IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Inter Partes* Reexamination of U.S. Patent No. 8,030,348

Entitled: NATURAL MARINE SOURCE PHOSPHOLIPIDS COMPRISING POLYUNSATURATED FATTY ACIDS AND THEIR APPLICATIONS

Issued: 4 October 2011 to Sampalis

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Examiner: Bruce Campbell

FIRST SUPPLEMENTAL DECLARATION BY DR. THOMAS GUNDERSEN IN SUPPORT OF REQUEST FOR INTER PARTES REEXAMINATION OF U.S. PATENT NO. 8,030,348

EFS WEB Filed

Mail Stop Inter Partes Reexam
Commissioner for Patents
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Alexandria, VA 22313-1450

I, Dr. Thomas Gundersen, state as follows:

1. My present position is CEO of Vitas AS - Analytical Pharma Services, Oslo, Norway. My Curriculum Vitae is attached hereto as Exhibit 1.

2. In 2011, I was asked by Aker Biomarine ASA to analyze lipid fractions extracted from two species of krill, *Euphausia superba* and *Euphausia pacifica*, to determine whether they contain phospholipids that have either eicosapentaenoic acid (EPA) or docosahexaenoic acid (DHA) at both the sn-1 and sn-2 positions of the phospholipid molecule. I performed this analysis which was the subjection of my Declaration dated October 4, 2011. Exhibit 2 to my 2011 Declaration was a laboratory report on the analysis. This report contained two sets of data presented in Appendix A and Appendix B. The data in Appendix A of my 2011 report is HPLC-

MS data which was used for preliminary analysis of the samples to determine if they contained phospholipid species with the appropriate molecular weights. The data in Appendix B of my 2011 report is HPLC-MS/MS (MRM) which definitively identifies the individual phospholipid species contained in the samples that were analyzed. The Appendix A data contained unintended mistakes (due to a cut and paste error when putting the report together) in the last panels presented for samples P308-8, P308-9, P308-10, P308-11, and P308-12. These mistakes do not affect the conclusions I reached with respect to the presence of the phospholipid species in the samples, which were based on the data presented in Appendix B of my 2011 report. Exhibit 2 attached hereto contains the corrected Appendix A data and original Appendix B data. The corrected Appendix A data is entirely consistent with the conclusions presented in my 2011 Declaration and Report, the results of which are summarized in the Table below which was provided with my 2011 Declaration.

Vitas ID	**Frac. #**	**Treatment °C/min**	**MRMs** [825+H]→184 [851+H]→184 [877+H]→184	**MRM 1** PC-EPA/EPA 826→524	**MRM 2** PC-EPA/DHA 852→524	**MRM 3** PC-EPA/DHA 852→550	**MRM 4** PC-DHA/DHA 878→550	**Conclusion**
P308-1	**IIa**	none	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-2	**IIa**	70/5	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-3	**IIa**	125/15	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-4	**IIb**	none	NO NO NO	NO	NO	NO	NO	n.d. PC-EPA/EPA n.d. PC-EPA/DHA n.d. PC-DHA/DHA
P308-5	**IIb**	70/5	NO NO NO	NO	NO	NO	NO	n.d. PC-EPA/EPA n.d. PC-EPA/DHA n.d. PC-DHA/DHA
P308-6	**IIb**	125/15	NO NO	NO	NO	NO	NO	n.d. PC-EPA/EPA n.d. PC-EPA/DHA

			NO					n.d. PC-DHA/DHA
P308-7	**IIa**	none	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P208-8	**IIa**	70/5	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-9	**IIa**	125/15	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-10	**IIb**	none	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-11	**IIb**	70/5	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-12	**IIb**	125/15	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-13	**n.a.**	n.a.	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-14	**n.a.**	n.a.	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-15	**n.a.**	n.a.	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA
P308-16	**n.a.**	n.a.	YES YES YES	YES	YES	YES	YES	Contains PC-EPA/EPA Contains PC-EPA/DHA Contains PC-DHA/DHA

3. The results presented in my 2011 Declaration do not suffer from a carry-over effect. I did include standard blanks in my analysis, but did not include that data in the original report as it was of minor importance and as it is not customary. Exhibit 3 attached hereto provides two examples demonstrating the absence of carry-over effect. In the first example, the highest standard is analyzed before a solvent blank. In the other example, a solvent blank is analyzed directly after a sample. The time and date of the analysis on the original data proves that these are run in series and that these controls were run in the very same sequence as the original samples. As can be seen, there are no carry over or memory effects. Carry-over effects are not expected as the design of the injector is of the ”flow through principle” meaning that the mobile phase is flowing through the autosampler needle for most of the analysis time of 18 minutes (in this case). The needle is also flushed on the outside in a “wash station” before the next injection. The HPLC used in the LC-MS (SQ) method is the type same as for the LC-MS/MS method. Carry-over was not an issue in these experiments.

4. Dr. Jaczynski argues that the setup used by Gundersen works through air-liquid convection and that this renders it unsure if the oil really was heated to 125 degrees Celsius for 15 minutes or 75 degrees for five minutes. This assumption is probably drawn because Dr. Jaczynski hasn’t understood the experimental setup in detail and thereby what heat transfer principle is actually applied. The heating of the lipid was performed in a 12 mm outer diameter 1.8 ml flat bottom glass vial. The metal heat block has flat bottom holes that match the vials perfectly with regards to outer diameter and depth. Thus, there is close contact with the bottom of the vial and the bottom of the heat block hole as well as the walls of the vial and the walls of the heat block hole. The oil in the vial is a small amount covering the bottom of the vial. The heat transfer is from the preheated metal heat block through the thin glass wall of the vial, primarily the bottom, and directly into the oil. It is thus not an air-liquid convection as stated by Dr. Jaczynski. Covering the vials with aluminum foil is not necessary as the setup is inside the oven with 125 degrees ambient temperature. The temperature of the small amount of oil reaches 125 degrees in seconds using this principle. Using the analogy of Dr. Jaczynski, this type of heating would be similar to touching the metal sides inside the kitchen oven and that this off course will cause rapid severe pain indicating very efficient heat transfer.

5. I further declare that all statement 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.

Respectfully submitted,

Dr. Thomas Gundersen

Date: April 18, 2012

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