

The possibilities

FOR PATENTING SUPPLEMENT FORMULATIONS

By **Lindsay Moore, PhD**

Can a company protect its hero-product formulations under the law, make it worth investing in research and development, and prevent competitors from copying them? Contrary to the prevailing wisdom within the supplement industry, the answer is ‘yes’ – if a formulation embodies some discovery or new proprietary knowledge.

Intellectual property, and in particular a *patent*, is critical to protecting product formulations. Patents are the ‘holy grail’ of such formulations, and if a company owns a strong patent it has a *limited monopoly* in the marketplace that allows it to prevent competitors from copying or otherwise trading on its recipe or formulation for the term of that patent.

Consequently, patent-protected formulations allow a company valuable ‘lead time’ in the marketplace during which to recoup R&D investment, provide a powerful competitive advantage, and allow greater profitability through premium pricing for its protected product(s) that can not be obtained elsewhere. For this reason, some dietary-supplement companies are taking a page from the pharmaceutical strategy playbook, forsaking public-domain recipes from herbal manuals that cannot be protected, and starting to develop patent-protected product formulations.

The test of what is patentable and what can freely be copied by competitors, is largely tied up with whether the formula-

tion is ‘obvious,’ or, to use a strange legal term, ‘nonobvious.’

To be ‘obvious’ means that those who are learned in herbal folklore would understand – based upon the common knowledge of the herbal canon – why the various ingredients were put together. Thus, if chamomile and peppermint were combined into a recipe designed to settle upset stomachs, the rationale for the formulation would be obvious to anyone who had read an herbal. Such a recipe could be used or copied legally by any company in commerce, but it couldn’t be patented because the knowledge it is based upon is ‘folklore,’ which is already, and by definition, in the public domain or commons for all to use.

However, if it isn’t obvious, for example, that herb ‘A’ plus another herb ‘B’ of a certain species delivers enhanced efficacy in a way previously unrealized (or because either herb was harvested at a critical moment in its life-cycle), it may be considered to be nonobvious, and it could then be patented! If the combination isn’t *obviously* part of the herbal canon or folklore, then maybe, assuming everything under the sun hasn’t already been discovered, the formulator has discovered a new causal relationship. Because that is just what patents exist to protect, the formulator may be able obtain patent protection and enjoy a legal monopoly in the marketplace.

Consider the pharmaceutical model that, as a case in point, takes the basic elements of carbon, hydrogen, fluorine, nitrogen, and oxygen and forms them into a new combination (a ‘molecule’) known, in this case, as fluoxetine hydrochloride, or more popularly as PROZAC, to treat depression. That molecule is what the pharmaceutical company patents. With dietary supplements, the as yet largely unexploited but patentable model is the same

– an herbalist takes individual herbs in the canon, and imaginatively combines them, not into a molecule but into a new product formulation that delivers a certain result, and that is thereby patentable.

To date, the supplements industry has principally preferred to borrow its recipes from the common knowledge base of folklore, thus producing commodity products that are easily copied by others, and so denying itself the highly advantageous monopoly of patent protection.

As a result, just saying that ‘an herbal manual says so’ or concocting an obvious collage of ingredients won’t get a patent. However, assuming creativity and the novel and meaningful orchestration of herbs to create

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new causal relations, identifying the mechanism behind the new formulation, and demonstrating efficacy, patent protection *is* available even for herbal formulations.

Thus, when intellectual property is part of a corporate strategy, the law can protect valuable business property such as product formulations, while also providing competitive advantages in the form of product formulation patents that can be leveraged by clever strategists to serve the highest of corporate purposes, or be used as currency for strategic alliances, mergers and acquisitions.

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