

# Intellectual Property, Gene Patenting, & Research Misconduct

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# Types of intellectual property

Protection of intellectual property

(United States Constitution, Article 1, Section 8):

*“The Congress shall have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries ...”*

- Trade secrets: states typically have primary jurisdiction (until recently), especially when it comes to theft of trade secrets
- Trademarks: states/federal
- Copyrights: largely federal (Copyright Act of 1976)
- Patents: federal (Patent Act of 1790)

# Property rights

- Property can be classified as real (i.e., real estate or land) or personal
- Personal property can be tangible or intangible
- Intellectual property (IP) is usually intangible, but an embodiment of IP (i.e., a document for which an author holds a copyright) can be tangible
- In research, personal property rights and IP rights can exist simultaneously. A cell line is tangible personal property for which a researcher holds rights. The cell line may also be associated with IP rights at the same time.

# Trade secrets

“A trade secret is information that is not publicly known, but that confers an economic value upon its owner *and* that its owner takes reasonable steps to maintain as secret”.

How do courts decide if something qualifies?

1. Information was not readily available by independent research
  2. Information was used in business operations
  3. Information provided a competitive advantage
- **Trade secrets have no expiration date as long as information remains secret:**  
The Coca-Cola recipe is locked in a vault; if the recipe ever becomes public, the owners will lose protection!
  - **Economic Espionage Act of 1996:** makes theft of trade secrets a federal crime that can lead to fines and/or jail time.

# Trade secrets protect the livelihood of companies

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Friday, May 13, 2016

## Irvine Engineer Named in New Indictment Alleging Theft of Trade Secrets from Two Medical Device Companies

*SANTA ANA, California* – A federal grand jury has issued a superseding indictment that charges an Irvine engineer with stealing and possessing trade secrets belonging to two former employers, both of which develop and manufacture medical devices used to treat cardiac and vascular ailments.

Wenfeng Lu, 43, of Irvine, was named in a 12-count superseding indictment returned by a grand jury on Wednesday.

The indictment alleges that Lu stole the confidential and proprietary trade secrets from two different medical device companies with research facilities in Irvine, where Lu worked from January 2009 until he was arrested in 2012.

During this time, Lu travelled to the People's Republic of China (PRC) multiple times – sometimes soon after allegedly downloading trade secrets from an employer's computer and emailing information to his personal email account. Lu was arrested as he prepared to board a plane to the PRC in November 2012, according to court documents. Lu appeared "to be in the process of setting up a company with other individuals in the PRC to manufacture medical devices," an FBI agent wrote in an affidavit previously filed in this case.

"Intellectual property theft poses a grave threat to businesses and the employees who depend on those businesses for their livelihoods," said United States Attorney Eileen M. Decker. "Moreover, when the stolen material is destined for foreign entities seeking to compete with American businesses, as it was in this case, IP theft also threatens the security of our nation. This is one of the reasons that my Office now prosecutes IP crimes out of a National Security Division."

Lu was initially indicted in this case in December 2012. That indictment included allegations related only to one of the companies' trade secrets. The new indictment incorporates the allegations related to four trade secrets owned by the other.

Information was stolen and brought overseas despite precautions such as:

1. Limiting physical location of information and securing the area
2. Limiting personnel who can access the information
3. Labeling physical documents as "confidential"

## Defend Trade Secrets Act of 2016

- Introduced by President Obama
- Consistent federal law
- Goods can be seized from companies that steal trade secrets

Macrina, F. (2014). *Scientific Integrity: Text and Cases in Responsible Conduct of Research* (4<sup>th</sup> ed.). Washington, D.C.: ASM Press.

<https://www.justice.gov/usao-cdca/pr/irvine-engineer-named-new-indictment-alleging-theft-trade-secrets-two-medical-device>

<https://digitalguardian.com/blog/new-law-puts-federal-muscle-behind-trade-secret-protections>

# Trademarks

*“Trademarks embody pictures, sounds, writings, devices, or objects that allow the owner to identify and distinguish some idea, concept, service, or product from those of a competitor”.*

## **Protection of an idea that conveys the reputation of a product or service**

- In the US, trademarks issued by the US PTO in 10-year periods
- Foreign trademark protection must be sought separately in each jurisdiction
- Example: GlaxoSmithKline (GSK) v. Gadikota Sarath Kumar Reddy’s company “GSK Life Sciences” (2016 in India)
  - *Well-known GlaxoSmithKline logo (mark) and name were used in nearly identical fashion by GSK Life Sciences to advance their own company (through possible confusion) based on the good reputation of another well-established company.*



# Copyrights

*“A copyright protects the expression or presentation of an idea, but it does not protect the idea itself. Work to be copyrighted must be fixed in some type of tangible medium. This includes material that must be accessed in some way with the assistance of a machine. Anyone can use your ideas even if they’re protected by copyright”.*

- Example: Review articles
  - *Copyright permission is needed to reproduce tables and figures from an original work in a review article. The text of the review article relies on previous work but also includes new text and explanations that are offered independent copyright protection as a derivative work.*
- Originality is required for copyright protection
  - *“Originality means only that the work owes its origin to the author, i.e., it is independently created, and not copied from other works.”*
  - Owner has rights to reproduce, distribute, sell, and transfer. Can appoint others to do the same

# Copyrights

- “Work for hire”
  - Employee prepares copyrightable materials as part of his/her job
  - Employer still owns the copyright
  - The task must be explicitly assigned
    - Example: writing a company manual
      - If an employee writes a instrument manual as part of their job, the business owns the copyright
      - If an employee writes the manual without explicit instructions or assignment, the employee owns the copyright
- Fair use of copyrighted material for personal/non-profit efforts:
  - Criticism
  - News reporting
  - Teaching
  - Research/scholarship
- Example: photocopying part of a textbook for use in your class versus selling the copies to students to cover copying fees.

# Case study: Copyrights

- A high school chemistry teacher used to sell the answers to previous AP Chemistry exams dating back to the 1970's to assist teachers in preparing students for the AP Chemistry exam. The College Board complained and said such actions violate copyright laws.
- What types of violations are in play?
- What if the material was provided to the teachers free of charge by means of the "third party"?
- What about posting copies of your research publications on your group's website?

We can not sell the past AP Chemistry exams in any form, be that print, electronic, magnetic, or optical. This is because the College Board has told me not to! They have expressly stated that they will NOT license the questions. All sites that have the AP materials (except the College Board's) are posting that information in violation of the owner's copyright. Sorry, but they threatened to sue me over this issue.

# Patents

- Patent Act of 1790 confers specific legal protections to individual(s) to exclude others from making, using, or selling a particular invention
  - Patents are enforced for 20 years from earliest filing date
  - If the invention involves FDA review, can be extended for 5 years
- Currently, patent law is specific to individual countries
- To be patentable, the invention or subject matter must be:
  - Useful
  - Novel (different than *originality* for copyrights)
  - Non-obvious
  - Reduced to a practice
    - Someone “skilled in the art” should be able to practice the claimed invention/method
- The inventor is the patent owner and is granted personal property rights. The owner can thus assign the rights to others as well.

# Patents

- First-to-invent versus first-to-file
  - First-to-invent: must be able to prove when an idea is conceived
    - United States used this system until 2013 (last country to switch)
  - First-to-file: doesn't matter when an idea is conceived
    - United States also includes a “grace” period of 1 year (unique)
- When should a patent be filed?
  - Ideally as soon as the conceived invention is reduced to practice
  - Needs to be within in one year of first “public” disclosure
    - Prior disclosure (publication, public meeting) may result in loss of foreign patent rights unless a provisional patent or utility patent is filed prior to the disclosure
    - Filing with PTO can protect foreign rights if foreign application(s) are filed within the subsequent 1 year
- Provisional patents: General Agreement on Tariffs and Trade (1995)
  - Less formal & expensive than a utility application
  - Can be a copy of a manuscript prior to publication
  - Should be filed prior to any “public” disclosure
  - Good for 1 year... provides a buffer for foreign applications
  - Not reviewed by PTO

# Biotechnology Patents

- Patents must be “useful” and “not be frivolous or injurious to the well-being, good policy, or sound morals of society” (Lowell v. Lewis).
  - Both requirements held up to a fairly minimal threshold
  - Prevents patents of genomic information without a specified use
- Patents can cover anything made by humans, including genetically modified organisms (Diamond v. Chakrabarty)
  - Non-human lifeforms can be patented if human intervention can be demonstrated
  - Had a significant impact on the rise of biotechnology
- Legislation in 2004 and 2011 (along with interpretations of the 13<sup>th</sup> Amendment) regulates patenting of “claim[s] directed to or encompassing a human organism”
  - Does not prevent methods that might be applicable to humans
  - Currently unclear if it applies to complete humans, or also “broadly defined as transgenic human cells, tissue organs”

# Gene Therapy and Sequence Patenting

- Patents of gene therapy related to somatic cells much more common and acceptable to PTO than germ line cells – occasional germ-line related patents have been issued
- Naturally occurring genetic sequences are not patentable, but lab-developed sequences are patentable (Molecular Pathology v. Myriad Genetics)
  - Cannot patent discovered or isolated sequences
  - Can patent developed sequences based on nature, such as complementary DNA

# Ethics of Recombinant DNA

- Initial experiments by Paul Berg combining a viral DNA sequence that produced tumors with a bacterial DNA strand from E. Coli
  - This led to fears that this might create tumors in humans
  - Additional research into recombinant bacterial plasmids led to the call for a temporary moratorium
- Asilomar Conference
  - Established many safety standards for biological research, including establishing biological containment levels that corresponded to the danger of the experiment
  - Led to a series of NIH Guidelines
  - Important for maintaining trust between scientists and the public

# Human Genome Project and Genetic Information

- Mapped of entire human genome, completed in 2003 – led to a number of important ethical considerations
  - Genetic information can provide numerous benefits, but may also be easily misused or misinterpreted – more knowledge is not always beneficial to the patient (i.e. genetic disposition towards an untreatable disease)
  - FDA has a policy requiring medical-related genetic testing to be performed under the supervision of a medical professional, except for specific diseases (Parkinson's, Alzheimer's etc.)
  - Two laws (HIPAA in 1996 and GINA in 2008) prevent discrimination based on genetic information – broadened by ACA in 2010 as a cover for all preexisting conditions
  - Important that all genetic information be obtained with informed consent for both use and sharing of related data
  - Privacy concerns important due to specific identification possible

# Genome Editing

- Rapid development of CRISPR/Cas9 and other genome editing technologies bring numerous ethical concerns
  - When is its use patentable?
  - Dangers from off-target and mosaic effects
  - Potential to disrupt entire ecosystems of non-human organisms (i.e. mosquitoes)
  - Use in somatic vs germline cells?
    - Germline modification has been declared “irresponsible”
    - Groups in China, the UK and the US have edited germline and embryo cells
    - Germline/Embryo modification not currently funded by NIH (But not banned in the US)
  - Other non-disease based genetic alterations
    - Physical/mental enhancement?
    - Addiction Treatment?
    - De-extinction? (i.e. Dinosaurs/woolly mammoths)
    - Chimera species? (Either with humans or between non-human organisms)
    - Gene drives to kill invasive or disease-spreading species?

# Discussion Questions

- Should the genome sequence data of dangerous pathogenic agents be restricted or placed in the public domain? Why?
- How should information discovered by genetic technology in one family member be treated if it could affect other family members?
- Should federal proposals that involve research on human genetic diagnostics and therapeutics be subjected to a review of their ethical implications?

# References

- <https://policy.psu.edu/policies/rp02>
- <https://www.brown.edu/research/research-misconduct-policy>
- Resnik, D.B.; Master, Z. Policies and Initiatives Aimed at Addressing Research Misconduct in High-Income Countries. *PLoS Med.* **2013**, 10(3): e1001406.
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# Reporting an Allegation of Research Misconduct

- Research institutions have the primary responsibility for investigating allegations of research misconducts for research funded through federal agencies such as NIH and NSF.
- Allegations of research misconduct are reported to the institution's Research Integrity Officer (RIO).
- All individuals associated with the research institution have a responsibility to report any form of research misconduct.
- Allegations could be reported in person directly to the RIO or anonymously through an ethics "hot-line".
- Research integrity officer determines if allegations are specific and credible, and as such if it warrants an inquiry.
- An inquiry is ordered if allegations are determined to meet the definition of research misconduct - Falsification, Fabrication, and Plagiarism (FFP).

# Confidentiality must be afforded to all involved in the process

- Confidentiality of complainant(s) and respondent(s) must be protected by the RIO.
- Complainant(s) should be protected from retaliation as it relates to their conditions of employment.
- Respondent(s) may retain legal counsel or a non-lawyer advisor who may be present during interviews or meetings with the inquiry or investigation committees.

# Conducting an Inquiry

- Research Integrity Officer (RIO) forms an inquiry committee.
- Purpose of an inquiry is to mainly fact-finding to determine if an investigation is needed.
- Committee members are qualified personnel within and outside the institution.
- Members should not have real or apparent conflict of interest.
- Make up of the committee is subject to objections by respondent(s).
- Research Integrity Officer takes custody of evidence (research records)
- Research Integrity Officer presents the charge to the committee stating clearly the purpose of the committee, and a description of the allegation(s) against the respondent(s).
- Committee issues an inquiry report stating whether there is enough evidence to warrant an investigation. Also recommend any action(s) needed in cases when an investigation is not required.
- Respondent(s) can comment or offer a rebuttal of the report.
- If an investigation is recommended, then the RIO must notify complainant(s), respondent(s), appropriate institutional officials, research sponsors of the decision.

# Conducting an Investigation

- Research Integrity Officer (RIO) forms an investigation committee.
- Purpose of committee is to examine the allegation(s) and evidence in-depth to determine if research misconduct has been committed and to what extent.
- Members could also have served on the inquiry committee and should have no real or apparent conflict of interest. Members of committee could be from within the institution or outside and are subject to objections by respondent(s).
- RIO takes custody of relevant evidence (research records) not previously obtained during the inquiry stage.
- RIO submits a written charge to the committee, clearly outlining the allegation(s) uncovered during the inquiry stage, clearly defines what constitutes research misconduct, and identify the respondent(s).
- Investigation committee determines, based on “preponderance of the evidence” if research misconduct has occurred and to what extent. Also identifies who is responsible. During this process, the committee can interview respondent(s), complainants(s), and all relevant witnesses.
- Committee issues a report which is subject to comments/rebuttals from the respondent(s). The report outlines what sanctions have been imposed and any other administrative actions taken by the institution.
- The RIO accepts or rejects committee’s report - reason for rejection must be consistent with federal definition of research misconduct, institutional policies, and the evidence presented in the case.
- RIO submits the committee’s report and respondent(s) comments to external sponsors and determines if law enforcement agencies, journal editors, collaborator(s) of the respondent(s) should be notified of the outcome of the investigation.

# Post Investigation Considerations

- Restoration of respondent(s) reputation if it is determined that research misconduct had not occurred or if allegations were not made in good faith.
- Restoration of complainant(s) reputation and protection from retaliation.
- If allegations were not made in good faith, the RIO determines what administrative actions against complainant(s) is/are needed.
- RIO is responsible for retaining all records involved and generated during the entire process.