



Protecting Intellectual Property

Intellectual property can be a company's most important asset.

By Robert Nick

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The importance of protecting intellectual property and patenting nutraceutical products parallels the pharmaceutical industry scenario where medical progress is very dependent on pharmaceutical patents. Strong patent protection provides economic incentives for innovation and many products would not have been introduced if adequate patent protection had not been available.

What is Intellectual Property?

Intellectual property refers to things created by the mind, such as inventions, identifying symbols and creative expressions. Patents, trademarks and copyrights are vehicles that are used to protect the rights to intellectual property. Patents specifically provide protection for inventions.

A patent is essentially an agreement between the government and an inventor where the government gives the inventor certain rights to his invention for a specified period of time and in return, the inventor gives the government a disclosure of the invention. The right conferred by a U.S. patent is the right to exclude others from making, using or selling the invention throughout the U.S. or importing the invention into the U.S. for a specified period of time. For most inventions, this time period is 20 years from the date of filing a patent application.

The patent system in the U.S. goes all the way back to 1790 when, for the first time in history, the intrinsic right of an inventor to profit from his invention was recognized by law. As stated in Article 1, section 8 of the U.S. Constitution, "Congress shall have the power...to promote the progress of science and useful arts by securing for limited

times to authors and inventors the exclusive right to their respective writings and discoveries."

Why are Nutraceutical Patents Important?

A patent for a nutraceutical product has several beneficial attributes: it distinguishes one product from another and it rewards the investment of time, money and effort associated with research. In addition, it stimulates further research as competitors invent alternatives to patented inventions, and it encourages innovation and investment in patented inventions by permitting companies to recover their research and development costs during the period of exclusive rights. Because pharmaceuticals and nutraceuticals can often be copied, at a small fraction of the innovator's research and development costs, companies could not attract the investment needed to conduct the high cost of drug development research, without the assurance of strong patent protection.

The limited term of a patent also furthers the public interest by encouraging quick commercialization of inventions, thereby making them available to the public sooner rather than later. Patents also allow for more latitude in the exchange of information between research groups, help to avoid duplicate research, and, most importantly, increase the general pool of public knowledge.

What are the Benefits of Patenting an Invention?

Patents can provide improved credibility for technology and protection from theft. A patented formula for treating heart disease, for example, cannot be copied by a company marketing their products directly to consumers. In addition, patent protection is a good vehicle for raising capital, starting a new company or licensing inventions. Patents are tangible assets that can be sold or licensed. A license may be negotiated for exclusive or non-exclusive use and may include upfront payments, annual licensing fees, milestone payments and/or royalties.

The value of an invention should not

be underestimated. Patented nutraceutical and pharmaceutical products, formulations or processes can have considerable value. Pravachol and Plavix, for example, were two of the biggest drug products in 2003, with sales of each exceeding \$2 billion.

One of the most important assets that a company can have is its patent portfolio and as *Fortune* magazine once reported —“The fastest way to financial freedom is a successful invention.”

Can All Inventions be Patented?

An invention may be patented if it is new, useful and non-obvious. In order for the invention to be considered new, the subject matter of the invention is not or cannot be inferred to be part of what is already known. New or novel in this context means “new to the public,” and something that has previously been used or known but has not been made available to the public (for instance, if it has been kept a secret) is not a bar to patentability.

The non-obvious requirement prevents someone from taking advantage of the patent system and obtaining protection for something that is a mere extension or trivial variation of what is known. Generally, the test for non-obviousness is based on what a reasonable person skilled in the field to which the invention pertains, at the time the invention was made, would consider to be non-obvious.

Patentable inventions include compositions of matter, processes, machines and articles of manufacture. Certain types of distinct and new varieties of plants and the unique and ornamental design of an invention can also be patented.

With regard to patenting nutraceutical and pharmaceutical products or processes, process patents may be difficult to enforce because the burden of proof to show that a patent has been infringed is the responsibility of the patent owner. As such, the patent owner must prove that the manufacturing process covered by the patent was used to manufacture the particular chemical or formulation. This can be difficult to show where there are many possible process variants. Ultimately, the value of an invention depends on successful commercializa-

tion and how well a patent protects the final product.

Summary

A company’s intellectual property portfolio is one of its most important assets. For

the nutraceutical industry, protecting an innovative formulation, process or product by securing adequate patent protection distinguishes one product from another and provides economic incentives to promote medical progress. **NW**