

## Management of Confidential Information

### Intellectual Property Licensing/NIH Perspective

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## Definition of Confidential Information

- Information, including a formula, pattern, compilation, program device, method, technique, or process, that:
- derives independent economic value, actual or potential, from no 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
- is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

## Definitions Continued

- "Improper means" includes theft, bribery, misrepresentation, breach or inducement of a breach of duty to maintain secrecy, or espionage through electronic or other means.
- "Misappropriation" means: (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.

## Governing Law for Confidential Information

- Generally, in the United States, protection for confidential information/trade secrets comes in part from contract law and in part from state law (with a few exceptions).
- At this time, approximately all U.S. states have adopted all or portions of the Uniform Trade Secrets Act (UTSA).
- Economic Espionage Act of 1996 (codified at 18 U.S.C. §§ 1831-1839 makes the theft or misappropriation of a trade secret a federal crime.

## Relationship of Patents and Confidential Information

- Underlying theme is protection of intellectual property.
- One approach: holding everything as confidential information.
- Patent approach: taking all (or a portion thereof) of an entity's confidential information and dedicating them to the public in return for a patent grant.

## Duration of Confidential Information

- Theoretically, protection of confidential information can extend indefinitely.
- U.S. example: formula for Coca-Cola.
- Term of a patent is twenty (20) years from its priority date.
- The lack of formal protection, however, means that a third party is not prevented from independently duplicating the confidential information.

## Remedies for Misappropriation

- **Actual** or **threatened** misappropriation may be enjoined.
- An injunction shall be terminated when the trade secret has ceased to exist.
- The injunction may be continued for an additional reasonable period of time in order to eliminate commercial advantage that would be derived from the misappropriation.

## Remedies Continued

- In exceptional circumstances, an injunction may condition future use upon payment of a reasonable royalty for no longer than the period of time for which use could have been prohibited.
- Exceptional circumstances include, but are not limited to, a material and prejudicial change of position prior to acquiring knowledge or reason to know of misappropriation that renders a prohibitive injunction inequitable.

## Remedies Continued

- Damages can include both the actual loss caused by misappropriation and the unjust enrichment caused by misappropriation that is not taken into account in computing actual loss.
- In lieu of damages measured by any other methods, the damages caused by misappropriation may be measured by imposition of liability for a reasonable royalty for a misappropriator's unauthorized disclosure or use of a trade secret.
- If willful and malicious misappropriation exists, the court may double any putative award.

## Miscellaneous Points

- If (i) a claim of misappropriation is made in bad faith, (ii) a motion to terminate an injunction is made or resisted in bad faith, or (iii) willful and malicious misappropriation exists, the court may award reasonable attorney's fees to the prevailing party.
- An action for misappropriation must be brought within 3 years after the misappropriation is discovered.

## Determining Factors: Confidential Information

- (1) The extent to which the information is known outside the business.
- (2) The extent to which the information is known by employees and others involved in the business.
- (3) The extent of the measures undertaken by an employer to protect the secrecy of the information.
- (4) The value of the information to the employer.
- (5) The amount of effort or money expended by the employer in developing the information.
- (6) The ease or difficulty with which the information could be properly acquired or duplicated by others.

## Protection of Confidential Information

- **Non-Disclosure Agreement (NDA)**
- **Confidential Disclosure Agreement (CDA)**

## What is an NDA/CDA?

- A contract between two or more parties where the subject of the agreement is a promise that information conveyed will be maintained confidentially.
- A contract in which the parties promise to protect the confidentiality of information that is disclosed during employment or another type of business transaction.

## Why are NDAs/CDAs important?

- One cannot obtain a patent in the US if the invention was described in a printed publication in this or a foreign country more than one (1) year prior to the filing of a US patent application.
- For example, disclosure of proprietary pre-publication information by an NIH scientist to an entity.

## Why are NDAs/CDAs important?

- Use of NDAs and CDAs have become ubiquitous in the global, information-based economy.
- Use of NDAs and CDAs is most prevalent in high technology fields (e.g. computer software, biotechnology, semiconductors.)
- Lack of knowledge of NDAs/CDAs will result in a competitive disadvantage to entities unfamiliar with the nuances of NDAs/CDAs.

## Types of NDAs/CDAs

- Mutual: one or more parties are exchanging confidential information.
- Mutual Example: providing confidential information for a company to evaluate and the company provides you with confidential information about their marketing strategy.
- Unilateral: used when only one party is making a disclosure; for example, providing an unpublished patent application to a contractor or investor.

## Elements of an NDA/CDA

- Definition of confidential information.
- Exclusions from confidential information.
- Obligations of receiving party.
- Time periods, and
- Miscellaneous provisions.

## Definition of Confidential Information

- List of the types or categories of confidential information at issue in the agreement.
- The purpose is to establish the boundaries or subject matter of the disclosure, without actually disclosing the confidential information.
- Example: Confidential Information includes programming code, financial information, related software materials and innovative processes.

## Exclusions From Confidential Information

- Information that was known to the party to whom the information is disclosed about the Confidential Information prior to its disclosure under the CDA/NDA.
- Information about the Confidential Information that is or becomes generally available to the public through no fault of the party to whom the information is disclosed.
- Information about the Confidential Information that is subsequently made available to the party to whom the information is disclosed from any third party that is not under a confidentiality obligation to the disclosing party.
- Information that is required to be disclosed by operation of law or court order.

## Obligations of the Receiving Party

- The receiving party must hold and maintain the information in confidence and limit its use.
- Under most state laws, the receiving party cannot breach the confidential relationship, induce others to breach it or induce others to acquire the secret by improper means.
- Most parties will accept these contract obligations without discussion.

## Time Periods

- Some agreements require that the receiving party maintain the secret information for a limited period of years.
- Example language: "the receiving party shall not use or disclose the Confidential Information for a period of five years from the date of execution of the agreement."
- You can often negotiate the time period.
- Disclosing parties want an open period with no limits; receiving parties usually want a short period. Five years is a common length in American nondisclosure agreements.

## Time Period Continued

- Length of time generally will depend on the relative bargaining power of the parties.
- Caveat: when disclosing or receiving patent applications, be aware that a confidentiality agreement may not be needed because of statutory publication requirements (i.e. PCT, US Patent and Trademark Office.)

## Miscellaneous Provisions

Include such matters as:

- Which state's law will apply in the event the agreement is breached.
- Whether arbitration will be used in the event of a dispute.
- Whether attorney fees will be awarded to the prevailing party in a dispute.

## Importance of Laboratory Notebooks

- Establishing priority of invention often depends on such documentation as laboratory notebooks.
- Failure to keep a laboratory notebook may result in loss of a priority contest with another inventor.
- For example, when one is accused of misappropriating confidential information, if a laboratory notebook shows that one was in possession of the contested information before any access to the adversary's information, this helps to negate a claim that the confidential information was stolen from the adversary.

## NIH and Confidentiality

- NIH's primary concern is preserving confidentiality of data prior to filing a patent application.
- NIH's policy states that NIH will not embargo publication of scientific data in the interest of filing a patent application.
- What does this mean? NIH will file a rush patent application to preserve rights that may be disclosed by that publication.

## NIH and Confidentiality

- However, NIH scientists will not readily share data with for-profit (and in some cases, non-profit) entities without a CDA/NDA in place prior to discussions regarding that data, unless there is a compelling reason to the contrary (i.e. public health reasons.)
- In recent years, NIH scientists have become aware of putting CDAs/NDAs into place prior to CRADA negotiations and preliminary license discussions.

## NIH and Confidentiality

- 35 USC § 209: Confidentiality of licensee reports to NIH.
- Requires periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with.
- Exception: The report shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 (FOIA).

## FOIA

- Freedom of Information Act (5 USC § 552)
- Provides conditions under which agency information can be distributed to the public.
- Exceptions: 5 USC § 552(b)

## FOIA Exceptions

- (1)(A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;
- (4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;
- (5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

## FOIA Exceptions

- (6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
- (8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or