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How To Protect Health Care Trade Secrets With Covenants

By **Erik Weibust and Katherine Rigby** (May 25, 2022, 6:56 PM EDT)

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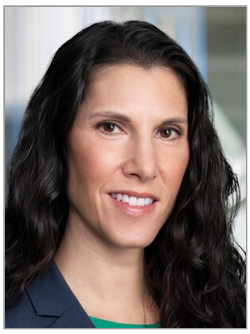

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The health care industry is vast and encompasses a wide array of businesses as diverse as pharmaceutical and biotechnology companies, medical device manufacturers, contract research and manufacturing organizations, hospital systems and physician practices, health insurers, pharmacies, research universities, diagnostic testing laboratories, and many others.

While these businesses may seem to an outsider to have little in common beyond sharing the goal of improving patient outcomes and health care delivery — and even then, their perspectives and methods often vary — one other thing they all undoubtedly share is the need to protect their most sensitive information.

While some health care companies are, of course, subject to the Health Insurance Portability and Accountability Act and other statutes that protect patient records,[1] all health care companies, regardless of the nature of their business, have other types of information that they would like to keep secret: formulations, designs, viability and optimization data, manufacturing processes, research and development programs, profit margins and other financial information, sales forecasts, algorithmic models, customer lists, and so on.

And while some of these may be better off patented, certain information either is not patentable or is more valuable if maintained as a trade secret. Indeed, often the most sensitive information is developed before a company is ready to apply for a patent and should be kept secret at least until it does so.

A recent example of companies electing trade secrecy over patents involves the COVID-19 vaccines; while there was much debate during the pandemic about whether vaccine manufacturers should waive their patent rights in the name of public health, even had they done so the effect thereof would have been substantially limited because their manufacturing processes are typically maintained as trade secrets.

One common measure to protect against the most common threat to a company's trade secrets — insiders, such as employees — is the use and enforcement of noncompetes and other post-employment restrictive covenants.

While noncompetes have been the target of both the federal and state governments for several years, because of the pandemic there has been more attention paid to their use in the health care industry.

Indeed, this year alone, there have already been no fewer than 66 noncompete bills proposed in at least 21 state legislatures across the country, with some 26 of them involving the health care industry.

One law that has already passed this year is in Colorado, which, among many other things, expressly permits physicians to disclose their continuing practice of medicine and new professional contact information to any patient with a rare disorder, without being subject to damages resulting from that

disclosure or from the physician's subsequent treatment of any such patient.[2]

Patents Versus Trade Secrets

Whether to obtain a patent or maintain information as a trade secret is a very fact-intensive inquiry that should be evaluated carefully.

Patents offer strong legal protections and certainty, as they give the patent holder approximately 20 years of market exclusivity, i.e., the right to exclude others from practicing the patented inventions.

To obtain a patent, however, an applicant must provide "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."[3]

Contrast this level of public disclosure required to obtain a patent with a trade secret, which explicitly derives its economic value from "not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information."[4]

In this regard, patents and trade secrets are polar opposites, though their intended effect — protecting intellectual property — is the same.

Often, by the time an invention is commercialized, fewer than 20 years remain on the inventor's window of exclusivity.

It nevertheless makes sense to patent many inventions because they can be reverse engineered or independently developed by a competitor, the inventor wants certainty surrounding market exclusivity, there is limited capacity to protect the trade secret in the manner required by law, or investors demand it, among a bevy of other considerations that may come into play. Yet some inventions are better maintained as trade secrets.

For example, a manufacturing process often cannot easily be ascertained by third parties, and its expected useful life may exceed 20 years.

An example of this in the pharmaceutical context is the hormone replacement therapy drug Premarin. Wyeth Pharmaceuticals LLC developed this drug in the 1940s and obtained several patents.

Long after those patents have expired, however, Wyeth and its successor remains the exclusive manufacturer or Premarin; there is no generic version available. This is not for lack of trying, but rather because no generic drugmakers have been able to replicate the extraction process, which involves extracting conjugated estrogens from pregnant mare urine, of all things, and Wyeth has maintained that process as a trade secret.[5]

Had Wyeth patented this process, its monopoly over Premarin may well have ended decades ago, and it necessarily would have provided a road map for others to follow.

A more recent example involves the COVID-19 vaccines. Many aspects of the vaccines were patented, but the manufacturing methods and techniques often were not, and were instead maintained as trade secrets.

There was considerable debate during the pandemic about whether private companies should waive their patent rights in the name of public health. India and South Africa proposed to suspend portions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, an international treaty that provides minimum standards for the protection of intellectual property.[6]

The proposal would effectively have required vaccine makers in more developed countries like the U.S. to waive their patent rights so that the vaccines could be manufactured by generic drugmakers, purportedly for broader distribution in the developing world.[7] But the effect of such a waiver would have been severely limited because the vaccine manufacturing processes are largely maintained as trade secrets.

As James Pooley, a noted expert in this field, has explained:

> You see, published patents are available for anyone to read and learn from, and developing countries still have the option to compel licenses from patent owners if needed to address serious domestic needs, including pandemics. But patents are only a part of most stories of technology transfer, because in order to actually build the factory and produce the goods, you need to know more than what's in the patents.
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> For some traditional pharmaceuticals, this lack of know-how may not be a showstopper. The patent claims may describe a particular small molecule that provides a certain therapeutic effect. If you already know how to make pills, then manufacturing it can sometimes be relatively straightforward. Sometimes, but not always.
>
> Moreover, biopharma generally, and mRNA vaccine technology in particular, are quite different from traditional drugs. Developing a process to reliably produce these medications at scale is astonishingly difficult and depends on years of experimentation involving cell growth times, temperatures, and other variables. That body of knowledge represents the trade secrets of the developers. It is enormously valuable, and not just for making COVID-19 vaccines. Creating other therapeutics based on the mRNA platform would be much easier and quicker with the benefit of knowing what tends to work and what doesn't.[8]

The purpose of this example is not to stir debate about the merits of the proposed suspension of the TRIPS Agreement or other similar proposals. Rather, it is intended to highlight that patenting manufacturing processes is not always in the manufacturer's best interest. This is particularly true with respect to emerging technologies, such as mRNA, that are not easily reverse engineered or independently developed.

What Are Reasonable Measures to Maintain Secrecy?

To be entitled to protection under the federal Defend Trade Secrets Act and the Uniform Trade Secrets Act — which has been adopted in one form or another by every state other than New York — information must not only derive independent economic value from not being generally known, but its owner must take reasonable measures to maintain its secrecy.[9]

The adequacy of such measures will depend to some degree on the nature of the information, the industry, the resources of the company, and the like, and is naturally a very fact-intensive inquiry.

On the most basic level, such measures may include need-to-know access to sensitive information, password protections, multifactor authentication, confidentiality/nondisclosure agreements, computer use and data security policies and procedures, robust training, and even monitoring.

Most trade secret cases involve allegations of misappropriation by insiders, such as employees, whether with malice or just due to carelessness or a misunderstanding of their obligations.

Thus, another effective measure that is frequently employed to protect trade secrets and confidential information is a requirement that employees execute post-employment restrictive covenants, such as covenants not to compete and covenants not to solicit.

Noncompetes prohibit former employees from working in a competitive role in a defined geographic area for a certain amount of time; nonsolicits prohibit the solicitation and sometimes servicing of customers with whom the former employees worked or about whom the former employees learned confidential information, or from recruiting and often hiring former colleagues.

These covenants are commonly employed in the health care industry with executives, scientists, engineers and others who have access to confidential information and trade secrets, as well as salespeople and account managers who have similar access to sensitive information and serve as the face of the company with respect to customers and could thus harm a company's goodwill by moving to a competitor and taking those customers.

In states that permit noncompetes and nonsolicits — most do — they must protect a legitimate business interest to be enforceable, such as confidential information, trade secrets, and customer goodwill/relationships, and must be reasonable in time, geographic scope, and scope of proscribed activities.

These are very fact-intensive inquiries, and the laws governing noncompetes and nonsolicits vary from state to state and have been the subject of increased attention and scrutiny by the federal and many state governments over the past few years.

Noncompetes and nonsolicits are very commonly used at pharmaceutical, biotech and medical device companies, for example, and there is often litigation when an executive, salesperson, scientist or engineer moves to a competitor.

The same goes for executives and data scientists at hospital systems and health insurers, among many other roles at all kinds of employers in the health care industry. If the departing employee takes trade secrets, there are usually independent claims asserted as well under the DTSA or a state UTSA.

Not All Restrictive Covenants Are Created Equally

Many people know that noncompetes and nonsolicits are generally not enforceable in California, and they may know that the same is true in North Dakota and Oklahoma.

Several states that do enforce restrictive covenants, however, prohibit their use with low-wage workers and other limited classes of employees. These rules and exceptions are applicable regardless of the industry, or the type of company within an industry, and would thus apply broadly in the health care industry.

But what a lot of people do not know is that there is a separate statutory scheme in several states for certain health care workers, typically clinicians, and that many states do not permit the enforcement of noncompetes and/or nonsolicits against those workers regardless of how reasonable the covenant may be, or how similar covenants are treated in other industries — or even in other sectors of the health care industry.

This is often the result of state legislatures making policy determinations about the sanctity of the clinician-patient relationship, and sometimes is a recognition of the fact that many communities have few options for practicing clinicians, and that limiting their mobility could have adverse consequences on patient care.[10] In other states it is simply the result of effective lobbying.

For example, in our home state of Massachusetts, noncompetes are not permissible in

> [a]ny contract or agreement which creates or establishes the terms of a partnership, employment, or any other form of professional relationship with a physician registered to practice medicine ... which includes any restriction of the right of such physician to practice medicine in any geographic area for any period of time after the termination of such partnership, employment or professional relationship.[11]

The same restriction applies in Massachusetts to nurses, psychologists and social workers.[12] At least a dozen other states similarly place statutory restrictions and/or conditions on the use of noncompetes with certain health care workers, typically clinicians.[13] In some states, such as Arizona and Ohio, while there are no industry-specific statutes governing noncompetes, courts have placed heighted scrutiny on them in the health care context.[14]

This issue has been even more at the forefront as a result of the pandemic; this year alone, there have already been no fewer than 66 noncompete bills proposed in at least 21 state legislatures across the country, with some 26 of them involving the health care industry and eight being COVID-19-related.

For example, there are bills currently pending in Connecticut, Louisiana, Minnesota and Missouri that would prohibit the use of noncompetes with many physicians, a bill pending in Florida that would require any physician restrictive covenants to include an option to buy out the restrictive covenant,

and a bill pending in Massachusetts that would prohibit the use of noncompetes with physician assistants.[15]

Just last year, South Dakota amended its general noncompete law to prohibit noncompetes with many health care providers.[16]

On other side of the coin, although Washington, D.C., passed a near total ban on noncompetes in 2020 that is currently scheduled to go into effect on Oct. 1, medical specialists, which include licensed physicians who have completed a residency and earn more than $250,000 in compensation per year, are excluded from the ban and may be subject to noncompetes provided certain technical requirements are met.[17]

Bills are introduced every day in state legislatures across the country, and many never see the light of day, but there is undoubtedly a trend nationally not only toward limiting the effect of noncompetes generally, but of doing so in the health care industry in particular.

Fortunately for employers, the employees typically protected by these statutes and heightened judicial scrutiny are not of the type that would necessarily have access to a company's trade secrets.

Rather, they primarily apply to patient-facing clinicians who are not hired by competitors for access to trade secrets, and there is thus little risk of misappropriation, but rather for their skills and to fill specific patient care needs.

Hospitals and physician practices should nevertheless consider the use of noncompetes and nonsolicits with clinicians, if permitted by law, to protect customer relationships.[18] And health care companies of any ilk would be well advised to do so with executives, scientists, engineers, salespeople and the like, as an additional measure to protect their trade secrets.

While a failure to do so may not result in a trade secret losing its legally protected status, nor will noncompetes and nonsolicits protect against outside threats, they give companies another avenue by which to protect themselves against malicious or careless insiders, the most likely sources of misappropriation.

Conclusion

In sum, companies in all sectors of the health care industry should take reasonable measures to protect their most sensitive information from misappropriation by employees, collaboration partners, vendors and outside threats such as hackers and hostile foreign actors.

Because insiders, such as employees, are the group most likely to misappropriate confidential information and trade secrets, one nonexclusive measure should be the use of post-employment restrictive covenants, such as noncompetes and nonsolicits.

Employers must be cognizant of the rapidly changing state laws governing the enforceability of such covenants, however, including that many states prohibit their use with certain types of health care workers, typically patient-facing clinicians.

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[1] See 42 U.S.C. §1320d, et seq.

[2] Colorado HB22-1317; see also https://www.tradesecretsandemployeemobility.com/2022/05/articles/non-compete-agreements/colorado-continues-its-crackdown-on-restrictive-covenants/.

[3] 35 U.S.C. §112.

[4] 18 U.S.C. § 1839(3)(B); see also Uniform Trade Secrets Act, § 1(4)(i) (1985).

[5] See Orly Lobel, Filing for a Patent Versus Keeping Your Invention a Trade Secret, Harvard Business Review (Nov. 21, 2013), https://hbr.org/2013/11/filing-for-a-patent-versus-keeping-your-invention-a-trade-secret.

[6] TRIPS stands for Trade-Related Aspects of Intellectual Property Rights, and it requires signatories to pass laws supporting intellectual property rights, but it does not affect the private ownership of those rights. See James Pooley, The Big Secret Behind the Proposed TRIPS Waiver, IPWatchdog.com (May 25, 2021), https://www.ipwatchdog.com/2021/05/25/big-secret-behind-proposed-trips-waiver/id=133905/.

[7] Incidentally, India and South Africa are home to robust generic pharmaceutical industries.

[8] James Pooley, The Big Secret Behind the Proposed TRIPS Waiver, IPWatchdog.com.

[9] 18 U.S.C. § 1839(3)(A); see also Uniform Trade Secrets Act, § 1(4)(ii) (requiring reasonable "efforts").

[10] Similar policy considerations—as well as self-interest, no doubt—have led every state in the country to prohibit attorneys from entering into noncompetes and non-solicits that restrict their ability to practice law. Unlike in the healthcare industry, however, these restrictions are typically found in the rules of professional conduct or disciplinary rules, not enshrined in law. See Model Code of Prof'l Conduct R. 5.6 and DR 2-108. Although the American Medical Association ("AMA") discourages any agreements that "unreasonably restrict the right of a physician to practice medicine for a specified period of time or in a specified geographic area on termination of a contractual relationship" and "do not make reasonable accommodations for patients' choice of physician," recognizing that these agreements "can disrupt the continuity of care, and may limit access to care," such agreements are not prohibited under the AMA Code of Medical Ethics. AMA Code of Medical Ethics Opinion E-9.02.

[11] Mass. Gen. Laws ch.112, § 12X.

[12] Id., §§ 74D, 129B, and 135C.

[13] See, e.g., Colo. Rev. Stat. Ann. § 8-2-113(3) (physicians); Conn. Gen. Stat. Ann. § 20-14p (physicians); Conn. Gen. Stat. Ann. § 20-681 (home healthcare providers); 6 Del. C. § 2707 (physicians); Fla. Stat. § 542.336 (physicians); Ind. Code. § 25-22.5-5.5-1, et seq. (physicians); N.H. RSA § 329:31-a (physicians); N.H. RSA § 315:18 (podiatrists); NMSA 1978, § 24-1i-1, et seq. (dentists, osteopathic physicians, physicians, podiatrists, certified registered nurse anesthetists, certified nurse practitioners, certified nurse-midwives); R.I. Gen. Laws § 5-37-33 (physicians); SDCL 53-9-11.1 (physicians, physician assistants, certified nurse practitioners, nurse-midwifes, certified registered nurse anesthetist, registered nurses, and licensed practical nurses); T.C.A. § 63-1-148 (physicians (except emergency medical specialists), podiatrists, chiropractors, dentists, optometrists, osteopathic physicians, and psychologists); Tex. Bus. & Com. Code Ann. §§ 15.50(b)-(c) (physicians); W. Va. Code §§ 47-11E-1, et seq. (physicians).

[14] See, e.g., Valley Med. Specialists v. Farber, 194 Ariz. 363, 369 (1999) ("We therefore conclude that the doctor-patient relationship is special and entitled to unique protection. It cannot be easily or accurately compared to relationships in the commercial context. In light of the great public policy interest involved in covenants not to compete between physicians, each agreement will be strictly construed for reasonableness."); Ohio Urology, Inc. v. Poll, 72 Ohio.App. 44, 452053 (1991) ("These covenants should be strictly construed in favor of professional mobility and access to medical care and facilities.").

[15] CT SB.99, SB.1087, HB.5772; FLA S.842, H.1449; LA HB.483; MA H.2051, S.1211; MN HB.1917, SB.2130; MO SB.223.

[16] SDCL 53-9-11.1 (effective July 1, 2021) (applies to physicians, physician assistants, certified

nurse practitioners, nurse-midwifes, certified registered nurse anesthetist, registered nurses, and licensed practical nurses).

[17] D.C. Code § 32-581.01.

[18] Clinicians often have relationships with their employer's patients (i.e., customers), which is an independent reason that a post-employment restrictive covenant may be appropriate and enforceable. This article's discussion of post-employment restrictive covenants is limited to their use to protect trade secrets, not customer goodwill.
