UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS

Petitioner

v.

AKER BIOMARINE ANTARCTIC AS

Patent Owner

Case: IPR2018-01730

U.S. Patent No. 9,072,752 B1

DECLARATION OF RAKESH KAPOOR, PH.D.

1. I have agreed to provide testimony in support of Rimfrost AS's Petition for *Inter Partes* Review of U.S. Patent No. 9,072,752 B1.

2. I am not directly compensated by either Hoffmann & Baron, LLP or the Petitioner. I have no financial interest in this proceeding, and the potential for any future financial benefit is not affected by the content of my testimony or the outcome of this proceeding. My compensation from my employer, Bioriginal Food & Science Corp. ("Bioriginal"), is not in any way related to the outcome of the proceeding.

3. I received my Ph.D. in Physiology[1] from University of Saskatchewan, Saskatoon, Canada in 1993, my Masters in Pharmacognosy[2] from the University of Delhi, India in 1983, and my Bachelors in Pharmacy from the University of Delhi, India in 1980. My *Curriculum Vitae* is attached hereto as Appendix A.

4. As of 2007, I had advanced degrees in Physiology, Pharmacognosy and Pharmacy, and an understanding, through both my education and over ten years' of applied experience, of biochemistry, organic chemistry, lipid chemistry, and

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[1] Physiology is the study of life and how living cells and tissues function, enabling

With over 20 years of global expertise, Bioriginal has carved out a niche by scientifically combining nutritional ingredients from all over the world, directly from the source, to create unique and efficacious solutions. Bioriginal is passionate about nutritional ingredients and the health benefits they provide, discovering, anticipating trends and pioneering within the Food and Nutraceutical industries since 1993. Bioriginal has developed proprietary methods and systems to provide customized turnkey solutions for our customers that help them compete and win in a highly competitive space. Bioriginal is headquartered in Saskatoon, Canada with facilities throughout the USA, Europe and Asia."

https://www.bioriginal.com/about-us/.

6. From 1997 to 2003, I was Product Development Manager at Bioriginal. As Product Development Manager my responsibilities included: developing formulations for soft gels, emulsions, flavored oils, etc.; educating customers on the benefits and use of omega-6s and omega-3s essential fatty acids; optimizing processes to manufacture herbal tinctures and herbal extracts; SOP development for unit operations in accordance with GMP; process scale up; developing

analytical methods to analyze various products; organizing clinical trials; training and supervising of technical staff; developing technical and promotional material; providing regulatory advice to customers; and optimizing production process for standardized herbal extract, so as to make it economically viable and maximize the extraction of active principles.

7. Currently, I am Director, Science & Technology at Bioriginal, a position I have held since 2003. As Director my responsibilities include: evaluation of new business opportunities; new technologies; management of clinical research; training sales staff on scientific aspects of products; product development (flavored functional drink mixes, dietary supplements, emulsions, etc.,), process scale up, process optimization, equipment selection, for unit operations in accordance with GMP, process validation; analysis of scientific literature; providing regulatory advice to staff and customers; interacting with regulatory authorities, and, in connection with one ingredient, providing self-affirmed GRAS (Generally recognized as safe).

8. At Bioriginal, I have advised, and continue to advise, technical people working in food industry on techniques of incorporation of omega-3 essential fatty

Bioriginal customers, I would conduct searches on various well-known on-line databases including PubMed,[3] Scopus®[4] and the FDA GRAS Notice database. GRAS Notices were useful as they often contained detailed information on the ingredients which had not been published elsewhere.

10. Since at least 1999, I have used FDA GRAS Notices and related FDA generated information (e.g., response letters) as a source of information regarding the uses, sources and chemical compositions of potential ingredients.

11. Moreover, since at least 1999, if a full GRAS Notice and/or an FDA response letter could not be downloaded from the FDA GRAS Notice database

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[3] PubMed is a free resource that is developed and maintained by the National Center for Biotechnology Information (NCBI), at the U.S. National Library of Medicine (NLM), located at the National Institutes of Health (NIH).

[4] Scopus® is an abstract and citation database of peer-reviewed literature: scientific journals, books and conference proceedings, owned by Elsevier.

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