UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS

Petitioner

v.

AKER BIOMARINE ANTARCTIC AS

Patent Owner

Case: IPR2018-00295

U.S. Patent No. 9,320,765

DECLARATION OF ROBERT S. MCQUATE, Ph.D.

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1. I have agreed to provide expert testimony in support of Rimfrost AS's Petition for *Inter Partes* Review of U.S. Patent No. 9,320,765. My *Curriculum Vitae* is attached hereto as Appendix A.

2. For my work related to this *Inter Partes* Review, I serve as an independent contractor engaged through GRAS Associates, LLC, from whom I receive compensation for my services. I am not directly compensated by either Hoffmann & Baron, LLP or the Petitioner. Other than through GRAS Associates, I have no financial interest in this proceeding, and the potential for any future financial benefit is unaffected by the content of my testimony or the outcome of this proceeding. My compensation from GRAS Associates, LLC is not linked to the outcome of the case.

SUMMARY OF MY OPINIONS

3. I have been asked to give my opinion as to whether, in 2006 and thereafter, persons ordinarily skilled in the art of ingredients extracted from plant and marine and other sources and interested in krill- and/or krill oil-related information as food ingredients or nutraceutical products for use in humans, when exercising reasonable diligence, would have searched online for information regarding krill

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substances, and in particular through the FDA's directories of GRAS Notices for krill-related substances. In my opinion, they would have done so. See below.

4. I have also been asked to give my opinion as to whether, in 2006 and thereafter, persons ordinarily skilled in the art of ingredients (substances) extracted from plant and marine and other sources and interested in krill- and/or krill oil-related information as food ingredients or nutraceutical products for use in humans, when exercising reasonable diligence after locating through an Internet search reference to a GRAS Notice identifying the GRAS Notice substance as "Krill-derived lecithin", would have been able to access, that is, obtain a copy of, the GRAS Notice promptly through a Freedom of Information Act (FOIA) request. In my opinion, they would have been able to do so. See below.

5. In my opinion, persons ordinarily skilled in the art of ingredients extracted from plant and marine and other sources and interested in krill- and/or krill oil-related information as food ingredients or nutraceutical products for use in humans, when exercising reasonable diligence, (1) would have no later than August 5, 2007, been able to find reference to GRAS Notice 226 ("GRN 226") submitted by Enzymotec, Ltd. regarding the substance entitled "Krill-derived Lecithin" (Exhibit 1048); (2) would have known to prepare and submit a FOIA request to the FDA to obtain a copy of GRN 226; and (3) subsequently would have been able to promptly obtain a copy of GRN 226 from the FDA through the FDA FOIA process.

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6. Specifically, as discussed below in more detail, in my opinion, in 2006 and thereafter, persons ordinarily skilled in the art of ingredients extracted from plant and marine and other sources and interested in krill- and/or krill oil-related information as food ingredients and nutraceutical products for use in humans, when exercising reasonable diligence, would have known that GRAS notices were indexed and were searchable by substance at the FDA website.

7. Thus, by searching, *inter alia*, for "krill", at least as early as August 5, 2007, an interested individual, seeking information regarding krill- and/or krill oil-related information as food ingredients or nutraceutical products used in humans, would have necessarily ascertained the existence of GRAS Notice 226 (GRN 226), submitted by Enzymotec, Ltd., regarding the substance identified as "*Krill-derived Lecithin*" (Enzymotec, Exhibit 1048), and thereafter could have obtained a copy through, *inter alia*, a FOIA request submitted to the FDA.

8. Upon the FDA's "filing", on May 31, 2007, of Enzymotec GRAS Notice 226 (GRN 226) (Exhibit 1048), GRN 226 became available to the public through, *inter alia*, a FOIA request submitted to the FDA. In my experience, FOIA requests for complete GRAS notices, such as the GRN 226, are uncomplicated because they do not contain much or, in many cases, any confidential information that would require the FDA to segregate and redact any information (such as, toxicology studies or detailed manufacturing processes or dietary intake

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calculations) and, as such, the FDA would promptly provide the information to any member of the public submitting a FOIA request.

9. No later than August 5, 2007, Enzymotec GRN 226 (Exhibit 1048) was indexed and was searchable by substance, e.g., a search for krill-derived lecithin, krill and lecithin, or the component words, and such a search would have yielded GRAS Notice 226. See Exhibit 1052 (https://web.archive.org/web/20070805011458/http://www.cfsan.fda.gov:80/~rdb/opa-gras.html) and the discussion below.

10. Moreover, given FDA's designated policy that was in place in 2007 as reported in its Freedom of Information Annual Report 2007 (see Exhibit 1062, https://www.fda.gov/RegulatoryInformation/FOI/FOIAAnnualReports/ucm148025.htm), the FDA would have fulfilled uncomplicated FOIA requests, such as one for GRN 226, within twenty business days. Consequently, an interested person who searched the Internet and requested a copy by FOIA would have been able to obtain a copy of GRN 226 by August 31, 2007.

11. I have also been asked to provide my opinion on the presence of ether phospholipids in the krill oil produced by Neptune and Aker and possible adverse health effects, i.e., Platelet Activation Factor, which could cause inflammatory responses following ingestion. I note that such concerns were not addressed by Neptune's Expert Panel, and they do not appear to have been addressed by Aker's

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