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THE EMERGING ROLE OF TRADE SECRETS IN LIFE SCIENCES

Changing Patent Protections

U.S. and foreign patent systems have suffered legislative and judicial reverses as to subject matter eligibility for patenting, a rising bar of obviousness due to increasing skill of the art, insights aided by artificial intelligence (AI) tools, procedural artifacts for no-risk post grant invalidation by granting agencies, and awakening of once dormant antitrust and public policy limits. Although patents must be pursued when copying is inevitable, trade secrets can provide an important strategic complement when trying to protect intellectual property rights.

Growth of Trade Secrets

Trade secret law has continued to evolve over the decades. All states – except, notably, New York – have adopted laws modeled on the Uniform Trade Secrets Act (UTSA) which codify basic trade secret law principles, preserve differences from patent law, and standardize certain key definitions. In 2016, Congress passed the federal Defend Trade Secrets Act (DTSA) which created a federal private right of action for trade secret misappropriation under the Economic Espionage Act. The DTSA was passed in recognition of rapidly advancing technologies and the desire to be competitive in the global economy. Among other things, the DTSA allows a trade secret holder to bring a case in federal court, provides for the potential *ex parte* seizure of property to prevent the propagation and dissemination of a stolen trade secret, enjoinder from actual or threatened misappropriation, and double damages. The DTSA also includes a safe harbor for whistleblowers. In addition, there are other legal mechanisms to protect trade secret information, including i) the TRIPS Agreement Article 39 committing all parties to effective protection of “undisclosed information,” ii) the long standing in rem jurisdiction of the U.S. International Trade Commission (ITC) to investigate and recommend to the

U.S. President's designee (U.S. Trade Representative-USTR) approval (or disapproval, i.e. veto) of judgments for granting general or limited exclusion orders banning imports of articles affected by unfair competition such as trade secret misappropriation abroad or in the U.S., iii) a general regimen of data and technology protection under U.S. export and investment control laws, and iv) control of federally funded life sciences R&D at universities and companies.

Trade Secret Considerations

There are some benefits to protecting intellectual property as trade secrets rather than through patent, including the theoretically indefinite duration of trade secrets. In addition, there is a broad scope of information covered as trade secrets under the DTSA which defines trade secrets as "all forms and types of financial, business, scientific, technical, economic, or engineering information" where the owner has taken "reasonable measures to keep such information secret" and "information derives independent economic value, actual or potential, from not being generally known." 18 U.S.C. § 1839(3). Further protections of trade secrets are built into court litigation and administrative agency appeals, which frequently enter protective orders to safeguard confidential information. Exceptions under the Freedom of Information Act (FOIA) protect trade secrets from public disclosure where procurement and regulatory requirements mandate disclosure of trade secrets to the government.

However, there are also drawbacks to protecting intellectual property as trade secrets since protections may be undermined and duration uncertain if there is un-remediated misappropriation, independent creation by others, or reverse engineering. Employees are a key link to both protecting and potentially losing trade secrets. One of the potential sources of leaking trade secret information – which risks destroying its status as a trade secret – is reverse engineering by scientists and engineers who are increasingly mobile and may be subject to limited non-compete post-employment. However, abuses of noncompetition laws have led to U.S. federal and state governments putting significant boundaries on how and when such a restrictive covenant can be imposed, its duration and scope, and sanctions for failure to observe the new boundaries. California, Oklahoma and North Dakota have long banned such non-compete agreements, DC has recently banned them, and courts in other states apply strict scrutiny to claims of enforcement. Even so, employers can utilize non-solicitation and confidentiality agreements, which are effective post-employment, to protect trade secrets. In addition, nondisclosure agreements (NDAs) between companies related as licensor-licensee, vendor-customer, and joint venturers are routinely upheld and are a valuable tool in protecting trade secret information.

Recent examples of the growing importance of trade secrets and the changing level of patent protections in the life sciences space are highlighted below:

1. The ITC recently issued an exclusion order on account of trade secret misappropriation, barring Dawoong, a Korean pharma company, from importing products directly competitive with Allergan's Botox™ (Botulinum toxin) products, even though the misappropriation occurred abroad. This was consistent with earlier rulings outside the life sciences space.
2. In enforcing the Biological Price Competition and Innovation Act (BPCIA), a biosimilar applicant seeking FDA marketing approval commits a deemed act of infringement by submitting the application for a biosimilar covered by one or more patents of a primary marketing-approved biologic "reference product," similar to practice in Hatch-Waxman (H-W) processing for small molecule drugs, with some procedural differences. FDA delays marketing approval for 30 months to allow the primary to sue the applicant. The BPCIA process is more complicated than the H-W proceedings because product comparisons for reference products vs. biosimilars depend on process information. The BPCIA statute and regulations impose a mandatory exchange of process information between primary and biosimilar applicant known as the "patent dance" with strict protective order limits to avoid destruction of trade secrets. But the mandate is not enforceable in federal court. So, some biosimilar applicants demur when asked to the dance. Senate bill 659, (Patent Transparency Act) with bipartisan requires primary market approved holders to list applicable patents. On December 27, 2020, then President Trump signed a must-pass Consolidated Appropriation Act with the usual extraneous baggage of such funding bills including as section 325, Division BB the "Biological Product Patent Transparency Act." By June 30, 2021, the FDA must provide a searchable list of licensed biologics updated monthly.
3. Patents require a written description of the invention, and enablement of the invention including identification of best mode. The American Invents Act of 2011 (AIA) bars litigation over any alleged failure to disclose best mode, eliminating a long standing distraction, particularly where this issue is intertwined with alleged inequitable conduct.
4. The COVID-19 pandemic led many pharma/biologic companies in good faith to share results early and restrain themselves from patent enforcement. But, some use private funds to develop and to sell finished vaccines products, if and when approved by FDA, to avoid granting a royalty-free patent license to the U.S. Government with a right to sublicense competitors. Purchases of vaccine were in place from the onset. The restraint may fade away.
5. Regulations under the Foreign Investment Risk Review Modernization Act (FIRRMA) can block majority or minority investment in U.S. companies by foreign persons or entities if the target company is a major source of protected information in areas of life sciences such that a proposed acquisition would threaten U.S. national security (e.g. toxins). Similarly, some

exports from the U.S. of articles or related technology may be limited under regulations of U.S. Departments of State, Defense, Commerce and Treasury.

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