

## Covering Pharma and Patents

Tricky Things You Should Know

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- Patents are critical to the pharmaceutical industry. Drug makers obtain patents for the actual chemical substance, formulations, dosages, manufacturing processes, and method of use, which refers to the disease to be treated.
- There are many other patents that can be obtained for a medicine, but over the past several years, the pharmaceutical industry has increasingly been criticized for using patents to the game system.

- Why would a company do this? A patent lasts 20 years, although time spent developing a drug after an initial patent has been filed can eat into this timeframe. Since a patent precludes other companies from selling a version of a drug, companies want to extend patent protection.
- This is a valid business strategy, but sometimes, the pharmaceutical industry is accused of going too far. And there are several approaches that have caused controversy.

- One is called product hopping, which describes only modest reformulations that are made to a medicine but without offering any substantive therapeutic advantages.
- In a controversial case a few years ago, a company sought to switch Alzheimer's patients to a newer, more expensive version of an older pill before generic competition emerged. The drug maker hoped to convince doctors and patients that its new drug was more convenient and, therefore, boost prescriptions before generic versions of the older pill became available. Why? The patent on the older pill expired a few months out, while the patent on the new medicine did not expire until 2025.

- Another tactic is called patent thickets. This refers to the use of numerous patents that cover minute differences or processes associated with a medicine, but critics say this distorts patent law because erstwhile competitors are precluded for years from selling their own versions.

- A widely known example is Humira, a medicine sold by a company called AbbVie for treating rheumatoid arthritis and other ailments. The company has filed dozens of patents, some of which do not expire until 2023, even though the so-called core patent – arguably the most important patent – expired in 2016.
- This has made it impossible for rivals to compete, which angers consumer advocates who say the U.S. health care system is the loser. Humira generated about \$13 billion in U.S. sales last year, but the patent thicket delays lower-cost alternatives from becoming available.

- Still another maneuver is called pay-to-delay, which describes a sort of grand bargain between a brand-name drug maker and one or more generic companies. The deals emerge from patent litigation – a brand-name company claims that a generic company, which wants to sell a cheaper version of a drug, has infringed on its patent. So a lawsuit is filed that eats up time and money.
- How do the deals work? A brand-name drug maker settles a patent lawsuit by paying cash or transferring something else of value to a generic rival, which agrees to delay launching its copycat medicine until a specific date in the future. This gives the brand-name drug maker more time to sell its medicine without lower-cost competition.

- The pharmaceutical industry has contended the deals are not only legal, but actually allow lower-cost drugs to reach consumers faster than if patent litigation drags on for years. But the FTC, which has gone to court several times to protest such agreements, has claimed the agreements cost U.S. consumers an estimated \$3.5 billion annually.

- A newer issue emerged a few years ago with the Affordable Care Act, which created a mechanism for companies that hope to sell biosimilar versions of expensive brand-name biologics. A so-called patent dance takes place in which the biosimilar company provides information to the brand-name drug maker in order to establish whether or how patent litigation begins. The process takes time, however, and has delayed the launch of several biosimilars into the U.S. market.

- Finally, there was one clever gambit tried by a drug maker nearly two years ago. The company transferred several patents on a best-selling drug to a Native American tribe and then licensed the sales rights back for a small sum. Why? The drug maker complained that it faced two different kinds of patent litigation with generic companies.

- One was the usual patent litigation with different generic makers. But the other was a newer type of challenge that can be made with the U.S. Patent & Trademark Office. Known as inter partes reviews, these allow generic companies to more easily and more quickly file claims. The company argued the tribe was entitled to sovereign immunity, which meant the patents couldn't be challenged before the PTO and the drug maker could protect its sales a while longer. But the courts ultimately disagreed.