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Regulations and protection for functional food products in the United States

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ABSTRACT

In line with increasing concern and attention to health, functional foods and dietary supplements have been gaining popularity and prominence for their role in disease risk reduction and benefit to health in the recent past. Development of these food products has become a hot research area in the academia and the industry. As in the biotechnological and pharmaceutical industries, research and development of health food products are often risky and require enormous resources. In this article, the current governmental regulations and patent protection, two prime factors for paving the way for developing and marketing functional foods and dietary supplements in the United States, have been discussed. The newly reformed requirements of patenting natural matters in view of Supreme Court rulings such as *Mayo*, *Myriad* and *Alice* are highlighted, and we provide suggestions and advice for a better intellectual property protection for these products.

Contents

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1. Introduction

Modern medicine and advances in biotechnology have helped humans to live longer and healthier nowadays. In the United States, the number of Americans aged 65 and older is expected to grow by more than 50% over the next 25 years, implicating an elevated health cost in the near future (Stone, 2014).

Consumers have become increasingly interested in the health benefits that are naturally found in foods, causing an awareness of the importance of health foods, including functional foods and dietary supplements. It was estimated that organic food alone brought in $31.5 billion in the U.S. in 2012 (Brodwin, 2014). The ever-growing functional food and drink market increased 1.5 times globally, reaching $24.2 billion USD in 2010, and a projected growth to $29.8 billion in 2014 (Nutritional Outlook, 2011).

Undoubtedly, the functional foods and dietary supplements market would be worth developing for its intrinsic as well as financial benefits. Millions and billions of dollars have been invested into the research and development of these products. To minimize the financial risks of such costly and long-term investments, one must learn about the legal practices, laws and regulations that may be detrimental to the product's success in the market. It is essential to be familiar with related governmental regulations, seek proper intellectual property (IP) protection for the product, and strategize wisely to reduce risks in the investment and to maximize profitability.

Obtaining IP protection such as patenting not only grants inventors an exclusive right on making, using and selling of the products but also helps to attract investment to foster future research and development. Such was the case with BioHarvest Limited; it was an Israeli biotechnology company that had patented its newly developed technology on culturing fruit and vegetable cells in 3D bioreactors, producing super-foods rich in phytonutrients in highly bioavailable and efficacious forms. The company moved from Israel to the U.S. and partnered with the University at Albany with a funding of $1.2 million in 2014. The company marketed one of its developed products VINIA™ in the U.S. in January 2015, a red grape cell powder that was found to have beneficial effects on cardiovascular disease, type II diabetes and metabolic conditions (Area Development, 2014; PR Newswire, 2015).

This article will cover various factors that would affect the development and marketing of functional foods and dietary supplements in the U.S., including the governmental regulations and stance on these products, and summarizes keynotes in seeking patent protection for these products. In particular, the impact of recent court rulings such as *Mayo*, *Myriad* and *Alice* on patent eligibility of nature-based products and uses thereof is highlighted. Last but certainly not least, suggestions and advice for a proper IP protection will be provided.

2. Governmental regulations

2.1. *Statutory definitions of functional foods and dietary supplements*

Safety and labeling of foods and beverages are closely regulated and overseen by the United States Food and Drug Administration (FDA) under the provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act was enacted in 1938, codified in Chapter 9 of Title 21 of the United States Code (21 USC), and has been continuously amended by various Acts and supplemented by the Title 21 of the Code of Federal Regulations (21 CFR) (United States Food and Drug Administration (FDA), 2015). In particular, the Dietary Supplement Health and Education Act (DSHEA) passed in 1994 supplements the FD&C Act with new provisions specialized for dietary supplements. At present, there is no statutory definition for "functional foods" *or* "nutraceuticals" by the FD&C Act or related provisions, but the FDA acknowledges that the two categories are regulated by the FD&C Act. Table 1 summarizes the terminology and definition of several statutory and ordinary terms related to health food products.

Generally, "functional foods" and "dietary supplements" are food products that provide extra benefits to one's health in addition to basic nutritional values. These terms are sometimes used interchangeably due to their ambiguous definitions, despite the fact that they are usually considered as two separate categories of food products. Functional foods resemble conventional foods and can be foods added with or are abundant in ingredients that promote well-being or reduce risks of disease. Examples include natural foods such as soybean, walnut and pomegranate juice with intrinsic beneficial properties, and fortified foods added with dietary supplements such as orange juice fortified with calcium (Heller, 2009), whereas dietary supplements typically represent isolated or synthetic ingredients that are not consumed as a usual meal, and can be a capsule or tablet containing vitamins, minerals, herb extract