace	0.9	1.0	–	0.2	0.5	0.3
16:4(n-1)	–	–	0.5	–	–	–	–	–	–	6.3	–	–	–	–
18:4(n-3)	2.0	3.1	3.5	5.2	6.0	3.0	2.7	3.2	6.2	0.9	2.2	2.5	2.7	1.2
20:4(n-6)	–	–	–	0.4	–	–	–	–	–	4.7	–	–	0.4	0.4
20:4(n-3)	0.2	–	0.3	0.2	–	–	–	0.1	trace	–	–	0.2	0.4	0.1
22:4(n-6)	–	–	–	–	–	–	–	–	–	trace	–	–	0.2	–
22:4(n-3)	1.3	–	trace	–	–	–	–	trace	–	trace	–	–	–	–
20:5(n-3)	11.4	4.8	9.2	7.0	6.4	1.7	2.1	5.3	6.0	2.1	18.4	23.4	13.1	14.4
22:5(n-6)	1.1	–	–	–	–	–	–	–	–	–	–	–	–	–
22:5(n-3)	0.3	0.3	–	–	–	–	–	0.1	–	2.1	–	–	0.2	–
22:6(n-3)	6.1	4.9	7.9	8.4	5.5	0.9	0.8	7.1	7.8	16.5	5.5	11.0	8.1	7.5
Minor fatty acids[b]	3.3	1.5	4.3	4.6	1.0	3.2	0.6	4.0	2.8	1.8	0.5	0.9	0.8	0.4

When all of the omega-3 fatty acids are calculated, including those not appearing in Table 1, the total is 28.6%. (Tallon Decl., ¶ 116, 117).

Therefore, it would be obvious to a POSITA for the krill oil to include from about 20% to 35% omega-3 fatty acids as a percentage of total fatty as set forth in Claims 7, 13 and 19. (Tallon Decl., ¶ 228).

Claims 8, 14, and 20 further define the encapsulated krill oil of Claims 7, 13, and 19, respectively. Claims 8, 14, and 20 further define the encapsulated krill

krill oil, wherein from about 70% - 95% of said omega-3 fatty acids are attached to the phospholipids.

In Fricke (Exhibit 1010) krill samples were taken from the Scotia Sea (caught in December 1977) and from the Gerlache Strait (caught in March 1981). Krill samples of 5 kg were quick frozen and stored at -35 °C until analyzed. Liquid extraction was performed according to Folch *et al.*, *J. Biol. Chem.* 226:497-509 (1957) (Exhibit 1017), which uses a polar solvent, choroform:methanol, in a ratio of 2:1 (v/v). Samples were analyzed by thin layer chromatography and gas liquid chromatography and gas liquid chromatography/mass spectrometry. (Exhibit 1010, p. 0001, 2nd col.) (Tallon Decl. ¶¶ 93-96).

Fricke noted that, in the 1977 sample, the free fatty acid (FFA) content is about twice that of the 1981 sample. Fricke believed that the high value could be the result of the longer storage time of the 1977 sample. (Exhibit 1010, p. 0002, 2nd col.) (Tallon Decl., ¶96).

To confirm this belief, samples of the same haul were cooked on board immediately after hauling and stored under the same conditions. This resulted in a a FFA content which was much lower, ranging from 1% - 3% of total lipids. Fricke noted that the low FFA content of the freshly caught krill also was

confirmed by Ellingsen, Ph.D. *thesis, University of Trondheim,* 239-316 (1982). (Exhibit 1010, pp. 0002-0003) (Tallon Decl., ¶ 96).

Table 1 in Fricke provides the amount of each lipid class in the total lipid composition. (Exhibit 1010, p. 0002) (Tallon Decl., ¶¶ 100). Tables 4 and 5 provide the omega-3 fatty acid composition of each phospholipid class. The omega-3 fatty acids in Tables 4 and 5 reproduced below, are identified as 18:3(n-18:3(n-3), 18:4(n-3), 20:5(n-3), 21:5(n-3), 22:5(n-3), and 22:6(n-3). (Exhibit 1010, pp. 0004-0005), (Tallon Decl., ¶ 102).

TABLE 4

Fatty Acid Analysis of Polar Lipid Classes of *Euphausia superba* Dana

Polar lipid	PC		PE		LPC		PI		PA + Cl	
Sample	12/1977	3/1981	12/1977	3/1981*	12/1977	3/1981*	12/1977	3/1981*	12/1977	3/1981*
14:0	4.5 ± 1.1	2.8 ± 1.1	2.9 ± 1.1	–	9.1 ± 5.4	4.2	3.5 ± 0.3	3.2	6.0 ± 1.4	–
15:0	–	–	–	–	–	–	–	1.6	–	–
16:0	43.7 ± 7.2	25.7 ± 1.4	42.7 ± 9.3	24.2	40.5 ± 8.9	18.7	33.9 ± 5.9	24.9	39.3 ± 6.3	23.7
16:1(n-7)	3.7 ± 0.4	2.2 ± 0.3	2.0 ± 1.0	1.9	4.4 ± 2.3	2.8	2.2 ± 0.9	1.2	3.6 ± 0.8	4.3
18:0	1.8 ± 0.5	1.5 ± 0.2	3.2 ± 1.0	2.9	2.1 ± 0.3	1.5	6.1 ± 1.0	7.3	2.5 ± 0.1	2.6
18:1(n-7)	7.7 ± 0.8	6.1 ± 0.8	15.0 ± 3.9	16.3	9.7 ± 3.7	4.0	11.6 ± 3.3	10.9	12.3 ± 0.6	14.7
18:1(n-9)	9.2 ± 1.7	5.4 ± 1.1	5.4 ± 2.1	6.8	10.3 ± 3.3	7.3	6.5 ± 0.4	7.9	4.9 ± 1.5	8.7
18:2(n-6)	1.6 ± 0.1	1.1 ± 0.1	1.0 ± 0.6	1.0	1.1 ± 0.8	1.6	1.7 ± 0.7	1.7	1.4 ± 0.1	1.5
18:3(n-3)	–	0.8 ± 0.2	–	–	–	1.1	–	0.6	–	1.6
18:3(n-6)	–	2.7 ± 0.4	–	0.7	–	3.8	–	–	–	1.7
18:4(n-3)	–	–	–	–	–	–	–	–	–	0.8
20:1(n-7)	–	–	–	–	–	–	–	–	–	–
20:1(n-9)	0.6 ± 0.1	0.9 ± 1.1	–	0.8	–	0.8	–	1.1	–	1.1
20:5(n-3)	10.7 ± 0.6	29.9 ± 2.2	10.5 ± 4.9	21.1	2.6 ± 0.1	31.2	8.1 ± 0.1	20.1	1.9 ± 1.0	19.7
21:5(n-3)	1.0 ± 0.7	1.1 ± 0.0	–	0.7	–	1.6	–	1.9	–	0.8
22:1(n-7)	–	0.9 ± 0.1	–	–	–	1.0	–	–	–	–
22:1(n-9)	–	1.7 ± 0.2	–	–	–	1.5	–	1.4	–	–
22:5(n-3)	0.9 ± 0.6	0.6 ± 0.2	–	0.9	–	1.1	–	1.8	–	–
22:6(n-3)	6.2 ± 0.6	11.5 ± 1.0	7.6 ± 2.3	19.2	1.2 ± 0.2	12.2	1.8 ± 0.7	10.1	1.1 ± 0.3	15.5
Phytanic acid	0.7 0.6	–	–	–	–	–	–	–	–	–

TABLE 5

Fatty Acid Analysis of Neutral Lipid Classes of *Euphausia superba* Dana

Neutral lipid	TAG		FFA		DG		MG		WE + SE	
Sample	12/1977	3/1981	12/1977	3/1981	12/1977*	3/1981*	12/1977*	3/1981*	12/1977*	3/1981*
12:0	0.5 ± 0.1	–	–	0.8 ± 0.2	–	–	–	–	3.7	–
14:0	23.3 ± 0.2	21.8 ± 2.0	7.9 ± 1.0	5.1 ± 0.7	4.5	6.1	2.1	3.5	14.8	8.8
15:0	0.5 ± 0.1	–	–	–	–	0.5	–	1.2	–	–
16:0	29.9 ± 1.6	21.8 ± 1.8	32.5 ± 1.1	12.1 ± 2.2	19.4	16.9	9.6	10.3	25.1	37.8
16:1(n-7)	8.9 ± 1.9	13.1 ± 0.3	4.8 ± 1.0	4.9 ± 0.5	5.6	7.1	2.0	6.6	10.8	8.8
18:0	1.5 ± 0.2	1.8 ± 0.3	1.6 ± 0.2	0.7 ± 0.1	2.1	2.0	–	2.1	2.2	2.6
18:1(n-7)	5.9 ± 1.1	6.6 ± 3.1	12.9 ± 2.7	8.5 ± 2.2	14.7	7.5	73.7	10.9	15.8	17.5
18:1(n-9)	11.9 ± 3.6	12.1 ± 2.5	7.1 ± 0.6	4.7 ± 1.3	6.5	10.4	2.3	14.5	14.3	11.9
18:2(n-6)	0.7 ± 0.5	1.0 ± 0.2	1.5 ± 0.1	0.9 ± 0.7	2.1	1.3	0.8	1.3	1.9	–
18:3(n-3)	–	–	–	0.7 ± 0.2	–	0.8	–	–	–	–
18:3(n-6)	–	4.1 ± 1.0	–	1.5 ± 0.7	0.7	3.0	–	1.8	–	–
18:4(n-3)	–	–	0.6 ± 0.2	3.5 ± 1.2	–	–	–	–	–	–
20:1(n-7)	0.5 ± 0.1	–	–	–	0.5	–	–	–	–	–
20:1(n-9)	0.8 ± 0.2	1.3 ± 0.0	0.5 ± 0.1	1.0 ± 0.3	0.8	0.8	–	0.6	–	–
20:5(n-3)	1.0 ± 0.1	3.3 ± 0.5	11.8 ± 2.2	30.0 ± 2.1	15.8	28.8	2.9	26.8	5.1	11.9
21:5(n-3)	–	–	0.5 ± 0.4	0.9 ± 0.2	–	0.7	–	1.4	–	–
22:1(n-7)	–	–	0.8 ± 0.3	–	2.0	–	–	–	–	–
22:1(n-9)	–	0.5 ± 0.2		0.9 ± 0.4	1.5	1.3	–	0.8	–	–
22:5(n-3)	–	–	0.5 ± 0.3	0.5 ± 0.1	2.5	–	–	1.0	–	–
22:6(n-3)	–	0.7 ± 0.2	6.3 ± 2.4	12.1 ± 1.5	7.0	8.2	1.7	12.8	–	–
Phytanic acid	5.6 ± 0.8	4.1 ± 0.6	1.5 ± 0.6	1.3 ± 0.7	1.5	1.6	1.4	1.3	0.8	0.7

Therefore, the amount of omega-3 and each lipid class relative to the total lipid can be easily calculated by multiplying the amount of omega-3 fatty acids for each lipid class by the amount of the particular lipid class in the total lipid composition. This provides the amount of omega-3 associated for each lipid class. The total amount of omega-3 fatty acids associated with the lipid classes that constitute phospholipids can then be added. The total amount of omega-3 associated with phospholipids can then divided by the amount of omega-3 in the total lipid from all lipid classes to provide the percentage of omega-3 fatty acid attached to phospholipid is determined. (Tallon Decl., ¶¶ 103-109). For the March 1981 sample, 74.81% of the omega-3 fatty acids are attached to phospholipids

assuming the 3% free fatty acid content disclosed in Fricke. The calculation for the December 1977 sample is 82.03%. (Tallon Decl., ¶¶ 103-114).[4]

Accordingly, it would have been obvious to a POSITA to ascertain krill oil has omega-3 fatty acids attached to phospholipids in the range between the 70%-95% as required by Claims 8, 14, and 20. (Tallon Decl., ¶¶ 228-231).

Claims 11 and 17 further define the encapsulated krill oil of Claims 1 and 12, respectively, wherein the krill oil includes less than 0.45% w/w arachadonic acid. Bottino (Exhibit 1007) is a study of the fatty acids of phytoplankton and *Euphausia superba*. After being sorted by hand, samples from various depths were extracted for lipids using a chloroform:methanol 2:1 v/v mixture utilizing the methods of Folch *et al.*, 1957. (Exhibit 1007, p. 0001, 2nd col.) (Tallon Decl., ¶ 115). Table 3 presents the fatty acids of the Antarctic krill *as a weight percentage percentage of total fatty acids.* (Exhibit 1007, p. 0004). Table 3 of Bottino

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[4] Even if one assumes a 1% FFA content disclosed as the low end of Fricke or 4% FFA as disclosed in Budzinski, the values of omega-3 fatty acids attached to phospholipids as calculated all fall between the 70%-95%. (Tallon Decl. ¶¶ 111-114).

reproduced below discloses that arachadonic acid [20:4 (n-6)] constitutes 0.4% of fatty acids. (Exhibit 1007, p. 0005) (Tallon Decl., ¶ 116).

Table 3. Fatty acids of Antarctic phytoplankton and euphausiids (as weight per cent of total acids)

Fatty acid													*Euphausia superba* (average of 3 stations)	
18:2(n-3)	3.7	3.3	2.4	3.1	3.3	3.0	2.7	2.1	7.1	12.0	1.2	1.7	2.4	2.1
22:2(n-6)	-	-	-	-	-	0.8	0.9	1.6	2.0	-	-	-	-	-
22:2(n-3)	-	0.6	0.7	1.4	1.4	-	-	-	-	-	-	-	-	-
18:3(n-6)	0.3	0.3	0.3	0.2	0.2	-	-	-	0.2	0.3	0.2	0.3	0.2	0.1
18:3(n-3)	0.9	0.7	0.6	0.7	0.7	0.7	0.3	0.2	0.1	0.2	0.2	0.3	1.2	0.9
20:3(n-6)	0.4	0.2	-	trace	0.9	trace	-	0.3	2.6	0.1	-	0.1	-	-
20:3(n-3)	0.2	0.2	0.3	-	-	-	-	trace	0.9	1.0	-	0.2	0.5	0.3
16:4(n-1)	-	-	0.5	-	-	-	-	-	-	6.3	-	-	-	-
18:4(n-3)	2.0	3.1	3.5	5.2	6.0	3.0	2.7	3.2	6.2	0.9	2.2	2.5	2.7	1.2
20:4(n-6)	-	-	-	0.4	-	-	-	-	-	4.7	-	-	0.4	0.4
20:4(n-3)	0.2	-	0.3	0.2	-	-	-	0.1	trace	-	-	0.2	0.4	0.1
22:4(n-6)	-	-	-	-	-	-	-	-	-	trace	-	-	0.2	-
22:4(n-3)	1.3	-	trace	-	-	-	-	trace	-	trace	-	-	-	-
20:5(n-3)	11.4	4.8	9.2	7.0	6.4	1.7	2.1	5.3	6.0	2.1	18.4	23.4	13.1	14.4
22:5(n-6)	1.1	-	-	-	-	-	-	-	-	-	-	-	-	-
22:5(n-3)	0.3	0.3	-	-	-	-	-	0.1	-	2.1	-	-	0.2	-
22:6(n-3)	6.1	4.9	7.9	8.4	5.5	0.9	0.8	7.1	7.8	16.5	5.5	11.0	8.1	7.5
Minor fatty acids[b]	3.3	1.5	4.3	4.6	1.0	3.2	0.6	4.0	2.8	1.8	0.5	0.9	0.8	0.4

The 0.4% is less than the upper limit of 0.45% required by claims 11 and 17. Furthermore, the 0.4% in Table 3 is a percentage of fatty acids. The claims require the total krill oil to contain less than 0.45% arachadonic acid. Since fatty acids constitute only a limited percentage of total lipids, the amounts of arachadonic acid recorded by Bottino would be significantly less than 0.45% total lipids. (Tallon Decl., ¶¶ 116-118; Exhibit 1007, p. 0005, Table 3.). Accordingly, it would

have been obvious to a POSITA that krill oil contains less than 0.45% arachadonic acid. (Exhibit 1007, p.0005, Table 3. (Tallon Decl., ¶¶ 232-233).

Reason to combine

A POSITA would have been motivated to combine Bottino with the other references set forth in Ground 1 because of the heightened interest and analysis and reporting of fatty acid levels of *Euphausia superba.* Bottino explains that the study of krill at the time of the article (1974) had become intensive as a result of its potential importance as food. (Exhibit 1007, p. 0001, 1st col.). The health benefits of omega-3 fatty acids, particularly in connection with cardiovascular disease, was also well established. (*See, e.g.*, Bunea, Exhibit 1020, pp. 0001-0001-0002). Moreover, it was known that "[k]rill oil has a unique biomolecular profile of phospholipids naturally rich in omega-3 fatty acids and diverse antioxidants significantly different than fish oil" and that "[t]he association between phospholipids and long-chain omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing bioavailability…." (Bunea, Exhibit 1020, p. 0002, col. 1-2.) (Tallon Decl., ¶ 30). Accordingly, a POSITA would have considered the teachings of Bottino to

ascertain the various fatty acid levels, including arachadonic acid when determining the fatty acid levels in the krill oil. (Tallon Decl., ¶¶ 234-235).

D. CLAIM CHART

CLAIMS	REFERENCES
1. Encapsulated krill oil comprising:	**Sampalis I (Exhibit 1012)** P. 0004, 2nd col. "Each patient was asked to take two 1-1-gram **soft gels** of either **NKO**[5] or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
1(a). a capsule containing an effective amount of krill oil,	**Sampalis I (Exhibit 1012)** P. 0004, 2nd col. "Each patient was asked to take two **1-gram soft gels** of either **NKO** or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
1(b). said krill oil comprising from about 3% to about 15% w/w ether phospholipids.	**Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1.

[5] NKO is Neptune's commercial krill oil product.

	Phosphatidylcholine is ~34% of krill lipids. And **Tanaka (Exhibit 1014)** P. 0003, 1st col., Table I. 23.0 +/- 1.2% of krill phosphatidylcholine are alkylacylphosphatidylcholine (AAPC). Therefore, **AAPC is present at 7.82%.** (23% x .34 = 7.82%)
2. The encapsulated krill oil of claim 1, wherein said krill oil comprises at least 30% total phospholipids w/w.	**Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1. Total phospholipids **45.7%** +/- 1.6 12/1977 **44.0%** +/- 2.0 3/1981
3. The encapsulated krill oil of claim 1, wherein said krill oil comprises at least 30% phosphatidylcholine w/w.	**Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1. Phosphatidylcholine **35.6%** +/- 0.1 12/1977 **33.3%** +/- 0.5 3/1981
4. The encapsulated krill oil of claim	**Fricke (Exhibit 1010)**

1, wherein said krill oil is a polar solvent extract of krill.	P. 0001, 2nd col. "Krill samples of 5kg were quick-frozen and stored and -35C until analyzed. Subsamples prepared from the core of the 5kg samples were homogenized in a mortar under liquid nitrogen, and lipid extraction was performed according to **Folch *et al.* (15).**"[6]
5. The encapsulated krill oil of claim 1, wherein said capsule contains a phytonutrient derived from a source other than krill.	**Randolph (Exhibit 1011)** P. 0004, 1st col., paragraph [0008]. "In another aspect, the composition can comprise **rosehips and krill oil**. In yet another aspect, the composition can comprise rosehips, blackberry, blueberry, elderberry and krill oil."
6. The encapsulated krill oil of claim 1, wherein said krill oil further comprises	
6(a). from about 3% to about 10% w/w ether phospholipids;	**Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1.

[6] Folch et al., "A simple method for the isolation and purification of total lipides from animal tissues J Biol Chem. 1957 May; 226(1):497-509. "The lipides were extracted by homogenizing the tissue with 2: 1 chloroform-methanol (v/v)." (Exhibit 1017, p. 497)

	Phosphatidylcholine is ~34% of krill lipids. And **Tanaka (Exhibit 1014)** P. 0003, 1st col, Table I. 23.0 +/- 1.2% of krill phosphatidylcholine are alkylacylphosphatidylcholine (AAPC). Therefore, **AAPC is present at 7.82%.** (23% x .34 = 7.82%)
6(b). from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w;	**Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1. **Total phospholipids =** **45.7** % +/- 1.6 12/1977 PC is 35.6% of krill lipids Ether phospholipids = 7.8% See 6(a) Subtract total lipids from ether phospholipid to get non-ether phospholipid 45.7% - 7.8%=37.9 Therefore, non-ether phospholipid would be around **37.9%.**

	Total phospholipids = **44.0%** +/- 2.0 3/1981 PC is 33.3% of krill lipids Ether phospholipids = 7.8% See 6(a) Subtract total lipids from ether phospholipid to get non-ether phospholipid 44.0%-7.8%=36.2 Therefore, non-ether phospholipid would be around **36.2%.**
6(c). and from about 20% to 50% w/w triglycerides.	**Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1. Lipid Composition of Antarctic Krill (*Euphausia superba*) Triacylglycerols **33.3 %** +/- 0.5 12/1977 **40.4 %** +/- 0.1 3/1981
7. The encapsulated krill oil of claim 6, wherein said krill oil further comprises	
7(a). from about 20% to 35% omega-3 fatty acids as a percentage of total fatty	**Bottino (Exhibit 1007**

acids in said composition.	P. 0002, Table 1. Omega-3 fatty acids[7] (as weight percent of total acids of Euphausia superba) of whole krill: Station 8--**30.5%** Station 9--**26.8%** Station 11--**25.0%** Pp. 0004–0005, Table 3 Omega-3 fatty acids[8] as weight percent of total acids of Euphausia superba: **28.6%**
8. The encapsulated krill oil of claim 7, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said phospholipids.	**Fricke (Exhibit 1010)** Pp. 0002 and 0004-0005, Tables 1, 4, and 5; and attached analysis. Table 1 provides the amount of each lipid class in the total lipid. Tables 4 and 5 provide the omega-3 fatty acid composition of each phospholipid class. Therefore, the amount of omega-3 in each lipid class relative to the total lipid can be calculated by multiplying the amount of omega-3 fatty acid for each

[7] Omega-3 fatty acids include 18:2(n-3), 18:3(n-3), 18:4(n-3), 20:5(n-3), and 22:6(n-3)..

[8] Omega-3 fatty acids include 18:2(n-3), 22:2(n-3), 18:3(n-3), 20:3(n-3), 18:4(n-3), 20:4(n-3), 22:4(n-3), 22:5(n-3), and 22:6(n-3).

	lipid class by the amount of the particular lipid class in the total lipid composition. This is done for each lipid lipid class. The amount of omega-3 associated with phospholipid is then divided by the total amount of omega-3 in the total lipid to provide the percentage of omega-3 fatty acid attached to phospholipid. Using this calculation, **74.81%** (3/1981 sample) and **82.03%** (12/1977 sample) of the omega-3 fatty acids are attached to phospholipids. (Tallon Decl., Appendix B)
9. The encapsulated krill oil of claim 1, wherein said krill is Euphausia superba.	**Tanaka (Exhibit 1014)** P. 0002, 1st col. "A lipid extract of krill (**Euphausia superba**) was a generous gift from Itano Refrigerated Food Co. (Tokushima, Japan)." or **Fricke (Exhibit 1010)** P. 0001, Abstract. "The lipid classes, fatty acids of total and individual lipids and sterols of Antarctic krill ***(Euphausia superba***

	Dana) from two areas of the Antarctic Ocean…" **Sampalis I (Exhibit 1012)** P. 0004, 1st col. "Neptune Krill Oil™ (NKO™) is a natural health product extracted from Antarctic krill also known as ***Euphausia superba***. *Euphausia superba*, a zooplankton crustacean, is rich in phospholipids and triglycerides carrying long-chain omega-3 polyunsaturated fatty acids, mainly EPA and DHA,"
10. The encapsulated krill oil of claim 1, wherein said capsule is a soft gel capsule.	**Sampalis I (Exhibit 1012)** P. 0004, 2nd col. "Each patient was asked to take two 1-gram **soft gels** of either NKO or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
11. The encapsulated krill oil of claim 1, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.	**Bottino (Exhibit 1007)** P. 0005, Table 3. Arachidonic acid [20:4(n-6)] include **0.4% of total fatty acids.**

12. Encapsulated krill oil comprising:	**Sampalis I (Exhibit 1012)** P. 0004, 2nd col. "Each patient was asked to take two 1-gram **soft gels of** either **NKO** or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
12(a). a capsule containing an effective amount of krill oil,	**Sampalis I (Exhibit 1012)** P. 0004, 2nd col. "Each patient was asked to take two **1-gram soft gels** of either **NKO** or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
12(b). said krill oil comprising from about 3% to about 10% w/w ether phospholipids;	**Fricke (Exhibit 1010)** P. 0002, 1st col., Table 1. Phosphatidylcholine is ~34% of krill lipids. And **Tanaka (Exhibit 1014)** P. 0003, 1st col., Table I. 23.0 +/- 1.2% of krill phosphatidylcholine are

	alkylacylphosphatidylcholine (AAPC). Therefore, **AAPC is present at 7.82%.** (23% x .34 = 7.82%)
12(c). from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and	**Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1. Total phospholipids = 45.7 % +/- 1.6 12/1977 PC is 35.6% of krill lipids Ether phospholipids = 7.8% See 6(a) Subtract total lipids from ether phospholipid to get non-ether phospholipid 45.7% - 7.8%=37.9 Therefore, non-ether phospholipid would be around 37.9%. Total phospholipids = 44.0% +/- 2.0 3/1981 PC is 33.3% of krill lipids Ether phospholipids = 7.8% See 6(a) Subtract total lipids from ether phospholipid to get non-ether phospholipid 44.0%-7.8%=36.2

	Therefore, non-ether phospholipid would be around **36.2%.**
12(d). from about 20% to 50% w/w triglycerides.	**Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1. Lipid Composition of Antarctic Krill (*Euphausia superba*) Triacylglycerols **33.3 %** +/- 0.5 12/1977 **40.4 %** +/- 0.1 3/1981
13. The encapsulated krill oil of claim 6, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.	**Bottino (Exhibit 1007)** P. 0002, Table 1 Omega-3 fatty acids (as weight percent of total acids of Euphausia superba) of whole krill: Station 8--**30.5%** Station 9--**26.8%** Station 11--**25.0%** Pp. 0004-0005, Table 3 Omega-3 fatty acids as weight percent of total acids of Euphausia superba: **28.6%.**
14. The encapsulated krill oil of claim 13, wherein from about 70% to 95% of said omega-3 fatty acids are	**Fricke (Exhibit 1010)** Pp. 0002 and 0004-0005, Tables 1, 4,

attached to said phospholipids.	and 5; and attached analysis. Table 1 provides the amount of each lipid class in the total lipid. Tables 4 and 5 provide the amount of omega-3 fatty acid composition of each phospholipid class. Therefore, the amount of omega-3 in each lipid class relative to the total lipid can be calculated by multiplying the amount of omega-3 fatty acid for each lipid class by the amount of the particular lipid class in the total lipid composition. This is done for each lipid class. The amount of omega-3 associated with phospholipid is then divided by the total amount of omega-3 in the total lipid to provide the percentage of omega-3 fatty acid attached to phospholipid. Using this calculation, 74.81% (3/1981 sample) and 82.03% (12/1977 sample) of the omega-3 fatty acids are attached to phospholipids. (Tallon Decl., Appendix B)
15. The encapsulated krill oil of claim 12, wherein said krill is Euphausia superba.	**Fricke (Exhibit 1010)** P. 0001, Abstract. "The lipid classes, fatty acids of total and individual lipids and sterols of

	Antarctic krill ***(Euphausia superba* Dana)** from two areas of the Antarctic Ocean…" or **<u>Tanaka (Exhibit 1014)</u>** P. 0002, 1st col. "A lipid extract of krill (**Euphausia superba**) was a generous gift from Itano Refrigerated Food Co. (Tokushima, Japan)."
16. The encapsulated krill oil of claim 12, wherein said capsule is a soft gel capsule.	**<u>Sampalis I (Exhibit 1012)</u>** P. 0004, 2nd col. "Each patient was asked to take two 1-gram **soft gels of** either **NKO** or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
17. The encapsulated krill oil of claim 12, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.	**<u>Bottino (Exhibit 1007)</u>** P. 0005, Table 3. Arachidonic acid [20:4(n-6)] include **0.4% of total fatty acids.**

18. Encapsulated Antarctic krill oil comprising:	**Sampalis I (Exhibit 1012)** P. 0004, 1st col. "**Neptune Krill Oil**™ (NKO™) is a natural health product extracted from **Antarctic krill** also known as *Euphausia superba*. *Euphausia superba*, a zooplankton crustacean, is rich in phospholipids and triglycerides carrying long-chain omega-3 polyunsaturated fatty acids, mainly EPA and DHA," P. 0004, 2nd col. "Each patient was asked to take two 1-gram **soft gels of** either **NKO** or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."
18(a). a soft gel capsule containing an effective amount of krill oil,	**Sampalis I (Exhibit 1012)** P. 0004, 2nd col. "Each patient was asked to take two 1-gram **soft gels** of either **NKO** or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial."

18(b). said krill oil comprising from about 3% to about 10% w/w ether phospholipids,	**Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1. Phosphatidylcholine is ~34% of krill lipids. And **Tanaka (Exhibit 1014)** P. 0003, 1st col, Table I. 23.0 +/- 1.2% of krill phosphatidylcholine are alkylacylphosphatidylcholine (AAPC). Therefore, AAPC is present at **7.8%.** (23% x .34 = 7.82%)
18(c). from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w;	**Fricke (Exhibit 1010)** P. 0002, 1st col., Table 1. **Total phospholipids = 45.7 %** +/- 1.6 12/1977 PC is 35.6% of krill lipids Ether phospholipids = 7.8% See 6(a) Subtract total lipids from ether phospholipid to get non-ether phospholipid 45.7% - 7.8%=37.9%

	Therefore, non-ether phospholipid would be around 37.9%. **Total phospholipids =** **44.0%** +/- 2.0 3/1981 PC is 33.3% of krill lipids Ether phospholipids = 7.8% See 6(a) Subtract total lipids from ether phospholipid to get non-ether phospholipid 44.0%-7.8%=36.2% **Therefore, non-ether phospholipid would be around 36.2%.**
18(d). and from about 20% to 50% w/w triglycerides.	**Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1. Lipid Composition of Antarctic Krill (*Euphausia superba*) Triacylglycerols **33.3 %** +/- 0.5 12/1977 **40.4 %** +/- 0.1 3/1981
19. The encapsulated krill oil of claim 18, wherein said krill oil further comprises	
19(a). from about 20% to 35% omega-3 omega-3 fatty acids as a percentage of	**Bottino (Exhibit 1007)**

total fatty acids in said composition.	P. 0002, Table 1 Omega-3 fatty acids (as weight percent of total acids of Euphausia superba) of whole krill: Station 8--**30.5%** Station 9--**26.8%** Station 11--**25.0%** Pp. 0004-0005, Table 3 Omega-3 fatty acids as weight percent of total acids of Euphausia superba: **28.6%.**
20. The encapsulated krill oil of claim 19, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said phospholipids.	**Fricke (Exhibit 1010)** Pp. 0002 and 0004-0005, Tables 1, 4, and 5; and attached analysis. Table 1 provides the amount of each lipid class in the total lipid. Tables 4 and 5 provide the amount of omega-3 fatty acid composition of each phospholipid class. Therefore, the amount of omega-3 in each lipid class relative to the total lipid can be calculated by multiplying the amount of omega-3 fatty acid for each lipid class by the amount of the particular lipid class in the total lipid composition. This is done for each lipid class.

	The amount of omega-3 associated with phospholipid is then divided by the total amount of omega-3 in the total lipid to provide the percentage of omega-3 fatty acid attached to phospholipid. Using this calculation, **74.81%** (3/1981 sample) and **82.03%** (12/1977 sample) of the omega-3 fatty acids are attached to phospholipids. (Tallon Decl., Appendix B)

VII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *Inter Partes* Review of Claims 1-20 of U.S. 9,078,905, followed by a grant of this Petition concealing Claims 1-20 of the '905 patent on the grounds detailed herein.

Dated: January 27, 2017

Respectfully submitted,

/James F. Harrington/
James F. Harrington
jfhdocket@hbiplaw.com
Registration No. 44,741

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(516) 822-3550

Attorney for Petitioner
Rimfrost AS

VIII. CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of to 37 C.F.R. §42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 12,957 words, including the parts of the brief exempted by to 37 C.F.R. §42.24(a) (that is, the word count does not include the table of contents, the exhibit list, mandatory notices under §42.8, the certificate of service or the certificate of compliance).

Dated: January 27, 2017

Respectfully,

/James F. Harrington/
James F. Harrington
jfhdocket@hbiplaw.com
Registration No. 44,741

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of January 2017, the foregoing PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ.*, including all Exhibits and the Power of Attorney, were served pursuant to 37 C.F.R. §§ 42.6 and 42.105, via Federal Express®, (Domestic - next day delivery, International – priority) on the following:

[Patent Owner Correspondence Address of Record (37 C.F.R. § 42.105(a)]

John Jones, Esq.
Casimir Jones, S.C.,
2275 Deming Way, Suite 310
Middleton, Wisconsin 53562

and

[Patent Owner (37 C.F.R. §§ 42.6(e)(2) and 42.105(a))]

Aker BioMarine Antarctic AS
Oksenøyveien 10, N-1327
1366 Lysaker, Norway

and

[Patent Owner's Litigation Counsel]

Andrew F. Pratt, Esq.
Venable LLP
575 Seventh Street, NW
Washington, DC 20004

By: /James F. Harrington/
James F. Harrington (Reg. No. 44,741)
Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset, NY 11791
jharrington@hbiplaw.com
Tel: (516) 822-3550

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS

Petitioner

v.

AKER BIOMARINE ANTARCTIC AS

Patent Owner

Case No.: IPR2017-00746

U.S. Patent 9,028,877

Issue Date: May 12, 2015

Title: Bioeffective Krill Oil Compositions

PETITION FOR *INTER PARTES* REVIEW

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ*.

TABLE OF CONTENTS

APPENDIX OF EXHIBITS

EXHIBIT NO.	EXHIBIT DESCRIPTION
1001	U.S. Patent No. 9,028,877 B2, filed September 18, 2014 ('877)
1002	U.S. Provisional Patent Application No. 61/024,072, filed January 28, 2008 ('072 Provisional)
1003	U.S. Provisional Patent Application No. 60/983,446, filed October 29, 2007 ('446 Provisional)
1004	U.S. Provisional Patent Application No. 60/975,058, filed September 25, 2007 ('058 Provisional)
1005	U.S. Provisional Patent Application No. 60/920,483, filed March 28, 2007 ('483 Provisional)
1006	Declaration of Dr. Stephen Tallon
1007	Bottino, N.R.,"The Fatty Acids of Antarctic Phytoplankton and Euphausiids. Fatty Acid Exchange among Trophic Levels of the Ross Sea", Marine Biology, 27, 197-204 (1974) (Bottino)
1008	Budziński, E., P. Bykowski and D. Dutkiewicz, 1985, "Possibilities of processing and marketing of products made from Antarctic krill". FAO Fish.Tech. Pap., (268):46. (Budzinski)
1009	Catchpole and Tallon, WO 2007/123424, published November 1, 2007, "Process for Separating Lipid Materials," (Catchpole)
1010	Fricke et al., "Lipid, Sterol and Fatty Acid Composition of Antactic Krill (Euphausia superba Dana)," LIPIDS 19(11):821-827 (1984) (Fricke)

1011	Randolph, et al., U.S. Patent Application Publication No. US/2005/0058728 A1, "Cytokine Modulators and Related Method of Use"(Randolph)
1012	Sampalis [I] *et al.*, "Evaluation of the Effects of Neptune Krill Oil™ on the Management of Premenstrual Syndrome and Dysmenorrhea," Altern. Med. Rev. 8(2):171-179 (2003) (Sampalis I)
1013	Sampalis [II] *et al.*,WO 2003/011873, published February 13, 2003, "Natural Marine Source Phospholipids Comprising Flavonoids, Polyunsaturated Fatty Acids and Their Applications" (Sampalis II)
1014	Tanaka [I] et al., "Platelet – Activating Factor (PAF) – Like Phospholipids Formed During Peroxidation of Phosphatidylcholines from Different Foodstuffs," Biosci. Biotech. Biochem., 59(8) 1389-1393 (1995) (Tanaka I).
1015	Tanaka [II] et al., "Extraction of Phospholipids from Salmon Roe with Supercritical Carbon Dioxide and an Entrainer", Journal of Oleo Science Vol. 53 (2004) No. 9, p.17-424 (Tanaka II)
1016	Beaudoin et al., "Method of Extracting Lipids From Marine and Aquatic Animal Tissues," U.S. Patent No. 6,800,299 B1 filed July 25, 2001 (Beaudoin).
1017	Folch et al., "A simple method for the isolation and purification of total lipides from animal tissues," J. Biol. Chem. (1957) 226: 497-509 (Folch).
1018	Kochian et al, "Agricultural Approaches to Improving Phytonutrient Content in Plants: An Overview," Nutrition Reviews", Vol. 57, No. 9, September 1999: S13-S18.

1019	Porzio et al., "Encapsulation Compositions and Processes for Preparing the Same," U.S. Patent No. 7,488,503 B1 filed March 31, 2004 (Porzio).
1020	Bunea, et al., "Evaluation of The Effects Of Neptune Krill Oil On The Clinical Course of Hyperlipidemia," Altern Med Rev. 2004; 9:420–428 (Bunea).
1021	Complaint filed in *Aker Biomarine Antarctic AS v. Olympic* Holding *AS, et al.,* 1:16-CV-00035-LPS-CJB (D. Del).
1022	Affidavits of Service Filed in *Aker Biomarine Antarctic AS v. Olympic Holding AS, et al.,* No. 1:16-CV-00035 LPS-CJB (D. Del).
1023	Federal Register Notice of Institution of Investigation 337-TA-1019 on September 16, 2016 by the ITC (81 Fed. Reg. pages 63805-63806)
1024	File History to U.S. Patent No. 9,034,388 B2, Serial No, 12/057,775 ('388 File History) 1024 Part 1 - Pages 1-450 1024 Part 2 - Pages 451-900 1024 Part 3 - Pages 901-1350 1024 Part 4 - Pages 1351-1800 1024 Part 5 - Pages 1801-2250 1024 Part 6 - Pages 2251-2700 1024 Part 7 - Pages 2701-3083
1025	File History to U.S. Patent No. 9,028,877 B2, Serial No, 14/490,176 ('877 File History) 1025 Part 1 - Pages 1-375 1025 Part 2 - Pages 376-724

1026	File History to U.S. Patent No. 9,078,905 B2, Serial No, 14/490,221 ('905 File History) 1026 Part 1 - Pages 1-450 1026 Part 2 - Pages 451-882
1027	Saether et al., "Lipolysis post mortem in North Atlantic krill", Comp. Biochem. Physiol. Vol. 83B, No. 1, pp. 51-55, 1986 (Saether).
1028	Hawley's Condensed Chemical Dictionary, p. 893, 13th ed.,1997 (Hawley's)
1029	Webster's New Universal Unabridged Dictionary, 2nd ed., p. 732, 1983 (Webster's)
1030	Tehoharides, U.S. Patent Application Publication No. US/2006/0013905 A1, "Anti-Inflammatory Compositions For Treating Multiple Sclerosis" (Tehoharides)
1031	Halliday, Jess, "Neptune-Degussa Deal to Develop Phospholipids, Adapt Krill Oil," http://www.nutraingredients-usa.com/Suppliers2/Neptune-Degussa-deal-to-develop-phospholipids-adapt-krill-oil, December 12, 2005 (Neptune-DeGussa).
1032	Grantham, G.J., "The Utilization Of Krill", UNDP/FAO Southern Ocean Fisheries Survey Programme (1977) (Grantham).
1033	Yoshitomi, U.S. Patent Application Publication No. US/2003/0113432 A1, "Process For Making Dried Powdery and Granular Krill" (Yoshitomi).
1032	Grantham, G.J., "The Utilization Of Krill", UNDP/FAO Southern Ocean Fisheries Survey Programme (1977) (Grantham).

1033	Yoshitomi, U.S. Patent Application Publication No. US/2003/0113432 A1, "Process For Making Dried Powdery and Granular Krill" (Yoshitomi).
1034	Kolakowska, A., "The influence of sex and maturity stage of krill (*Euphausia superba* Dana) upon the content and composition of its lipids", 1991, Pol. Polar Res. 12: 73-78 (Kolakowska).
1035	Breivik, U.S. Patent Application Publication No. US 2010/0143571 A1, "Process for Production of Omega-3 Rich Marine Phospholipids from Krill" (Breivik).
1036	Breivik, U.S. Provisional Patent Application No. 60/859,289, "Processes for production of omega-3 rich marine phospholipids from krill", filed November 16, 2006 (Breivik '289 Provisional)
1037	Breivik, WO 2008/060163 A1, "Process for Production of Omega-3 Rich Marine Phospholipids from Krill," International filing date November 15, 2007 (Breivik PCT).

I. THE PETITION

Petitioner, real party-in-interest, Rimfrost AS, a Norwegian corporation with its principal place of business at Vågsplassen, 6090, Fosnavåg, Norway, hereby petitions the Patent Trial and Appeal Board (the "Board" or the "PTAB") of the United States Patent and Trademark Office ("PTO"), pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.1 *et seq.*, to institute an *inter partes* review and to find unpatentable and cancel Claims 1-19 of U.S. Patent No. 9,028,877, entitled "Bioeffective Krill Oil Compositions," issued May 12, 2015 (Serial No. 14/490,176, filed September 18, 2014) ("the '877 patent"), assigned to Aker Biomarine Antarctic AS ("Aker"). The '877 patent is submitted herewith as Exhibit 1001. There is a reasonable likelihood that Petitioner will prevail with respect to at least one claim challenged in this petition.

II. MANDATORY NOTICES

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this petition.

A. Real parties-in-interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Olympic Holding AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, Bioriginal Food and Science Corp., and Petitioner, Rimfrost AS, are identified as

the real parties-in-interest. Several other entities have a majority ownership interest in the above-identified real parties-in-interest. Based upon those ownership interests, and in an abundance of caution, Petitioner also names Stig Remøy, SRR Invest AS, Rimfrost Holding AS, Pharmachem Laboratories, Inc., and Omega Protein Corporation as real parties-in-interest.

B. Related matters (37 C.F.R. § 42.8(b)(2))

Aker has asserted two patents – U.S. Patent Nos. 9,078,905 and 9,028,877 – in a lawsuit captioned *Aker Biomarine Antarctic AS v. Olympic Holding AS; Rimfrost AS; Emerald Fisheries AS, Rimfrost USA, LLC; Avoca Inc.;* and *Bioriginal Food & Science Corp.* Case No. 1:16-CV-00035-LPS-CJB (D. Del.). (Complaint, Exhibit 1021). The litigation is presently pending, although it has been stayed in view of Investigation No. 337-TA-1019 instituted by the United States International Trade Commission on September 16, 2016 as noticed in the Federal Register. The ITC proceeding is entitled *In the Matter of Certain Krill Oil Products and Krill Meal for Production of Krill Oil Products* and concerns U.S. Patent Nos. 9,028,877; 9,078,905; 9,072,752; 9,320,765; and 9,375,453. The ITC investigation lists as respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca Inc.,