Perchance to Dream ... Or Not

How pharmaceutical companies market sleep through branding.

Back in the 1960s, counting sheep gave way to a lilting commercial ditty as a means for solving the age-old problem of falling asleep: "Take Sominex tonight and sleep, safe and restful sleep, sleep, sleep." If you took two Sominex, you were guaranteed "100% safe sleep."

Popping pills of all sorts would become a hallmark of a baby boomer generation in the making. The lyrics of Jefferson Airplane's song "White Rabbit" fueled the acid rock imagination:

One pill makes you larger
And one pill makes you small
And the ones that mother gives you
Don't do anything at all

Our American love affair with pharmaceutical solutions now translates into a mega-industry in the world of sleep. In 2009, consumers spent about $1.9 billion just on sleeping pills with the soothing names of Ambien and Lunesta. These trademarks are masterful in their immediate ability to convey the impression of a nighttime wonderland of drug-induced sleep.

> The sleep-inducing claims for dietary supplements are every bit as nebulous as the realm of sleep and dreams.

The marketing of both over-the-counter (OTC) and prescription sleep aids is subject to federal Food and Drug Administration (FDA) regulation, as well as state tort laws and statutes that control deceptive marketing. The early FDA labeling regulations for over-the-counter sleep-aid drugs stem from an administrative rule-making process that began in 1975.

Those early discussions accompanying OTC sleep aid regulations reflect a primitive understanding of the function of sleep. Sleep is treated as a simple linear function: You fall asleep and then wake up. The only important variables are the time it takes to fall asleep and the number of times you wake up. (See Final Monograph, "Nighttime Sleep Aid Drug Products for the Over-the-Counter Human Use." 54 F.R. 6814-01 [February 14, 1989].)

In reality, burgeoning scientific research is slowly, but surely unraveling the mysterious wavelike functions that constitute the brain action of the sleeping and dreaming mind. Although sleeping and dreaming are inseparable activities, FDA regulations instead focus on what appears to be a form of "dreamless" sleep. The effect of sleeping pills on dream function is not mentioned as a potential health hazard.

Early forms of sleeping pills relied on antihistamine ingredients to induce a drowsy state. Newer formulations are far more potent. Ambien and Lunesta are both described in medical literature as "sedative-hypnotics." The sensational stories generated by their potentially deleterious side effects spawned a new set of FDA labeling requirements in 2007. They include a warning that those using these "sedative-hypnotic" drugs might engage in behaviors including driving, making phone calls, and preparing and eating food—all while asleep!

News of Tiger Woods' affairs also added a new term to our popular vocabulary: "Ambien Sex." A loss of inhibitions, a pleasant feeling of "drugginess" and memory loss can all occur while under the influence of Ambien. An equal percentage of Ambien users, however, identified "diarrhea" as its main side effect.

A largely unregulated category of sleeping pills includes dietary supplements. Naturally occurring soporifics include tryptophan, valerian and melatonin. Brands such as "Nature's Way Silent Night" and "Tranquil Sleep by Natural Factors" abound in this market space. The FDA regulates dietary supplements under a different set of regulations from prescription drugs. A dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market.

The sleep-inducing claims for dietary supplements are every bit as nebulous as the realm of sleep and dreams. Reading the ingredient labels themselves may just be enough to make one's eyes glaze over.

PAUL D. SWANSON is a shareholder and member of Lane Powell's Intellectual Property Practice Group, where his practice is primarily devoted to litigating patent, trademark, copyright, unfair competition, software development and trade secret law disputes. He regularly speaks and authors articles on intellectual property issues, and is a principal contributor to the firm's Patent Practice Professional Liability Reporter blog (www.patentpracticeliability.com). He can be reached at swansonp@lanepowell.com or 206.223.7391.