

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 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. 9,320,765.
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 Physiology¹ from University of Saskatchewan, Saskatoon, Canada in 1993, my Masters in Pharmacognosy² 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

¹ Physiology is the study of life and how living cells and tissues function, enabling organisms to live and interact with their environment.

² Pharmacognosy is the study of medicinal drugs derived from plants or other natural sources.

nutrition, as well as practical experience in the field of extraction. For further details, see my *Curriculum Vitae* attached hereto as Appendix A.

5. As Bioriginal states on its website: “Bioriginal is a global leader in delivering complete nutritional solutions to the Food and Nutraceutical industries. 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 acids into various food formulations including cheese, milk, salad dressings, butter, etc. I developed a process for the extraction of herbal materials to obtain maximal levels of active principle while optimizing production costs. I have also optimized

production processes for fermented herbal liquors (*Ayurvedic* medicines), herbal tinctures, and emulsions.

9. When investigating the uses and chemical composition of possible ingredients and their sources for use in connection with products developed for 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

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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.