While Not Right for Every Invention, Trade Secret Protection Has Its Appeal

Patenting has conventionally been the preferred way to protect intellectual property. There are good reasons for this: for example, it provides the most robust protection, enabling a patentee to sue in Federal court and obtain damages, an injunction, or both. And the establishment of the Court of Appeals for the Federal Circuit has stabilized U.S. patent law for a generation and eliminated the uncertainty caused by differing standards and application of the law in the several regional Circuit Courts of Appeal.

Recently, however, Federal Circuit and Supreme Court rulings, proposed and enacted changes to the patent laws, and a number of lower court rulings have upset the calculus favoring patents as the preferred intellectual property guardian. Injunctions are no longer necessarily "automatic," for example, and U.S. patents are now published 18 months after their earliest priority dates (typically many years prior to patent grant). Also, there have been attacks on patent-eligibility for certain subject matter, such as gene sequences, business methods, and diagnostic methods. These developments make it imperative that other forms of protection, specifically trade secrets, be considered before important technology is disclosed to the public in a manner that puts the intellectual property embodied therein at risk.

Trade secret exists as a common law means of protection, but 46 states have adopted some form of the Uniform Trade Secrets Act (the "Act"),1 which defines a trade secret as something that

> (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.2

This definition establishes the hallmark of using this form of protection: the ability for the intellectual property embodied in the technology to be kept secret. This is not a characteristic of mechanical or electrical inventions as these inventions can often be readily reverse-engineered. However, there are many inventions that can be protected by trade secret, almost all of which are in some way sufficiently complex that they cannot be reverse-engineered.

Trade secret misappropriation is defined in the Act as

> (i) acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or (ii) disclosure or use of a trade secret of another without express or implied consent by a person who (A) used improper means to acquire knowledge of the trade secret; or (B) at the time of disclosure or use knew or had reason to know that his knowledge of the trade secret was (I) derived from or through a person who has utilized improper means to acquire it; (II) acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use; or (III) derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use; or (C) before a material change of his position, knew or had reason to know that it was a trade secret ad that knowledge of it had been acquired by accident or mistake.3

Remedies for trade secret misappropriation include damages, injunctions, attorney's fees for "willful and malicious" misappropriation or bad faith, and protective orders to prevent disclosure of the secret.4

While these track the remedies available for patent infringement, trade secret protection suffers from being limited to state-by-state remedies and adjudication in state court (absent diversity jurisdiction). The burdens on the trade secret holder are also more onerous, since the requirement for "efforts that are reasonable under the circumstances to maintain its secrecy" raise issues of limiting disclosure to employees, heightened awareness of such disclosure and steps to prevent disclosure by former employees, and that companies establish internal procedures to protect trade secrets, particularly at companies actively engaged in research. These procedures can include formalized invention memoranda and policies protecting, *inter alia,* laboratory notebooks (locking them in drawers overnight, or prohibiting employees from taking them from the premises, etc.). The Act also imposes a three-year statute of limitations trade secret misappropriation.5

Illustrative of the power of trade secrets to protect important technology is the menopausal drug Premarin®, which, unlike almost all other pharmaceuticals, is not patented. Indeed, this drug has been on the market since 1942, unpatented, and even today is without any generic competition.6 The situation is the result, in part, of the nature of the drug: while its "key ingredients" are conjugated estrogens extracted from pregnant mares' urine,7 the "key ingredients" comprise a complex mixture of chemical compounds, any, all, or some combination of which may result in the drug's efficacy. There is no incentive for the drug's producer, Wyeth, to further determine or assess the exact nature of the drug's composition, since it holds as a trade secret the unique extraction process for making the drug. Generic drug companies are equally disincentived, since such a determination would amount to a new drug discovery program without any of the regulatory advantages that are available for other drugs (*i.e.*, there are no safety and efficacy results from the innovator for anything other than the mixture).

The scope of trade secret protection for Premarin® was tested in 2003, when Wyeth sued Natural Biologics for trade secret misappropriation regarding the process for producing the drug. Wyeth prevailed, winning a permanent injunction that barred Natural Biologics from producing a generic Premarin®.8 The Eighth Circuit affirmed both the judgment and the injunction, illustrating how the Act can be applied to protect this type of technology.9 The district court found, and the appellate court affirmed, that Wyeth took "appropriate steps to maintain the secrecy" of the extraction process, despite evidence that "non-Wyeth employees toured the [facility] without having signed confidentiality agreements; there were no posted signs inside the facility indicating that the [process] information was confidential; unmarked [process] documents were left on the manufacturing floor and unsecured in Wyeth's [facility]; not all Wyeth employees or vendors involved in the [process] signed confidentiality agreements; Wyeth identified chemicals used in the extraction process in two newsletters; unmarked documents were sent to third parties without any confidentiality designations affixed to them; and Wyeth allegedly failed to follow its own security policies."10 "Absolute secrecy is not required," the appellate court said. Rather, only reasonable efforts to maintain the trade secret need be taken.11 Using this same approach, the court held that Wyeth had established conduct by the defendant indicating misappropriation, including contact with former Wyeth employees, the similarity of the defendant's process and Wyeth's process, and "the absence of a credible record" of how the defendant independently developed its process.12 The court also cited with approval the notion that a trade secret can be "so unique that the emergence of a similar, slightly altered product gives rise to an inference of misappropriation."13

The lesson from this case is that for certain technologies trade secret protection may be the best way to protect the technology. This question may become critical for diagnostic methods, particularly genetic diagnostic methods that establish genetic changes that have the propensity to develop a disease. After the *Bilski14*, *Labcorp15*, *Prometheus16* and *AMP v. USPTO17* cases, the ability to protect such inventions by patenting is presently at risk. Yet the nature of genetic diagnostic methods, particularly for multigenic diseases characterized by germline and acquired mutations and epigenetic changes in gene expression levels, may be particularly amenable to trade secret protection. For example, the relationships between the several genes that are likely to be involved in developing diseases like diabetes, cardiovascular disease, and many cancers are expected to be complex. This complexity has seriously slowed development of genetic tests expected to be the product of the Human Genome Project.18 That level of complexity suggests that any genetic test that reliably predicts the likelihood for developing such diseases will be not only complex but almost impossible to reverse-engineer. Under these circumstances, it may be more fruitful to rely on non-disclosure of these relationships, for example by providing oligonucleotide arrays for hybridizing patient samples that are individually encrypted as to the location of the plurality of informative sequences on each array. Since such microarrays can contain tens of thousands of sequences, the informative ones can be "hidden" within the array and only identified by using an encryption code. Such encrypted arrays are unlikely to be easily reverse-engineered and thus are amenable to trade secret protection. Similar avenues for protecting diagnostic methods may be available for biomarkers and other technology relating to providing diagnostic information about complex systems.

Trade secret protection is not for everyone; inventive entities that require or benefit from publication, such as universities, cannot use this form of protection, and inventors whose technology can be reverse-engineered will gain little benefit. But for those companies that can, it is prudent to consider trade secret as a means of protection.

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Endnotes

1. Uniform Trade Secrets Act (1985). Massachusetts, New York, New Jersey and Texas are the exceptions.
2. *Id.* at § 1(4).
3. *Id.* at § 1(2).
4. *Id.* at §§ 2-4.
5. *Id.* at § 6.
6. *Wyeth v. Natural Biologics, Inc.*, 395 F.3d 897, 899 (8th Cir. 2005).
7. *Id.* at 899 n.2.
8. *Wyeth v. Natural Biologics, Inc.*, No. Civ. 98-2469 (NJE/JGL), 2003 WL 22282371 (D. Minn. Oct. 2, 2003).
9. *Wyeth*, 395 F.3d at 902-03.
10. *Id.* at 899-900.
11. *Id.* at 900.
12. *Id.* at 900-01.
13. *Id.* at 900 (citing *Pioneer Hi-Bred Int'l v. Holden Found. Seeds, Inc.,* 35 F.3d 1226, 1239-40 (8th Cir.1994)).
14. *Bilski v. Kappos*, 130 S.Ct. 3218 (2010).
15. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S.Ct. 2921 (2006).
16. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.,* 628 F.3d 1347 (Fed. Cir. 2010).
17. *Ass'n of Molecular Pathology v. U.S. Patent and Trademark Office,* 702 F.Supp.2d 181 (S.D.N.Y. 2010).

18. *See* Wade, Nicholas, "A Decade Later, Genetic Map Yields Few New Cures", The New York Times (June 12, 2010), *available* at http://www.nytimes.com/2010/06/13/health/research/13genome.html?_r=1