



If Necessity is the Mother of Invention, then Who's Your Daddy?

A brief overview of intellectual property rights in academia

By Amy Spicer



On occasion my office will be asked to review a contract on behalf of a faculty member who wishes to pursue consulting with a biomedical company, typically a drug or device manufacturer. These consulting arrangements occur through license agreements between the university and a company that plans to commercialize an invention owned by the university. The company may wish to have the expert advice of the inventor in order to best prepare to go to market with that invention. The advice of the inventor can also help companies with the rigorous steps required in an FDA approval process for new drugs and devices.

Often, these contracts specify that any invention or intellectual property (IP) developed by the faculty member during the consulting project will be the property of the company. According to the University of Michigan Technology Transfer website, IP is defined as “inventions and/or material that may be protected under the patent, trade-

mark and/or copyright laws, and sometimes by contract.” Yet these IP clauses in consulting contracts can conflict with policies at many universities, notably, Michigan, California, Minnesota, Cornell, and Stanford. The policies typically hold that the university has the first right of ownership of IP that is created by a faculty member employed by that university. Usually under these policies, the royalties from licensing an invention will be shared among the university, the inventors, and the schools and/or departments in which the inventors hold an academic appointment.

Notably, at Cornell, a faculty member may request permission to separate his or her effort related to an outside activity from effort at the university, so that IP developed during the outside activity will not fall under the university’s claim of ownership over faculty created IP (Cornell University, 2015).

An agreement to license IP will set out the rights and responsibilities related to the use and commercialization of IP. These agreements usually stipulate that the licensee must

work to bring the IP to use for the public good. In general, a licensee is selected based on whether the university believes the company will be able to commercialize the technology for the benefit of the general public. In some cases, the university will choose a start-up company as the best licensee due to the start-up’s focus and intensity on developing the invention. Other times, an established company with proven experience in similar technologies and markets can be the most successful choice (University of Michigan Tech Transfer, 2014).

IP rights can also be an issue when faculty members sign agreements with other institutions to do research; the issue of who owns any IP developed during the course of that research can be sticky. In these cases, investigators should be sure to involve their university’s office of technology transfer. That way, an “inter-institutional” agreement can be entered into wherein one of the institutions will take the lead in protecting and licensing the IP, sharing expenses associated with the patenting process and allocating any

licensing revenues (University of Michigan Tech Transfer, 2014).

The University and Small Business Patent Procedures Act of 1980, better known as the Bayh-Dole Act, gave universities the right to claim title to inventions created through research supported by federal funding. It was intended to be an economic development initiative to link academic innovation to the overall economy. Prior to the Act, rules about patent rights were varied, depending on the federal agency providing the funding. The overall government approach was that no single company should benefit from publicly funded research; therefore, only non-exclusive licenses would be granted. This deterred many companies from applying for licenses for academic inventions, due to the financial risks of investing in development of the invention, only to have competitors license the same invention once they knew it would be commercially viable. In 1978, there were 28,000 patents for inventions created through federally-sponsored research. However, less than 4% of those had been licensed (Loise & Stevens, 2010).

Before the Bayh-Dole act was implemented, no new medications developed through federally funded research at universities had been brought to market. Since the act went into effect, there have been more than 150 FDA approved drugs marketed for various diseases including cancer and HIV (Landrino McDevitt et al, 2014). In 2015 at the University of Michigan, there were a record 164 option and license agreements signed, and 160 U.S. patents issued for items as varied as new surgical instruments, genome sequencing software, and a massive open online course for contract law (Guest, 2015). Since the implementation of the act, rather than gathering dust on some federal agency shelf, inventions developed at universities have been patented and licensed so that they can be used to help patients and physicians around the world.

One pivotal case related to the Bayh-Dole Act was the 2011 Supreme Court decision in *Stanford University v. Roche Molecular Systems*. At the center of the dispute was ownership of a patent on a popular diagnostic test for HIV which had been developed by a Stanford faculty member, Mark Holodniy, working in partnership with scientists from Cetus. When Dr. Holodniy began working at Stanford, he agreed to assign invention rights to

his employer. However, when he visited Cetus, a small biotechnology company later acquired by Roche, he signed a confidentiality agreement that included a clause assigning invention rights to Cetus. Roche commercialized the assay developed by Holodniy and Cetus, and Stanford approached Roche for a share of the proceeds. However, negotiations between the company and the university were not fruitful, and Stanford filed a patent-infringement lawsuit against Roche. The Supreme Court ruled in favor of Roche, finding that Dr. Holodniy's confidentiality agreement with Cetus was superior to the agreement with Stanford (Kesselheim and Rajkumar, 2011).

An important lesson from this case is to foster a greater awareness among our researchers of the importance of IP clauses in contracts. Creating a balance between ensuring independence of judgment and fostering the transfer of inventions to use for the public good is a delicate task. University policies, federal regulations, and professional society guidelines, to a certain degree, have been created to support the innovative process while protecting subjects from harm.

So, to keep your researchers out of any messy situations, i.e., having to answer a "Who's your daddy?" question about their inventions, here are a few helpful tips regarding IP rights when entering into contracts:

- Do not sign any contract without reading it thoroughly. For example, watch out for clauses that would give away all of your IP rights, not just the rights related to the IP developed during the consulting engagement.
- Researchers should always have a personal attorney review any contract before signing it, since the contract would be an agreement between the researcher as an individual and the company, rather than a contract involving the university as the researcher's employer.
- Be aware of your institution's policies on IP rights. The policies are generally available on the university website. When in doubt, reach out to the technology transfer office for guidance.
- Before signing a consulting contract, check with your university technology transfer office, office of research, or conflict of

interest office to be sure that your rights and the university's rights are protected. ■

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Interested in learning more about IP?

Check out NCURA's micrograph, *A Primer on Intellectual Property* or Online Tutorial *Intellectual Property in Research Agreements* at www.ncura.edu



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