

Intellectual Property Laws: Protecting Pharmaceutical Products, Processes, and R&D from Competitive Challenges

Understanding the benefits and boundaries of intellectual property is important to all pharmaceutical companies.

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You can't see it or touch it; yet intellectual property (IP) is probably the most valuable group of assets your company owns.

It comes in many forms and can turbocharge or derail a company's expansion. So all companies, big or small, innovator or generic, must ensure that these valuable assets are secured and defended appropriately.

Patent protection

Patents are one way to protect IP. For example, chemicals, pharmaceutical formulations, methods of making chemicals, and methods of treating patients with chemicals or formulations may all be patented.

Patents ensure that only the patent owner (and its licensees) can lawfully make, use, and sell the patented invention for 20 years. If a pharmaceutical company's patent portfolio is cleverly developed, a string of patents can be used to create a sufficiently dense patent minefield of product and treatment-

method patents to completely block or minimize competition long past a single patent's normal 20-year lifespan. Patents also can be used to block competition until a new-generation product has been developed and successfully launched.

Generic and branded protections

Patents can be tools for generic companies as well. If a generics firm has a product that avoids infringing

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on an innovator's patent or improves upon a branded product, that product might be patentable and can be used to keep other generics off the market or generate income (e.g., licensing fees or damages after a litigation if a competitor sells an infringing product).

A branded company may pay to keep a generic product off-market rather than dispute the validity of its own patent in the courts or in the

Patent Office. Although US courts typically hesitate to hold patents invalid and place a heavy burden of proof on patent challengers to prove patent invalidity, they remain the best option for contesting patents and the only venue for generic drug patent litigation. It's not unusual for patents to be issued on previously known or obvious "inventions." Patent litigations typically involve drug products grossing more than \$1 million each day, so innovator and generic pharmaceutical companies are prepared to invest enormous financial resources to defend and attack pharmaceutical patents.

Trade secret protection

Another form of IP, the trade secret, is nonpublic information that gives its owner a competitive advantage. Trade secrets can include a list of customers or suppliers, a manufacturing or purification procedure, a formulation, a business plan for new product development, corporate merger-acquisition plans, or an invention. Trade secrets last as long as they remain secret.

Today, protecting the confidentiality of trade secrets is more difficult than ever, but no less

important. Although securing trade secrets involves employee education and employee nondisclosure agreements, the last recourse is in the courts, where even an injunction and damages may be insufficient to put the "trade secret genie" back into the bottle.

A trademark (e.g., a product name, brand name, or distinctive logo) and a trade dress (a distinctive

packaging design) also constitute IP and indicate a single source of products of a known quality. Rights to such IP can last forever, as long as they are continuously used and their use is policed. Copyrighted materials such as advertising or promotional materials, various types of original text, and print work are also IP and can be protected for about 100 years.

Ultimately, all IP is valuable and can be used as a business sword or shield.

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