Intellectual Property Considerations in Research

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Why should I worry about IP in collaborations?

- You’re using my technology beyond the scope of our agreement! (infringement)
- You can’t talk about that at a meeting because it’s proprietary information (NDA violations)
- Who owns this fabulous invention?
May be an issue when collaborating another company.

The second company may provide proprietary information (trade secrets) under a Non-Disclosure Agreement (NDA)

The NDA may limit what can be disclosed/discussed e.g. at a conference or in a publication (this can limit what can be disclosed/discussed with another party or at a meeting)
Who owns the widget?

- Under US laws, each inventor is presumed to be a 100% owner of the invention, unless there is an agreement otherwise.
- This means that each inventor can separately develop, market, license etc. the invention.
Ownership

- Vests originally in inventors
  - There may be an obligation to assign
- Patent can be assigned (i.e. ownership transferred)
  - Should record at PTO in order to avoid a subsequent purchaser for value and without notice
Who owns the widget?

- Ethicon Inc. v. United States Surgical Corp.

- Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.
Ethicon v. U.S. Surgical (Fed. Cir. 1998)

- Dr. Yoon is an MD who invented devices for endoscopic surgery.
- In 1980 Dr. Yoon asked Mr. Choi (an electronics technician) to help him with some projects. Mr. Choi was not paid nor was there any contractual obligation for Mr. Choi to assign his patent rights to Dr. Yoon.
- In 1982 the collaboration ended.
- In 1982 Dr. Yoon filed a patent application on a “safety trocar” (surgical instrument) and named himself as the sole inventor.
- In 1985 the patent issued and Dr. Yoon granted Ethicon an exclusive license.
Ethicon v. U.S. Surgical  
(Fed. Cir. 1998)

- In 1989 Ethicon sued U.S. Surgical for infringement of the patent.
- U.S. Surgical met with Mr. Choi and obtained a license from Mr. Choi to use safety trocars to which he contributed the development.
- U.S. Surgical then filed a motion to
  - 1) have Mr. Choi added as an inventor of the patent and
  - 2) have the infringement suit dismissed on the basis that Mr. Choi, as a joint owner of the patent, had granted U.S. Surgical a license to use the invention.
The technology (methods of quantifying HIV using PCR to evaluate therapeutic efficacy of HIV drugs) was developed by researchers at Stanford U. and Cetus.

In 1988 Dr. Holodniy joined Stanford as a research fellow.

Dr. Holodniy signed an agreement obligating him to assign his rights to any inventions to Stanford.

Dr. Holodniy worked with Cetus in the course of his research and signed a “Visitor’s Confidentiality Agreement” with Cetus, which included an assignment of rights to any inventions that were made “as a consequence” of the work at Cetus.
Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.

- Stanford sued Roche for infringement
- Roche asserted ownership of the patent based on the Visitor Confidentiality Agreement signed by Dr. Holodniy.

**Who owns the patents?**

- The agreement signed with Stanford stated, “I agree to assign or confirm in writing to Stanford and/or Sponsors that right, title and interest in ... such inventions as required by Contracts or Grants.” (emphasis added)
The agreement with Cetus stated the Dr. Holodniy, “**will assign and do[es] hereby assign** to CETUS, my right, title, and interest in each of the ideas, inventions and improvements”. (emphasis added)

The court held that the contract language “‘agree to assign’ reflects a mere promise to assign rights in the future, not an immediate transfer of expectant interests”

In addition, Stanford's *Administrative Guide to “Inventions, Patents, and Licensing”* states: “Unlike industry and many other universities, Stanford's invention rights policy allows all rights to remain with the inventor if possible.”
In contrast the language in the Cetus agreement of “I will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements” was an immediate assignment of future inventions to Cetus.

Roche therefore had title to the invention.
Who owns the widget?

- There needs to be a clear assignment of ownership (not a promise of assignment).

- It is important to have an agreement in place before the research starts.
Research Agreement

- What should be put into the research agreement
  - What is the scope of the research?
  - Who will pay for the research?
  - Who will pay for any IP associated costs, e.g. costs for obtaining the patent?
  - Who will own any inventions that arise from the research? Are there any restrictions on the ownership?
  - Are there any restrictions on disclosure?
The Cooperative Research and Technology Enhancement (CREATE) Act

- Promote collaborative research by promoting communication among researchers located at multiple organizations;
- Discourage those who would use the discovery process to harass co-inventors who voluntarily collaborated on research;
- To increase public knowledge; and
- To accelerate the commercial availability of new inventions
“(c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—

- Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—
AIA – America Invents Act

- “(1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;
- “(2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement;

and

- “(3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.
AIA – America Invents Act

- Changes to grace period exception – (applies to applications first filed on or after March 16, 2013).
- AIA maintains a limited “grace period” for a disclosure of the invention by the inventor or for an inventor-originated disclosure.
AIA – America Invents Act

- 35 USC 102(b)(1)(B) -

“A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if….

(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.”
On February 14, 2013, the USPTO published Guidelines regarding first inventor to file under AIA, including example scenarios.

“If the inventor or a joint inventor had publicly disclosed a genus, and a subsequent intervening grace period disclosure discloses a species, the intervening grace period disclosure of the species would be available as prior art under AIA 35 U.S.C. 102(a)(1). Likewise, if the inventor or a joint inventor had publicly disclosed a species, and a subsequent intervening grace period disclosure discloses an alternative species not also disclosed by the inventor or a joint inventor, the intervening grace period disclosure of the alternative species would be available as prior art under AIA 35 U.S.C. 102(a)(1).(emphasis added) Federal Register, Vol. 78, No. 31, Part IV, page 11077.”
AIA – America Invents Act

- What this may mean practically -

Example 1 -
- Company A attends a conference and presents a very general disclosure (genus) of the invention in hopes of attracting investment money or a research partner.
- A enters a research agreement with Company B and A + B subsequently publically discloses an exemplified embodiment (species) of the invention prior to the patent application being filed by A.

The disclosure of the species by A + B would likely prevent A from obtaining a broad patent on the general invention because the disclosure of the species by A+ B would be considered to anticipate the entire genus.
Example 2 –
- A + B disclose an obvious variant (alternative species) of the invention,

= A may not be able to obtain a patent unless it can be shown that what is claimed is not obvious over the alternative species. (A will not be able to rely on their earlier disclosure of the invention and assert the disqualification under 35 U.S.C.§102(b)(1)(B) of B’s disclosure as prior art.)
The “hidden costs” that can come from government funding - Bayh-Dole Act
History of the Bayh-Dole Act

- In the late 1970’s it was perceived that the US had lost its industrial edge.
- The number of patents being filed every year was declining.
- The US Gov’t owned 28,000 patents, with only 4% being developed commercially.
- A closer look at the US owned patents, showed that they were mostly from universities and the result of Gov’t research grants.
The Gov’t patents were also directed to basic research findings that were nowhere near a marketable product.

The private sector had little interest in developing the technology of the Gov’t patents because the Gov’t would not transfer ownership of the patents.

The Bayh-Dole Act was designed to bring together the basic research funded by the Gov’t with the development money of the private sector.
Bayh-Dole Act - Policy and Objectives
(35 U.S.C 200)

1) Use the patent system to promote the utilization of inventions arising from federally supported research
2) Maximum participation of small business firms in federally supported research
3) Promote collaborations between commercial concerns and NPOs
Bayh-Dole Act

4) Promote commercialization and public availability of inventions made in the US by US industry and labor

5) Ensure that the Gov’t obtains sufficient rights in federally supported inventions to meet the needs of the Gov’t and protect the public against nonuse or unreasonable use of inventions

6) Minimize the costs of administering policies in this area
1) Ownership by the funding recipient

Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention...
2) Disclosure requirements

i) Every contract is required to have provisions requiring that the contractor disclose back to the Gov’t any inventions. Failure to comply with the requirements may result in the Gov’t taking title of the invention. *Campbell Plastics*

ii) The contractor must tell the Gov’t within two years of disclosure of the invention to the funding agency whether the contractor will take title of the invention. Failure to timely elect title allows the Gov’t to assume ownership of the invention.
iii) The contractor must agree to file a patent application for any invention in which they elect to retain title.

iv) Any patent application filed must include a statement that the invention was made with Gov’t funding and that the Gov’t has certain rights in the invention.
3) **Rights retained by the Fed. Gov’t**

Even if the contractor elects to retain title of the invention, the Gov’t still gets a nonexclusive, nontransferable, irrevocable, paid-up license throughout the world.
What are the potential ramifications of failure to comply with the requirements of Bayh-Dole?

Campbell Plastics Eng. & Mfg. Inc. v. Brownlee

✓ Campbell Plastics received funding from DOD as a small business

✓ Campbell had continual communication with DOD keeping the Army informed on the progress of the projects and developments

✓ BUT, Campbell was also required to complete a DD Form 882, which is used to report any inventions

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Campbell Plastics Eng. & Mfg. Inc. v. Brownlee

Campbell either said there was no inventions on the DD Form 882, or didn’t complete the form at all.

Campbell then obtained a patent for some of the technology developed under the funding.

Based on Campbell’s non-compliance regarding the invention reporting requirements with the DD Form 882, the Gov’t assumed title of the invention.

Moral:
Campbell Plastics Eng. & Mfg. Inc. v. Brownlee

- **Total Assignments:**
  - Patent #: 5895537
  - Issue Dt: 04/20/1999
  - Application #: 089478
  - Filing Dt: 10/09/1997
  - Inventor: RICHARD G CAMPBELL
  - Title: SONIC WELDED GAS MASK AND PROCESS

- **Assignment:**
  - Reel/Frame: 011828/0396
  - Recorded: 05/15/2001
  - Pages: 6

- **Conveyance:** CONTRACTING OFFICER'S FINAL DECISION LETTER

- **Assignor:** CAMPBELL PLASTIC ENGINEERING & MFG., INC.
  - Exec Dt: 12/15/2000

- **Assignee:** UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY OF THE ARMY
  - Washington, District of Columbia 20515
  - Correspondent: U.S. ARMY SOLDIER & BIOLOGICAL CHEMICAL COMMAND ANSSB-CC/ BLDG E4435 (VICKI UPCHURCH) 5183 BLACKHAWK ROAD APG MD 21010

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The Federal agency under whose funding agreement the subject invention was made shall have the right to require the contractor, an assignee, or exclusive licensee...to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself,
March-In Rights (cont.)

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.
Who can exercise March-In Rights?

- 1) A potential competitor company*

- 2) A non-profit group, who wants the market open to other companies, usually to lower the price*

- 3) The Federal Gov’t

*through a petition to the Federal funding agency
Johns-Hopkins University owned several patents to stem cell separation technology that had been developed with NIH funding.

J-H licensed the patents to Baxter.

Baxter sued Cell-Pro under the patents for their stem cell separation device.

Cell-Pro lost the infringement suit, but then petitioned NIH to exercise March-In Rights.
Cell-Pro relied on the first clause of the March-In Rights:
“(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use”

NIH declined to exercise March-In Rights because the Baxter device was in the final approval stages and because Baxter had agreed to take steps to make sure that a stem cell separation device was adequately available.
Norvir (Abbott) and Xalatan (Pfizer) are products of significant interest. Essential Inventions (EI), a public interest group, petitioned NIH to exercise March-In Rights for both Norvir and Xalatan. Both petitions were based on the pricing of the drugs.
Norvir (Abbott) and Xalatan (Pfizer) (cont.)

EI based the petition on clause (2) of the March-In Rights: (2) action is necessary to alleviate health or safety needs which are not **reasonably** satisfied by the contractor. EI argued that the high pricing of Norvir and Xalatan meant that the contractor was not “reasonably” satisfying the health needs that are treated by these drugs.
Norvir (Abbott) and Xalatan (Pfizer) (cont.)

After hearing testimony from numerous parties, including Senator Bayh, the NIH concluded that March-In Rights under Bayh-Dole Act were not intended to be a means of price control and both petitions were denied.
Where do things stand now?

- So far all petitions for March-In Rights have failed, but it is still a viable avenue to gain access to patented technology funded by the Gov’t.
- Failure to properly follow the Gov’t procedures can result in loss of the patent rights by the contractor.
Preference for U.S. Industry
35 U.S.C. 204

no small business firm or nonprofit organization which receives title to any subject invention and no assignee or nonprofit organization shall grant to any person the exclusive right to use or sell any invention in the US, unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. – Can be waived under appropriate circumstances
Questions?

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