

Nutraceutical Patent Insights As Market Heats Up

By **Deborah Sterling and Kelsey Pitts** (December 10, 2024)

Nutraceuticals are food products or derivatives that both supplement the diet and support healthy functioning of the body. Probiotic yogurts, garlic capsules and echinacea, for example, all fall under the nutraceutical umbrella.

While nutraceuticals are frequently used to help with issues like arthritis and aid in areas such as digestion, sleep or blood pressure, they do not require U.S. Food and Drug Administration approval to be marketed and sold. This lack of stringent regulatory hurdles, combined with nutraceuticals' relative safety and bioavailability, make them a particularly attractive option for companies producing health and wellness products.

As companies expand into the growing nutraceutical market, however, it is important for them to understand how to secure patents on their innovations effectively.

This article discusses trends in both nutraceutical claim language and common patentability challenges to help stakeholders navigate the nutraceutical patent landscape and protect their innovations.

An Appetite for Nutraceutical Patents

The global nutraceutical market is valued at around \$400 billion to \$700 billion and is expected to grow at an 8% to 10% compound annual growth rate from now until around 2030.[1]

Many factors contribute to this expected growth, including the growing prevalence of lifestyle-related disorders, rising consumer focus on preventative healthcare and health-promoting diets, the increasing cost of so-called traditional healthcare, and a growing geriatric population.

In light of this robust market, it is not surprising that new nutraceutical formulations continue to increase in number. To secure the maximum value of these formulations and prevent others from copying them, stakeholders should obtain a nutraceutical patent.

Nutraceutical patents may cover a newly discovered or synthesized ingredient with proven health benefits, a unique extraction or synthesis process, a distinct formulation of ingredients, or a specific composition that enhances bioavailability or efficacy, for example.

As with any patent, a nutraceutical patent must comply with the U.S. Patent and Trademark Office's requirements for patentability, including being novel and nonobvious, having written description and enablement support, and claiming patentable subject matter.

While these requirements are universal, certain technology areas may present unique challenges to meeting them.

We analyzed nearly 80 U.S. nutraceutical patents and patent applications from 2005-2024



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to identify trends in both claim language and structure, and common patentability rejections from the USPTO. Our findings can help inform nutraceutical patenting strategy and provide guidance for prosecuting such patents.

How to Claim a Nutraceutical

Nutraceuticals are most commonly claimed according to the three following claim types: (1) the composition claim; (2) the method claim; or (3) the process of manufacturing claim.

Composition Claim

The composition claim is a popular claim type in nutraceutical applications, and it claims the nutraceutical product as a composition of matter. For example: "A nutraceutical [or nutritional or pharmaceutical] composition [for X], comprising [ingredients]."

X may refer to a variety of activities, such as "decreasing body weight" (U.S. Patent No. 7,410,660); "promoting sleep and/or alleviating pain" (U.S. Patent No. 9,375,463); or "preventing, mitigating, or treating a [liver] disease or condition" (U.S. Patent No. 10,842,805). Although, some nutraceutical applications omit the "for X" clause or include it in a narrowing dependent claim.

The nutraceutical may also be referred to, for example, as "[a] beverage consisting essentially of [ingredients]" (U.S. Patent No. 8,142,823), "[a] dietary supplement comprising [ingredients]" (U.S. Patent No. 9,308,189), or "a chewing gum consisting of [ingredients]" (U.S. Patent No. 10,441,535).

Method Claim

The second type of claim is the method claim, reciting a method of using a nutraceutical composition for a specific purpose. A typical method claim recites: "A method of/for [Y], comprising administering [to a subject in need thereof] [an effective amount of] a composition comprising [ingredients]."

Here, Y can also refer to a variety of actions, such as "temporarily reducing the desire to smoke" (U.S. Patent No. 8,241,680); "ameliorating one or more symptoms of breast microcalcification" (U.S. Patent No. 9,610,258); "promoting the gut health of an infant mammal subject" (U.S. Patent No. 11,524,022); or "reducing cancer stem cell growth ... [in] a cancer patient" (U.S. Patent No. 12,035,739).

Some method claims also define what an "effective amount" is via a clause such as "which is sufficient to alleviate said menopause" (U.S. Patent No. 7,381,432) or "wherein the effective amount [increases a feeling of fullness in the subject and decreases absorption of nutrients by the subject so that body weight is decreased]" (the '660 patent).

Process of Manufacturing Claim

The third type of claim is the process of manufacturing claim, the least popular claim type for nutraceutical patent applications. This claim type claims a process or method of manufacturing or producing the nutraceutical product.

A typical example is: "A method[/process] for preparing[/producing] a [nutraceutical/nutritional/pharmaceutical] composition, comprising [Z]." Z lists the steps for producing the nutraceutical, such as: "adding [ingredients] to a pharmaceutical,

nutraceutical, dietetic, or nutritionally acceptable vehicle" (the '660 patent).

These claim types are well known within established patent practice, indicating that nutraceutical makers do not need to reinvent the wheel when it comes to claiming nutraceuticals. Pharmaceuticals, for example, typically are claimed using the same claim types.

Challenges and Strategies for Nutraceutical Patents

While nutraceutical patent applications generally align with established claiming practice, they present some unique challenges to patentability. These challenges are explored below.

Patent-Ineligible Subject Matter

First, because nutraceuticals often are — or are derived from — natural products, their claims are commonly rejected as directed to patent-ineligible subject matter under Title 35 of the U.S. Code, Section 101.

Section 101, as interpreted by the U.S. Supreme Court in its 1980 decision in *Diamond v. Chakrabarty*, prohibits the patenting of "natural phenomena."

Accordingly, nutraceutical rejections under Section 101 typically occur when the claimed ingredients are extracts or naturally occurring products that: have not been otherwise modified, and do not produce different or unexpected characteristics (compared to the natural product) when combined with other ingredients.

For example, claim 24 of US20060222682A1, an application from Zija International Inc., was rejected in 2013 under Section 101, where the claim recited a composition that was "a mixture of: a portion of the leaves from a Moringa plant species; a portion of the seeds of the Moringa plant species; and a portion of the fruit from the Moringa plant species."

Because the claimed composition was nothing more than extracts from the Moringa plant in an unmodified form, the claim was rejected as being directed to patent-ineligible subject matter.

To avoid a patent-ineligible subject matter rejection under Section 101, nutraceutical applicants should be sure to modify any naturally occurring nutraceutical components.

Such modifications should create a meaningful difference from the component's natural counterpart, either in structure or in function, and the nutraceutical patent claims should emphasize these differences to avoid a "natural phenomena" rejection.

Utility Requirement

Second, nutraceutical patents often fall afoul of the utility requirement under Section 101.[2] The utility requirement holds that, to be patentable, an invention must be "useful," or have utility.

Lack of utility typically is found when a nutraceutical patent claims a composition or method that does "Q," but there is no substantiating evidence that the composition or method, in fact, does "Q."

For example, in *Petito v. Puritan's Pride*, a patent directed to "[a] nutritional composition for

the treatment of connective tissue in mammals" was held invalid for lack of utility and written description.[3] The U.S. District Court for the Southern District of New York noted in its 2014 opinion that "[w]hen utility as a drug, medicant, and the like in human therapy is alleged, it is proper for the examiner to ask for substantiating evidence."

Such evidence mostly provides experimental results, whether from human, animal or in vitro tests; however, in rare cases, substantiating evidence can be accomplished by analytical reasoning.

In *Petito*, the patent was ultimately held invalid as lacking utility because it provided no experimental results or educated reasoning at all, and instead recited merely a conclusory statement that the claimed ingredients would "synergistically act as a chondroprotective agent."

To avoid a lack of utility rejection, nutraceutical patent applicants should ensure that they have substantiating evidence that the nutraceutical does what is claimed.

The most reliable evidence comes in the form of test results or other experimental data. However, if experiments would be too costly or time-consuming, applicants may also provide reasoned statements explaining why the nutraceutical composition or method is expected to be useful for the claimed purpose.

Conclusion

In summary, nutraceuticals are a unique class of products and comprise a vibrant market at the intersection of nutrition, health and medicine.

The nutraceutical market is expected to continue to grow in response to increasing demand from health-conscious consumers, and nutraceutical patent application filings should continue to increase proportionally.

The insights discussed in the above analysis can help guide the prosecution and legal strategy for nutraceutical patents, an important asset for nutraceutical companies.

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[1] See <https://www.grandviewresearch.com/industry-analysis/nutraceuticals-market>; <https://www.fortunebusinessinsights.com/nutraceuticals-market-102530>; <https://www.arizton.com/market-reports/nutraceuticals-market>; <https://finance.yahoo.com/news/nutraceutical-market-expected-reach-revenue-145000592.html>

[2] Some courts attribute the utility requirement to both 35 U.S.C. §101 and 35 U.S.C. §112 and hold nutraceutical patents invalid under both sections. See, e.g., *Petito v. Puritan's Pride*, 1:13-cv-08040-PAE (S.D.N.Y. 2014).

[3] *Petito v. Puritan's Pride*, 1:13-cv-08040-PAE (S.D.N.Y. 2014).