Intellectual Property and Gene Patenting

May 12, 2015
Ownership of research data

• Who collected the data?
• Under whose direction and guidance were the data collected?
• Is there a valid obligation to assign the rights to another?

• NIH awards ownership of data collected to the grantee institution
  – Original lab notebooks and data remain with the institution
  – Grants can be transferred if relocation occurs but must be approved by the original institution

Ownership of research data

- **Freedom of information act (FOIA)**
  - The public has access to data obtained using federally funded research grants
    - Send a request to head of appropriate agency, specify records being sought, explain request
    - Agency has 20 days to respond by sending requested information or promising to respond
  - Includes data required to verify/replicate experiments, but not physical samples

- **NIH Policies**
  - Research records must be retained for 3 years after the funding ends but the funding agency has a right to access the data as long as the grantee is in possession of it
  - Public Access Policy: grantee must submit an electronic version of the final, peer-reviewed manuscript to PubMed Central
  - NIH has the right to inspect records that are pertinent to the award
  - If the PI leaves the grantee institution, the data remains the property of the grantee institution unless the grant is transferred


Intellectual property

- Intellectual property is a unique creation of the human mind
- Exists as an exercise of legal ownership conferred under the law
- Software
  - Tangible owner
  - Intellectual property owner

- Natural phenomenon can not be considered intellectual property
  - Utilization of a natural occurrence would be representative of intellectual property

Intellectual property

- Legal protection is available for four recognized forms of intellectual property
  - **Trademarks**
    - A distinctive symbol, name, phrase, etc., that businesses use to distinguish themselves
    - Protected by state and federal laws
  - **Trade secrets**
  - **Copyrights**
  - **Patents**

- Trademarks, copyrights, and patents are granted by federal government
  - facilitate dissemination of information
  - protecting proprietary interest
  - Find a proper balance between public and private control of data

- **Trade secrets**
  - Designed to prevent information from becoming publically available

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Intellectual property: trade secrets

• Information that is not publically available
  – Formula, pattern, program, method or technique
  – Confers economic value to owner

• State laws will protect trade secrets provided the company attempts to keep the secret, it has commercial value, can not be easily determined by independent research, and provides a competitive advantage
  – Trade secrets are difficult to protect
    • Employees intentionally or inadvertently reveal the secrets
    • Reverse engineering

• Law recognizes trade secrets because they promote the interests of commerce and industry
  – For some companies, trade secrets are more useful than other forms of intellectual property
  – Coca-Cola, if the company had patented the formula, it would have expired and company would have lost its share of the market
  – No expiration date as long as the information remains a secret
  – The company can make more money keeping the formula a secret

• Economic espionage Act of 1996
  – Makes the theft of trade secrets a federal crime
  – Monetary penalties, incarceration

• Trade secrets can be licensed to other parties
  – Recipient must be legally bound to keep the information a secret

Two ex-Coke workers sentenced in Pepsi plot deal

POSTED: 2:15 p.m. EDT, May 23, 2007

STORY HIGHLIGHTS

- Two former Coca-Cola workers receive prison terms
- Both were involved in plot to sell secrets to rival Pepsi
- A third suspect is set to be sentenced at a later date
- Plot was revealed last year by undercover FBI agents

ATLANTA, Georgia (CNN) -- Two former Coca-Cola employees were sentenced Wednesday to serve federal prison terms for conspiring to steal and sell trade secrets to rival Pepsi.

Joya Williams, 42, of Norcross received an eight-year prison term, while Ibrahim Dimson, 31, got a five-year term, according to a news release from the U.S. attorney's office for the Northern District of Georgia. Both were ordered to pay $40,000 in restitution.

Williams was convicted in February on charges that stem from a plot to offer samples of a new Coca-Cola product to Pepsi for $1.5 million.
TechForward Wins $22M In Best Buy Trade Secrets Suit

By Scott Flaherty

Law360, New York (November 21, 2012, 4:11 PM ET) -- A California federal jury has ordered Best Buy Co. Inc. to pay $22 million for unjust enrichment after finding the retailer willfully stole TechForward Inc.’s trade secrets and breached a confidentiality agreement concerning an electronics buy-back program.

The Nov. 16 jury verdict came after a trial over allegations that Best Buy and two of its affiliates misappropriated TechForward’s trade secrets and breached the terms of agreements the two sides reached after Best Buy approached TechForward for help developing the buy-back program, in which customers can resell devices for store credit worth a percentage of the original price.

The jury determined that Best Buy had stolen trade secrets — which included proprietary data on customers’ use of buy-back plans developed by TechForward, and on the resale values of electronics picked up through the programs — and found that the misappropriation led to the unjust enrichment of the Best Buy entities in the amount of $22 million, according to the verdict form.

Best Buy’s use of the trade secrets was “willful and malicious,” the jury verdict added.

Intellectual property: copyrights

- Protects the tangible way an idea is presented but not the actual idea
- A copyright exists once ideas are transcribed and become tangible
- Recommended that forms are filed with copyright office but not required

- Copyrighted works are protected for the life of the author +70 years
- “work for hire” – protected date of publication +95 years

- Two types of work that may be copyrighted
  - Original work
  - Derivative work

- Easy to meet the originality requirement for copyright (“the work owes its origin to the author”) but difficult to prove copyright infringement and assign a penalty

- The owner of a copyright has rights over the reproduction, distribution, and sale of the work

- “work for hire”
  - a work produced by an employee of a business
  - Copyright belongs to the business
Intellectual property: copyrights

• *Fair use* of copyrighted materials will not constitute an act of infringement
  – News reporting
  – Teaching
  – Research or scholarships
  – Criticism

  – Activity should be nonprofit in nature and should not decrease the value of the work
1. Can investigators post PDF’s of their articles on their group websites?

2. Many literature group meeting presentations are posted on group websites as an educational resource for other researchers. However, these presentations may contain figures or images from the literature. Are there copyright issues? How could they be resolved?

3. Is it alright to prepare a compendium of photocopied textbook chapters for a graduate course and hand them out to your students free of charge?
Carla is in medical school at State University. While taking a course that required extensive memorization, Carla developed a computer program that generates flash cards and quizzes from information and definitions provided by her instructor, the text, and the course website. This program was very helpful to Carla and she decides to use it for all of her classes. Carla develops a database to keep her material organized. She maintains the database on her personal computer. Carla tells some of her friends about her program and other students also hear about her program and want to use it. Carla decides this is a good way to make extra money. Carla expands the database and adds all of her computerized notes and definitions from her previous courses over her past 2 years in medical school. This includes information taken from her textbooks, previous exam questions, web pages, and lecture notes. Carla is careful to cite the appropriate sources for the information. She then charges students 40$ for the program and 15$ for course information within the database. Are there copyright issues that arise from this scenario? Would it matter if Carla only charged for the program and not the database? Can State University claim intellectual property rights to Carla’s program?
A new faculty member, Dr. Murray, is assigned directorship of a laboratory safety course. Since the course has no syllabus, over the course of two years, he writes a syllabus containing useful reference materials, well-documented procedures, and problem sets. This material is published on a website. However, after four years, Dr. Murray’s contract is not renewed, and upon leaving he removes the course syllabus from the university computer. When he finds a new institution, he uses these materials in a comparable course. When the department chair from his original institution, Dr. Bell, finds that the website and materials are missing, she confronts Dr. Murray. He claims that he owns to copyright and Dr. Bell’s university can license the site from him for $1000 per year. Dr. Bell claims that because she assigned him the laboratory safety course, the website was done on a work-for-hire basis, and her institution owns the copyright. Comment on the legal aspects of this scenario. Were Dr. Murray’s actions ethical?
Intellectual property: patents

- Intellectual property granted by the U.S. Patent and Trademark Office (PTO) to an inventor
  - Gives exclusive rights to the inventor to prevent others from using, making, or selling invention
  - Grantee must provide full disclosure

- Patent law is specific to individual countries

- Patent length is 20 years from the filing date and not renewable

- Patents can be sold or licensed to others

- Narrow provision in patent law that allows use of an invention for research purposes
  - For many years academic researchers believed they were protected from patent infringement under this exemption
Intellectual property: patents

Madey v. Duke University

United States Court of Appeals for the Federal Circuit
307 F.3d 1351 (2002)

Facts

In the mid-1980s, Dr. John M.J. Madey (“Madey”) (plaintiff) was a tenured research professor at Stanford University where he headed a well-respected free electron laser (“FEL”) research laboratory and owned several patents practiced by some of the lab’s equipment. Subsequently, Madey left Stanford for the physics department at Duke University (“Duke”) (defendant) where he was named director of a similarly-situated laser research lab. Madey also moved the equipment from the Stanford FEL lab to the Duke campus. After nearly a decade at Duke, Madey and the university had a falling out when Madey complained that Duke wanted to use the lab’s equipment for research areas outside the allowed scope of government funding. Duke subsequently removed Madey as lab director and Madey resigned in 1998. Duke continued to operate some of the equipment in the lab and Madey brought suit against Duke for patent infringement in the U.S. District Court for the Middle District of North Carolina. The district court granted Duke’s motion for summary judgment, holding that the experimental use defense applied to the university’s use of Madey’s patented laser technology. Madey appealed.
Intellectual property: patents

To be patentable, a subject matter or invention must be
- **Product of human ingenuity**
  - Human invention = does not exist in nature

- **Novel**
  - Must be new and innovative, not previously patented or disclosed

- **Nonobvious**
  - Must not be obvious to a person trained in the relevant discipline

- **Useful**
  - Must serve a worthwhile purpose
  - Example: Genome sequence data can not be patented, DNA patents must specify a use for the DNA in drug development, bioengineering, or diagnostics

- **Reduced to practice**
  - Someone trained in the field must be able to make use of the invention
  - Must be able to explain in enough detail that it is useful

- **Clear cut examples**
  - Benjamin Franklin – lightning makes static electricity, invented lightning rod
  - Galileo – Jupiter has moons, invented a telescope

- **Less clear in biotechnology world**
  - Digitalis occurs naturally in a plant, but humans can isolate a purified form digoxin
  - Mice exist in nature, but humans can create genetically altered mice with genes for specific human diseases
  - Natural stem cells occur in the human body, but the cell lines can be cultured and purified
**Intellectual property: patents**

- Patents should be filed as soon as the invention is reduced to practice
  - In the US, patents should be filed within one year of the first disclosure

- June 8, 1995 - provisional patent application
  - Less formal, less expensive
  - Should be filed before any public disclosure
  - Lasts for 12 months
  - Just a step in the process, formal application should be filed within one year
  - Establishes official US patent application filing date for the invention
Previously, the US was the only country with a “first to invent” policy
- Rewards the first inventor
- Fighting a patent dispute would be prohibitive to a small vendor
- Having sufficient time to prepare patent application leads to more complete applications, more complete disclosure, and more time to reduce the invention to practice

March 16, 2013, the US adopted a “first to file” policy
- Consistent with other countries
- Simple system
- US is still unique because retains the one year grace period after public disclosure
- Provisional patent applications become more important

Bayh-Dole Act (1980)
- Created to encourage patenting in universities and facilitate technology transfer from universities to the commercial marketplace
- In 1980, the federal government held title to 28,000 patents, but fewer than 5% were licensed to industry
- Madey v Duke University
- The act confers to universities and non-profit institutions the rights to discoveries resulting from federally-funded research
  - A portion of the revenue received from licensing the invention must be shared with the inventors; the remaining revenue must be used to support scientific research or education
  - File patent within one year
  - Use or sell majority in the US, manufacture majority in the US

Patent system encourages public disclosure in exchange for intellectual property rights
- Some companies use the system to prevent competition
- “blocking patents”
- Pharmaceutical companies strategize when releasing new drugs

Patent law and biotechnology

- **Lowell v. Lewis** (1817): to be patentable, an invention must be “useful” and must “not be frivolous or injurious to the well-being, good policy, or sound morals of society”
  - Moral utility is not a standard in patent law
  - Definition of useful becomes very important when talking about biotechnology patents

- **Diamond v. Chakrabarty** (1980)
  - Incorporation of multiple plasmids into a single bacterium that was capable of breaking down oil spills faster and more efficiently
  - Patent application included method of purifying bacterium, inoculum of the carrier material, and the genetically engineered bacterium
  - U.S. supreme court ruling that a human invention “is anything under the sun made by man”
  - Nonhuman life forms can be patented if there is evidence of human intervention in their creation

http://bannerwitcoff.com/_docs/library/articles/Chakrabarty.pdf
Patent law and biotechnology


  – Method for determining the ideal dosage of thiopurine drugs in treating autoimmune diseases
  – People metabolize the drug differently so doctors need to work hard to find the correct level to administer
    • The inventors discovered that the drug was most effective when the concentration of a particular metabolite in a blood sample fell within a narrow window
  – The patent recited method uses a fairly typical series of steps
    • administer the drug, determine the level of the metabolite, and if it falls outside of the window, the next dose should be decreased or increased for optimal effectiveness

  – Mayo bought and used the kits sold by Prometheus until 2004 when they began to perform their own diagnostic testing

  – Diagnostic methods that involve observing a natural correlation are not patent eligible because the relationship between the metabolite concentration and the optimized dosage was a "law of nature"

  – The courts found that the first two steps cited in the patent were just “data gathering” and the third step was not patent worthy

  – Critics say this will stunt the growth of personalized medicine (use of an individual’s genetic code to prevent, diagnose, and treat disease)
Patent law and biotechnology

- **Association for Molecular Pathology v. Myriad Genetics**
  - Case that challenged the validity of a patent owned by Myriad Genetics that covered isolated DNA sequences
    - Patent covered BRCA1 and BRCA2 genes and certain mutations that indicate a high risk of developing breast cancer
    - Patent allowed Myriad complete control over diagnostic testing and future research
  - Isolated DNA that does not exist alone in nature can be patented
  - cDNA can be patented
  - Myriad found the location and sequence of BRCA1 and BRCA2 but they did not invent anything
  - Patients perspective
    - Myriad’s use of the patents made it impossible to get a second opinion
    - Kept the cost of testing very high by eliminating competition (~4000$)

Obtaining a patent

- File a patent application with the patent and trademark office (PTO) in Washington, D.C.
- Biotechnology – patents take 3-5 years

- Inventor files a disclosure
  - Title and description of the invention
  - Thorough and concise description of the invention
  - Justification of why it is novel, how is it useful, what are the advantages, are there related prior patents
  - What are the disadvantages of the invention
  - Is the invention related to any prior work in the literature or the patent database
  - Describe commercial interest in the patent
  - Brief summary of the invention that can be publically disclosed
  - Provide dates of earliest conception, first disclosure, and first reduction to practice

Genetic technology and scientific integrity

• Human Genome Project (1990-2003)
  – Provided genetic mapping and DNA sequence information for ~30,000 human genes
  – Advancements in DNA diagnostics and therapeutics

  – Raised two main ethical issues
    • Genetic Engineering - prevention of disease using gene therapy
      – Duty to alleviate suffering and duty to respect human life
      – Harvesting of embryonic stem cells - controversial
      – Somatic – alters ones body cells and resulting changes are limited to that person, consistent with medication, localized risks
      – Germline – risks extend across generations
      – Enhancement engineering – can one be enhanced without creating other side effects?

  • Genetic Information
    – Mandatory genetic screening – jobs, insurance companies
    – DNA evidence and “genetic dogtags”
    – If one tests positive for disease, what are the available options for medication or to ameliorate the disease?
    – Will a patients relatives be informed if they are also at risk for the disease?
    – As more genetic tests become available, which ones should be universally administered to newborns?
    – What role should parental consent play in determining when children are screened?

http://www.actionbioscience.org/genomics/carroll_ciaffa.html
Genetic technology and scientific integrity

• Dilemmas
  – Validity and accuracy of the test
  – A person's welfare may or may not be enhanced by knowing they have a predisposition to a disease
  – Can not accurately predict the future and whether therapies or cures will be developed
  – Quality of life can not be predicted by genetic tests
  – Confidentiality of genetic information and test results
  – Use of genetic information for pre-employment screening
A 26-year old woman who has just had surgery for the removal of a parathyroid adenoma is found to carry a mutation on exon 11 for the RET proto-oncogene. You inform her that this test result is diagnostic of multiple endocrine neoplasia type 2. Since the inheritance pattern of this disorder is autosomal dominant, each of her 6 siblings as well as their children are at risk and should be screened so that a lifesaving prophylactic thyroidectomy can be performed on those who test positive. However, the woman informs you that she is on very bad terms with the rest of her family and refuses to contact them with this genetic information. Should you contact the relatives and urge them to be tested?