Protecting Trade Secrets Disclosed to the FDA

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Webinar Series

Presented by
Sharon M. Sintich, Ph.D.
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What is Protectable as a Trade Secret

Information, including a *formula, pattern, compilation, program, device, method, technique, or process*, that is

- Commercially valuable and not generally known; and
  - derives independent economic value, actual or potential, from **not being generally known** to the public or to persons who can obtain economic value from its disclosure or use
- The subject of **efforts that are reasonable under the circumstances** to **maintain its secrecy**

Cal. Civ. Code § 3426.1 (d)

Patents	*Trade Secrets*
Right to exclude others from making and using the information	Right to sue someone who has misappropriated the trade secret, no rights against person who independently developed or reverse engineered
Published and provided to the public; cannot be used at will by 3rd party	Maintained as a secret; once in the public – any innocent party can make or use the information at will
Limited in time	No time limit (as long as secrecy is maintained)
Time to obtain an issued patent is about 3 years or more	Effective immediately
Formal filing requirements and examination for inventiveness	No formal filing requirements and no examination process
Obtaining patent protection is costly	Low cost

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Uniform Trade Secrets Act (UTSA)

- Common Law allows for remedies for trade secret misappropriation
- UTSA provides a legal framework for improved trade secret protection
  - Completed by the Uniform Law Commission in 1979, amended in 1985
  - Approved by the ABA
- UTSA is an effort to codify the common law with proper clarification of rights and remedies
- Created to eliminate the uncertainties created by common law

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Uniform Trade Secrets Act

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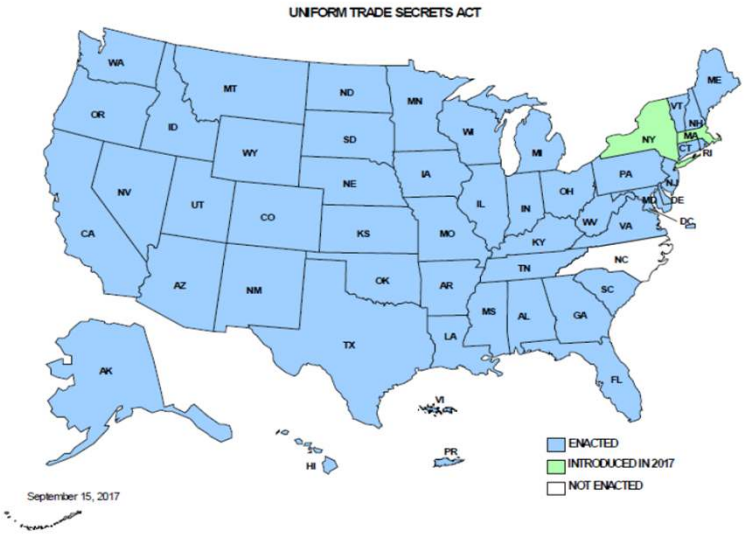

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Defend Trade Secrets Act (DTSA)

- Creates a federal, private and civil cause of action for trade secret misappropriation
- Provides a uniform statute to be applied nationwide in federal court
- Trade secret must be related to a product or service used in or intended for use in interstate or foreign commerce
- Does not preempt existing state trade secret laws

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UTSA	DTSA
§ 1(4) "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, 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	(3) the term "trade secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if— (A) the owner thereof has taken reasonable measures to keep such information secret; and (B) the information derives independent economic value, actual or potential, 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;
Broader definition: all information that derives economic value; does not define who must undertake the efforts	Limited to particular type of information; the examples listed should be included in the "all information" wording of the UTSA

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UTSA	DTSA
Broader definition of trade secret: "all information" that derives economic value	Limited to particular type of information; the examples listed should be included in the "all information" wording of the UTSA
No requirement on who must keep the information secret	Requires that the **owner** keep the information secret
Same definition of misappropriation	
Proper means: independent invention, reverse engineering, discovery under a license from the owner, observation of the item in public use or display, published literature	Proper means: reverse engineering, independent derivation or any other lawful means of acquisition
3 year statute of limitation after the date on which the misappropriation is discovered or by the exercise of reasonable diligence should have discovered	3 year statute of limitation
No seizure remedy	Ex parte seizure remedy (in extraordinary circumstances)
Other possible remedies: actual damages, injunctions, reasonable royalties, attorney fees, exemplary damages (2x for willful and malicious misappropriation)	Same as UTSA

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What is Misappropriation?

Acquisition or disclosure 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

"Improper Means" include

- Theft
- Bribery
- Misrepresentation
- Breach
- Inducement of a breach of a duty to maintain secrecy
- Espionage through electronic or other means
- Differ in the acts that are not included

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Patents vs. Trade Secrets

- Is this information patentable?
- What breath of claims can you obtain?
- How would you know if someone is infringing?
- Could you prove someone is infringing?
- Would the early public disclosure in a patent application give a competitor a leg up?
- How easy can the information be ascertained by examining the commercial product?
- How easy is it to keep the information secret?

Take Home: Need to compare the extent of patent protection and ability to enforce vs. the value you gave the competitor by providing a full disclosure

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Risks of Choosing Trade Secret over Patent Protection

- Level of protection varies significantly from country to country
- No right to exclude someone else who independently develops the trade secret
  - 3rd party may be able to obtain a patent on the trade secret and exclude you, depending on the timing and the application of the prior-user defense
- No protection from reverse engineering of the invention
- Only can sue those who misappropriated the trade secret
- Requires reasonable efforts to maintain secrecy
  - Difficult to restrict access after employees have left the company; high employee turnover is a risk
  - Requires strict control over transfer and contract provisions relating to the trade secret

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Efforts to Maintain Secrecy of a Trade Secret

- Level of protection varies significantly from country to country
- Keep a log of all individuals having access to the information
- Strictly limit access to employees who have a need to know the information
- Put procedures in place to require 3rd party vendors to keep information confidential and to limit access
- Encrypt all electronic communications regarding the information
- All physical documents regarding the information to carry a notice sufficient to identify the contents as trade secret information to which access is restricted

"HIGHLY CONFIDENTIAL - TRADE SECRET RESTRICTED ACCESS - UNAUTHORIZED COPYING OR DISTRIBUTION IS PROHIBITED "

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Trade Secret Remedies

- Injunction
- Criminal Prosecution
- Compensatory Damages
- Unjust Enrichment
- Attorneys' Fees
- Enhanced Damages
- Exclusion Order (ITC)
- Seizure (Fed. Act)

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Patents Remedies	*Trade Secrets Remedies*
Anyone infringing the patent claims can be liable	Only those who misappropriate the trade secret can be liable
No wrong doing or willfulness required	Requires wrong doing; must prove trade secret was improperly acquired
Injunctions could prohibit infringer from making and using invention	Injunction might not be commercially effective once trade secret is known to the public
To literally infringe, every element of the claim must be in the accused product or method	Proof of misappropriation can be based on circumstantial evidence, and does not require a showing that all elements are copied; substantial similarity or derivation is sufficient to establish misappropriation
Compensate for actual losses; but no unjust enrichment	Compensate for actual loss; and unjust enrichment is a possible remedy

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Disclosures by the FDA

- FDA may share non-public information (NPI) on its own initiative or in response to a FOIA request (5 U.S.C. § 552)
- Any person has a right to access federal agency records unless the information falls under one of the FOIA exemptions
  - Exception 4: Trade secrets
  - Exception 5: Privileged communications within or between agencies
- 21 CFR § 20.88 allows FDA to disclose NPI to state and local counterparts as part of cooperative law enforcement or regulatory efforts, if certain conditions are met

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FDA Definition of Trade Secret (21 CFR § 20.61)

(a) A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

(b) Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

(c) Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.

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Taking Advantage of the Exception

REQUIRED: Identify the trade secret information within submission

- At the time of filing or at a reasonable time thereafter

PRACTICE TIP: Consider where to insert the information within the submission

- Some sections of the submission are more likely to be released to a competitor under FOIA

CAUTION: FDA may release trade secret info if they believe the "trade secret" designation is frivolous

- Be thoughtful on what to designate
- Need reasons this information is a trade secret

- FDA may designate information as confidential, as well

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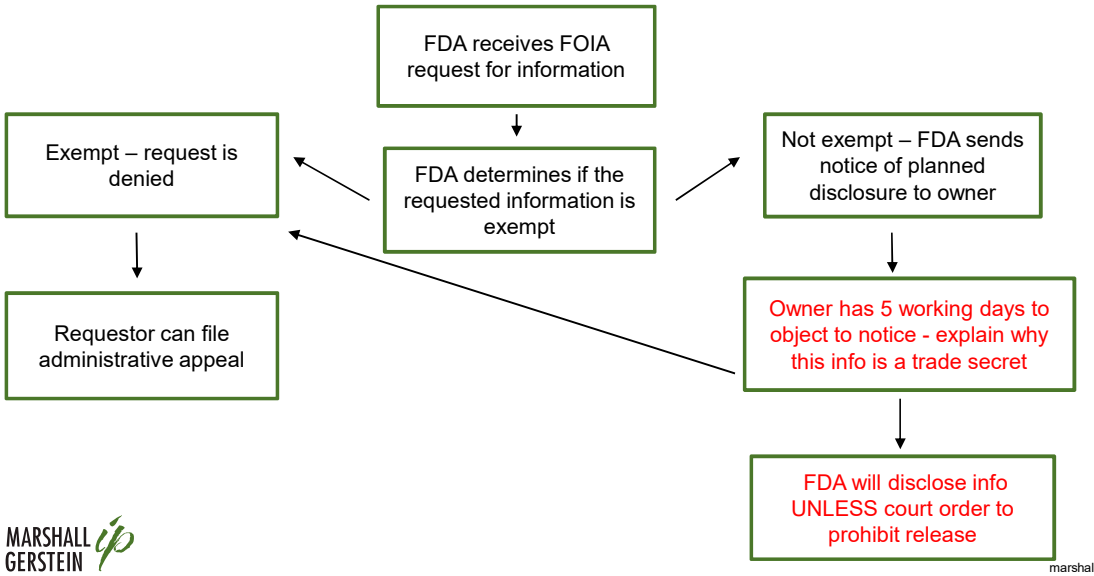
Responding to FOIA Request



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FDA Pilot Program to Increase Transparency

- Response to Stakeholder's request for greater transparency in the drug approval process and more access to usable information
- Determine if disclosing certain information improved public acess to drug approval information
- Disclose Clinical Study Reports (CSR) following the approval of NDA
  - Testing a process to select, redact and post CSR information on a public web site
  - Provide efficacy and safety information on the DRUGS@FDA site
  - Access will be more user friendly
- Concluded Pilot Program in March 2020

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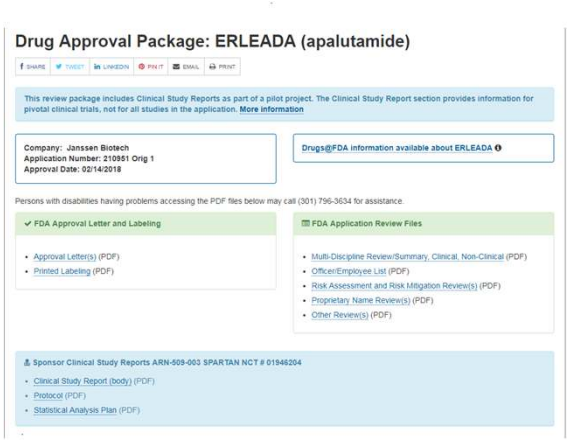
FDA Pilot Programs to Increase Transparency

- Redacted CSR summary will be posted
  - Study report body
  - Study protocol and amendments
  - Statistical analysis plan for each of the product's pivotal studies

ERLEADA Example:
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/erleada_210951_toc.cfm

Further info on Pilot:
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm589210.htm



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FDA Pilot Programs to Increase Transparency

- Considering to release additional information from Complete Response Letters (CRLs)
  - Clinical safety and efficacy info in CRL that could have significant public health value
  - Evaluating whether there is a subset of CRLs that are especially important to public health
  - Release of all CRLs would be burdensome as many would need to be redacted and not all letters would directly inform clinical practice
  - This release would be under existing statutory authority or new law

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FDA Pilot Programs to Increase Transparency

- Learned many best practices that will be applied to future efforts
  - Significant inefficiencies in having multiregional disclosure requirements relating to often identical clinical data summaries
  - Identified a potential approach that could facilitate a harmonized system for disclosing study reports
- Harmonized System for Disclosing Study Reports
  - International Library
  - On-Demand System – Public can request study reports of interest and the sponsor would then prepare the report
  - Standardized
  - Voluntary – Sponsor would have the choice of committing to use the international library system

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Other Disclosure by the FDA

- The FDA cannot disclose trade secret information to the States under 21 CFR § 20.88 without express written authorization from the owner or submitter
- Confidential Commercial Information (CCI) can be disclosed under 21 CFR § 20.88 without the owner's authorization, but it must be in the interest of public health to do so
- Agreement between the EMA and FDA to share complete list of inspection reports of facilities examined by each agency

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Practice Tips

- Review submissions and identify material that are exempt from FOIA
  - Only have 5 days to respond to FOIA request
  - Be prepared to provide basis that the information is valuable
  - Conduct periodic reviews to determine if information remain a trade secret after submission
- Review past CSRs and CRLs to determine what information is confidential
- Defendants in trade secret misappropriation cases should submit a FOIA request to obtain documents relating to the alleged trade secret
  - Induce a response from the FDA
  - FOIA cases usually resolved on summary judgment - court may rule there are no trade secret before a misappropriation trial

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Licensing Considerations –Trade Secret License

- Agreement whereby the IP owner grants the licensee permission to use some or all of the secret information
  - Licensee retains full title and all ownership associated with the trade secret
  - Risk = Licensee will not keep the information secret
  - Benefit = Maximizing royalties on the trade secret.
- The license may be exclusive or non-exclusive
- The right to use the trade secret can be limited to a defined period of time
- License can be revoked if the licensee fails to comply with the terms of the agreement
  - Conduct periodic reviews to determine if information remain a trade secret after submission

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Licensing Considerations –Trade Secret License

- Examples of trade secrets to license: formulas, assays, manufacturing methods
- The Licensee should also sign a nondisclosure agreement
  - NDA should clearly define the trade secret
  - NDA should limit the disclosures to purposes agreed upon by both parties
  - By signing, the licensee expressly accepts a duty to preserve secrecy of the information
  - Allows parties to understand what information is being transferred prior to execution of the license – the "**Black Box**" of information

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Licensing Considerations –Trade Secret Owners

- What mechanism and procedures should be used to divulge the contents of the "**Black Box**"
  - Restrictions on use of the information
  - Restrictions on who can view the information
  - Length of time the recipients has to examine the information
  - How much should they charge to view the information

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Licensing Considerations –Trade Secret Recipients

- What mechanism and procedures should be used to divulge the contents of the "**Black Box**"
  - What restrictions should they accept before execution of the license
  - What restriction should they accept on the future use of the information
  - What if the information is already in the public domain?
  - How much should they pay to look in the **Black Box**?

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Licensing Considerations – Practice Tips

- In the U.S., royalties cannot be paid on a patent that is not in force and the life of a trade secret might be indefinite,
- Royalties for a trade secret right may extend longer than those for a patent right
- Options:
  - Separate patent and trade secret agreements
  - Initial lump sum payment for trade secret
  - Clearly differentiate between patent and trade secret rights
  - Separate allocation of royalties to each of the rights
  - Appropriate decrease in royalty rate if patent terminates or expires
  - Grant a royalty-free license to patents
  - Grant a trade secret license but no patent license

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Questions?

Sharon M. Sintich, Ph.D.
312.474.6631
ssintich@marshllip.com