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Patenting Personalized Nutrition Is Challenging But Feasible

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Since the 1990s, there has been an increased effort to understand the complexity of how diet and the genome interact.

While nutrigenetics addresses how an individual's genetic makeup impacts the ability to digest, absorb and use nutrients in food, nutrigenomics addresses how nutrition influences expression of the genome.

Personalized nutrition, then, is the concept of adapting these two fields to fit any person's needs — from high-endurance athletes to diabetic, obese or allergic individuals.

While the intellectual property challenges faced in personalized nutrition are analogous in part to those of personalized medicine, there are unique issues brought about by the expansive universe of prior art and the difficulty of demonstrating objective evidence of nonobviousness.

The growth of the personalized nutrition industry cannot be overstated. Analysts at Grand View Research Inc. in San Francisco estimate sales for personalized nutrition products will reach $50 billion by 2025, up from approximately $11 billion today.[1]

And investment is coming from all sectors. For example, Nestle's most recent acquisition in August, Persona Nutrition, is a personalized vitamin program delivered right to customers' doors. Koninklijke DSM NV, meanwhile, has been investing and partnering with companies like MixFit Inc., Wellmetrix and Panaceutics Inc. to cover technologies such as personalized nutrient-rich beverages, personalized supplement gel packs and diagnostic platforms for personalized nutrition.

Food companies are not the only ones capitalizing on society's shift toward improved nutritional habits. Medical diagnostic firms, such as Illumina Inc. and Thermo Fisher Scientific Inc., are developing ways to extract and interpret test results. Technology companies like Apple Inc. are betting big on developing wearable technologies and integrated platforms for users to receive interactive feedback data. And food delivery companies, such as Uber Technology Inc.'s Uber Eats and Amazon.com Inc.'s Amazon Fresh, are developing ways to keep up with consumer demand for increased convenience.[2]

So how then do you patent discoveries in such a diverse field, where the problems of ensuring subject-matter eligibility lurk around every corner? Differing approaches to patenting innovations such as the identification of consumer demands, definition of the biomarkers of bioavailability, and differentiating dietary responders from nonresponders will require identification of nonobvious aspects of the inventions, as well as effective claim drafting to present inventions in a manner that conveys subject matter eligibility in both the U.S. and abroad.

Taking advantage of the recognition of a natural phenomenon and claiming it as a method of preparation may be one way to avoid subject matter eligibility issues for personalized nutrition claims.

On March 18, the U.S. Court of Appeals for the Federal Circuit held that certain claims directed to methods that utilize a natural phenomenon were patent eligible because they were more than merely an observation of an occurrence of the natural phenomenon. [3] For certain personalized nutrition claims then, the natural phenomenon could be relied upon to claim methods of using the natural phenomenon rather than claiming the phenomenon itself.

Recent Federal Circuit cases such as Exergen Corp. v. Kaz USA Inc.[4] also provide guidance that may be useful to help avoid subject matter eligibility issues. The claims at issue in Exergen were directed to methods of detecting human body temperature using radiation skin readings over an artery to electronically determine a body temperature approximation. The court held that the claims at issue were directed to substantially more than natural law because of the unconventional methods for detection.

In order to personalize a nutrition program, the methods involved can include one or more of the following: contextualizing data about an individual, contextualizing data from an ingredient or nutritional component, obtaining input from empirical evidence-based lifestyle and nutritional programs; and selecting a dietary program for the user that is based on information comprising genetics, biomarkers, profile, activities, background, clinical data and combinations thereof.

The challenge then will be to ensure identification of an unconventional use, or a method that is novel, independent of the recognition of the specific relationship between the ingested material and user's data. It is important to note that as in Exergen, even if the technology is conventional in other contexts, the fact that particular uses may have been known in the art would not alone be sufficient to make it conventional or routine and, thus, unpatentable.

While Federal Circuit decisions in personalized medicine cases such as Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Corp.[5] and Classen Immunotherapies Inc. v. Biogen IDEC[6] have been instructive in the traditional medical treatment field, they are likely less informative for personalized nutrition. Classen involved conventional immunizations, administered according to a new schedule. Vanda involved a conventional schizophrenia treatment, administered according to new criteria.

In both of these cases, the claims comprised a diagnostic step followed by an administration step. But what happens if the administration step is eating? In this case, it is vital to ensure that personalized nutrition claims practically apply natural relationships or include nonroutine or unconventional steps to be considered patentable under Title 35 of U.S. Code Section 101. The drafter will also need to ensure that one actor is responsible for the claimed method or run the risk of running into the barrier of divided infringement.

Proving nonobviousness by substantial evidence or an expectation of success can also be difficult in personalized nutrition. For pharmaceutical therapeutics, a lack of evidence of efficacy in a particular indication or having no reasonable expectation of success can carry the day for overcoming an obviousness assertion.

But what if the direction is to consume particular foods or vitamins/minerals? No doubt many of us have been told to eat a banana for a muscle twitch because it will increase your dietary magnesium and potassium. This is because magnesium and potassium are known to play important roles in muscle formation and regulation of contraction. The multitude of these common medicinal remedies increase the universe of prior art and diminish the ability to assert a lack of reasonable expectation of success.

However, even in view of a prima facie showing of obviousness, as long as a nexus between the claimed invention and the nonobviousness evidence exists, and where the evidence presented is reasonably commensurate in scope with the claims, objective indicia such as praise, copying by competitors, and commercial success should be taken into account in determining obviousness of a claimed invention.

Patenting and enforcing personalized nutrition inventions will likely be more straightforward outside the U.S. In Europe, for example, use of the same compound in the treatment of a particular group may constitute a new therapeutic application so long as it is carried out in subjects that are distinguished from previous subjects based on physiological or pathological status.

Distinguishing these patients can be done on the basis of generic markers, such as age, weight and gender, but also highly specific biomarkers such as mutational analysis and protein expression of cell surface molecules, similarly to the U.S. Moreover, a combination of diagnostic and therapeutic steps in Europe actually provide new options for patenting, rather than concerns for divided infringement.

In fact, drafting patent applications using a European style — meaning incorporating comparative studies using prior art compounds for example, and having literal support for each embodiment of a multistep method, so as to avoid choosing from multiple lists to show support — is quite common for typical pharmaceutical inventions and could be useful for personalized nutrition.

However, an eye toward claiming the inventions in the U.S. will need to be maintained to ensure compliance with subject matter eligibility standards.

The sheer number of technologies that are implicated in personalized nutrition represent a multitude of different challenges for protection. Effective claim drafting strategies and use of objective indicia of nonobviousness are just two examples of how to protect these innovations where science and technology can dictate what foods are right for us.

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[1] https://www.cnbc.com/2019/10/17/nestle-pivots-to-gain-a-foothold-in-the-personal-nutrition-market.html.

[2] https://www.cnbc.com/2020/01/19/personalized-nutrition-could-be-the-next-plant-based-meat-worth-64-billion-by-2040-says-ubs.html.

[3] Illumina, Inc. v. Ariosa Diagnostics, Inc. (Fed. Cir. 2020).

[4] 2016-2315, 2016-2341 (Fed. Cir. 2018).

[5] 887 F.3d 1117 (Fed. Circ. 2018).

[6] 659 F.3d 1057 (Fed. Cir. 2011).