

Patents and Perceptions

*Food technologies designed to improve public health should be promoted.
Thus patenting of functional food technologies has risen in recent years.*

by Scott Lloyd and Mary Jo Leber

The functional foods market in the United States is relatively immature compared with the European and Japanese markets, but continues to grow. As the market grows, so does the body of food technology patents generated by market participants. While the grant of a patent may exclude others from selling a product or using the process employed by the patent owner to create it, the only way to market the benefits of the product to consumers is to label the product according to those benefits. However, the closer the purported health benefits of a functional food product drift toward the area of disease treatment or prevention, the more likely the US Food and Drug Administration (FDA) will consider the functional ingredient a drug rather than a food ingredient. Thus while patented technologies may be employed to create improved functional food products, those products may fail due to the inability of their makers to create the level of consumer benefit awareness required for successful marketing. Moreover, many US consumers now get functional ingredients

from supplements, and may like to keep it that way.

Growing Functionality

Functional foods are foods which impart health benefits above and beyond those naturally found in even the most healthful foods, although the term is increasingly used to refer to healthy foods to which FDA-approved health claims can be attributed. The functionality comes from the addition of exogenous dietary ingredients. Examples include ingredients that provide antioxidant effects, impart a feeling of satiety, provide an energy boost, reduce cholesterol, reduce the risk of heart disease or otherwise contribute a health benefit.

Beverages currently dominate the functional foods market, particularly sports drinks, energy beverages and healthy fruit juice drinks. Functional ingredients which impart a feeling of satiety are popular, due to the ubiquitous interest in weight control. Antioxidants are a commonly added functional ingredient, as these can be incorporated by the addition of fruits, vegetables and common herbs and spices that are on the list of substances that are generally recognised as safe (GRAS) by FDA, do not require approval to be incorporated, and are recognised as healthy by consumers. Alternatively, foods without undesirable ingredients such as fats or salt may be considered functional. Allergens may be the next ingredients targeted for removal, as FDA is planning to hold hearings on allergen advisory labelling this September.

Patent Claims

Historically, food technology is not an area of frequent patenting, possibly due to the scrutiny that one must endure while endeavouring to gain proprietary rights that affect the food supply. However, food technologies designed to improve public health should be promoted. Thus patenting of functional food technologies has risen in recent years.

A review of patents and published applications with functional food-related titles reveals that most filings are classified as A61K, preparations for medical purposes. The next most frequently appearing IPCs relate to foodstuffs and biocides, respectively. Thus before the majority of patent applications have even been examined, it appears they were perceived as being more like drugs than foods by the classifiers. A number of patent publications claim health benefits instead of ingredient. US application 20020082223/US-A1, for instance, describes the 'use of flavonoid glycosides and steroidal glycosides from *Hosta* or their derivatives as functional ingredients in functional food, OTC and pharmaceutical composition to prevent or treat cancer'. US Pat. No. 6,955,812, similarly, describes a '[h]ealth food and preparation having an anti-obesity effect'. Focus is not on the fact that the invention is a health food, but that its purpose is to reduce obesity. This theme recurs throughout the patent literature. This becomes ironic in the event that the owner has its own patents cited by FDA to show that the covered products are for disease treatment, in

which case the health claims desired for labelling may not be approved.

Health Claim Regulation

In the US, there are two agencies that govern what types of health claims may be made legally for food products: FDA and the Federal Trade Commission (FTC). FDA's role is to regulate food products based on safety considerations, while the role of the FTC is to protect consumers from false advertising and impose civil penalties against perpetrators. The FDA position on the labelling of functional foods is that while some claims may be made about their content or health benefits, there must be data to support those claims. FDA rates the results of randomised, double blind clinical studies as the best supporting data, as discussed in its 'Evidence based review systems for evaluation of health claims'. However, FDA also may consider a substance a drug if it has been the subject of published clinical trials. In fact, the agency goes so far as to block foods containing approved drugs or biologics from the market, as well as those containing a 'biological product that has been the subject of substantial [published] clinical investigations' FDA is currently seeking comments on this provision. Thus on the one hand, testing must be conducted on food ingredients to support health claims, but if those tests are in the nature of clinical trials, they may cause the ingredients to be categorised as drugs and subject to more onerous safety regulations. While FDA compliance is important in the labelling

Source: Innova Database



Embodi (US) is promoted for containing red wine antioxidants.

of functional foods, the FTC has been more active in terms of taking enforcement action against unsubstantiated product claims in the US. Examples of recent initiatives include a broad effort to police health claims made over the internet and remove bogus weight loss products from the market, and settlements can exceed US\$100 million. Thus while the FTC does not promulgate any regulations that affect scientific standards imposed on the market for safety and efficacy of products, its activity is a strong deterrent to mislabeling or otherwise misleading in advertising.

Types of Claims

FDA defines the four basic classifications of food label claims on their website (www.cfsan.fda.gov): nutrient content, health, qualified health and structure/function claims. Sponsors must meet specific criteria to use each type of claim on a food label. Nutrient content claims may describe 'less', 'reduced', or 'more' (or other approved adjectives) quantities of specific substances from the lists of allowed substances. A nutrient content claim may be a relative claim, in which the nutrient content is compared with a reference food (e.g., 25% less fat than whole milk). The FDA also has a list of requirements for foods to be labelled with terms such as 'enriched', 'lean', or 'an excellent source of'. Antioxidant claims are treated as nutrient content claims. Implied claims, such as a 'good source of' a particular nutrient are also covered, as in the claim, 'Made with Whole Grain Quaker Oats'. Specific conditions must be met in order to use the term, 'healthy'. Foods targeted for children under the age of two are subject to more stringent requirements.

Health claims are statements that characterise the relationship between a substance and a reduction in the risk of a health condition or disease.

The claim must explicitly name both the specific substance and the particular disease or health condition, as in the following health claim for oatmeal; 'Diets high in oatmeal/oat bran and low in saturated fat and cholesterol may reduce the risk of heart disease'. Health claims can be expressed or implied by the product branding or other packaging attributes. The claim is limited to a statement of a reduction in the risk of a disease and cannot claim that the product is a treatment for it. This is the main difference between a food ingredient and a drug. The food ingredient is nutritionally beneficial in improving an aspect of overall health, which may reduce the risk of contracting a disease, whereas drugs are substances that treat diseases. This distinction is getting blurred as the physiological benefits of various botanical substances are determined. Health claims for foods that meet the FDA requirements may employ previously approved wording.

Wording the Claim

Qualified health claims contain a qualifying statement, such as 'although the evidence is not conclusive, eating a specific substance may reduce the risk of a specific disease'. FDA may issue a Letter of Enforcement Discretion – as they have for a qualified health claim that tomato lycopene may reduce the risk of prostate cancer – or a Denial, when evidence does not support the claim, as in the rejection of claims that lycopene can reduce a number of other cancer risks.

In structure/function claims, the wording of the claim is important in consideration of the substance as a food or a dietary supplement and not as a drug. The claim must discuss the effect of the nutritive value of the substance on a structure or function of the body, such as that the substance may help mitigate 'mild memory loss associated with ageing', rather than claim-



ing a benefit with respect to a disease, stated explicitly or implied.

Supporting Claims

The legal requirement applied to health claims is that they must meet the Significant Scientific Agreement (SSA) standard. This standard imposes upon the person making the claims the burden of showing to the satisfaction of the FDA that its claims are supported by studies and opinions of qualified professionals who have published materials that support the health claims. Exceptions are made for a few qualified health claims, or for claims based on an authoritative statement by a US scientific body as defined by Congress. An example of the latter exception is 'Heart Healthy' labelling of foods according to the standards of the American Heart Association with respect to lowering saturated fat and cholesterol in the American diet.

While SSA can be shown for the known qualified health claims and a few scientific bodies exist to support health claim labelling for functional food makers, most of the health claims necessary to distinguish functional foods from their counterparts on the grocery store shelves require the manufacturer to generate supportive data. Moreover, the manufacturer is further required to generate supportive data without having its studies deemed clinical trials, thereby thrusting its functional food product into classification as a drug and requiring the costly submission of a New Drug Application for market

approval. This creates a true disincentive for producers to develop functional foods. While drug companies are able to offset much of their regulatory overhead costs with high profit margins on products with extensive patent protection, food

companies are not able to price their products in a manner that allows such recoupment, nor do they benefit from consumer reimbursement by the insurance industry.

Blurring Boundary

As we become more knowledgeable about the mechanisms of action of botanical substances and exploit their properties by using them in functional foods or supplements, the division

FDA may issue a Letter of Enforcement Discretion – as they have for a qualified health claim that tomato lycopene may reduce the risk of prostate cancer – or a Denial, as in the rejection of claims that lycopene can reduce a number of other cancer risks.

between food ingredients and drugs is becoming increasingly blurred. Food crops have always been bred for more desirable traits. Now genetic modification is improving this process, allowing the production of foods with increased nutritional value. Moreover, ingredient extraction technologies have enabled product manufacturers to add functional ingredients from one food into another. In the event that a producer is successful at developing – and preferably patenting – sound functional food technology, the ultimate challenge remains to sell enough of the product to make it profitable. In the FDA report, 'The Economics of Food Labelling', studies are cited which indicate that the majority of consumers do read food labels, do consider

nutrition an important factor in purchasing decisions and do switch brands based on the nutritional information provided on the labels. The authors of the 2007 article, 'Do Food Labels Make a Difference?...Sometimes' propose that the primary effect of health claims on labels is pressuring food manufacturers to reformulate and introduce new products in order to avoid disclosing unhealthy properties or to be allowed to claim healthy properties, giving consumers healthier choices. Quaker Oats was one of the first companies to take advantage of FDA-approved health claims, for the consumption of oats in reducing the risk of heart disease. Quaker's marketing strategy was rewarded with increased sales, which rose 19% from 1997 – 2000, after FDA approval of the health claim. Similarly, new soy pro-

tein-containing product sales almost doubled from 1998 to 1999, after approval of a health claim that soy protein possibly reduces the risk of heart disease when combined with a low fat, low cholesterol diet.

The rapid increase in olive oil sales since 2004 has been attributed to the promotion of its health benefits, after the approval of the claim that 'limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product [Name

of food] contains [x] grams of olive oil'. National Starch commissioned a study on the effects of adding multiple health claims, which showed that adding two health claims to a product could increase its consumption up to 26%. The study also concluded that the health claims least likely to increase sales are those referring to the addition of probiotics.

Final Barrier

One may intuit that with patents granted and health claims approved for labelling, functional foods should succeed if the prices are reasonable. Not quite. For example, Ocean Nutrition Canada owns appreciable patent rights covering fish oil compositions and formulations that it has used to successfully market nutritional supplements containing omega 3 fatty acids to consumers. However, the company had little success in marketing its healthy ingredients in functional foods.

Why? Although ingredients may be available in functional foods at only a modest cost increase, many people may rather get omega 3s from a capsule than pay extra for enhanced food products, even though the end cost of using functional foods in lieu of nutraceutical products may be reduced on a units-per-dollar basis. As illogical as that may sound, it may be true. This may be due to a number of factors, including brand loyalty to unfortified competing products, scepticism about the taste of the food, or increased cost compared to other food products – not to be confused with dietary supplements, which those same consumers happily continue to purchase. Thus, even with patent and health claims intact, consumers may be more difficult to convince than the patent office or FDA. ♦

Scott Lloyd is a registered patent attorney and Lead Project Analyst for IP Solutions at Nerac. Mary Jo Leber, Ph.D. is a food scientist and Project Analyst at Nerac.