



# Innovations of Trade Secrets in Intellectual Property Rights

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## DESCRIPTION

A trade secret is generally defined as information that is kept under wraps and that gives the bearer of the trade secret a competitive edge or financial benefit. In trade secret lawsuits, damages have frequently been awarded at high levels, and trade secrets can be valued tens or even hundreds of millions of dollars. Misappropriation occurs when a trade secret is obtained by "improper means." However, if the alleged trade secret was independently developed, made known to the public, or was not kept a secret, then those defences may be able to defeat a claim for trade secret misappropriation. State common law and state statutes provide protection for trade secrets.

How to allocate the benefits of innovations is a crucial question in policy and strategy. The formal intellectual property (patents, trademarks, copyrights, and designs) as well as secrecy, complexity, lead time, and supplementary assets are among the appropriability mechanisms that innovators might select. Crucially, these mechanisms do not have to work alone and can be combined.

Studies in economics, finance, and strategy have placed a strong emphasis on patents. A patent gives the owner the temporary right to prevent others from utilizing the invention, but only after disclosing it. The purpose of the disclosure is to tell others so they can protect the invention and contact the owner to obtain a license. Disclosure lays the groundwork for further development, but it also encourages rivals to develop products that build on the invention. The innovation must be beneficial, innovative, and not obvious in order to be eligible for a patent (exceed a minimum inventive step).

Since the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), on which significant portions of the Biosimilars Act are clearly based, the Biologics Price Competition and Innovation Act of 2009

(the "Biosimilars Act") has been the single most significant legislative development for the industry of pharmaceutical products. Section 351 of the Public Health Service Act (PHSA) was amended by Congress to provide a route for Food and Drug Administration (FDA) clearance of biological products that are "biosimilar." Each biosimilar applicant must include a "reference product" in its application that was approved based on a complete application that included testing data and manufacturing information, was owned and submitted by another company, and contained a significant amount of trade secret information that is protected by the law.

Due to the fact that the Biosimilars Act permits biosimilar applicants to reference these previously approved applications, the implementation of the new legislative framework raises serious concerns under the Fifth Amendment of the Constitution, which forbids the taking of private property, including trade secrets, without "just compensation."

The U.S. Supreme Court ruled in 2013 that naturally existing human genes are not a subject matter for patents. This decision appeared to advance the constitutional policy behind intellectual property protection to foster scientific advancement and increase patient access to genetic testing by invalidating patents owned by Myriad Genetics relating to genes that cause breast cancer.

Ironically, genetic testing businesses continue to contend that information about the importance of genetic variants falls under the protection of trade secrets. This paper examines potential strategies for claiming trade secret protections for knowledge of the importance of genetic variants. In particular, we take into account five strategies: the introduction of extra march-in rights as per the Food and Drug Administration (FDA) or CMS regulations; voluntary responses from the scientific community; new Bayh-Dole Act-style march-in rights, patent law-style compulsory licensing, a public policy exception to trade secret protection, and extra march-in rights.

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