

Learning how to get along with others

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A veteran of the tech transfer business offers guidance on how to manage interuniversity research—and how to avoid the wrangling over IP that often accompanies invention.

Although I occasionally deal with a very senior faculty member who wishes for the ‘good old days’ when you didn’t need a material transfer agreement (MTA) to send a plasmid to a former graduate student, that world is gone forever. It takes more time and effort to collaborate today. The purpose of this article is to provide tips and insights into what you can do to prevent problems when collaborating with another university and to suggest issues that can arise when two institutions manage jointly owned intellectual property (IP).

Before the collaboration

The importance of IP within academia is increasing, and although the reasons for this are complex, the primary factors are somehow related to money (**Box 1**). So before initiating any collaboration with another laboratory, it’s wise to have a discussion about IP. This isn’t the time to determine that monies will be divided 70/30, but it helps to know if your collaborator has already started a company and is hoping for new IP to fuel it. Likewise, you should inform your collaborator if you already have multiple patents in the field and your technology transfer office is marketing them to the pharmaceutical industry. In short, it’s never wise to assume that your potential collaborator has the exact same goals as you, because they almost never do.

Before starting work, set up a semi-detailed work plan. It should describe which laboratory will perform which tasks and which scientists and resources will be involved. You can probably get a preliminary plan by just answering the questions: who, what, when, where and how?

When the work plan is in place, visit your technology transfer office. Because of a court

decision in the 1990s (the *Oddzon Products, Inc. v. Just Toys, Inc.* ruling¹) and a piece of 2003 federal legislation called the Cooperative Research and Technology Enhancement (CREATE) Act², it is vital to have a Joint Research Agreement (JRA) before beginning a collaboration. Entrepreneurs should read more about the Oddzon case, but the basics are that Oddzon—a toy football company—received an idea for a ball with tailfins under a confidentiality agreement from an independent inventor. Oddzon did not make that exact new ball but made one very similar to it. It received a patent on its design and proceeded to sue anyone selling a similar product until a company finally challenged Oddzon’s patent, which was held to be invalid because Oddzon had failed to inform the patent office of the confidential design

disclosed to it by the independent inventor. It was ruled that whereas the Oddzon design was different, it was ‘obvious’ in light of the independent inventor’s design.

The upshot of this case is that applicants are now required to give the patent office all references, not just published references. You can imagine how difficult this can make a research collaboration if all e-mails between scientists can be considered prior art against a patent application filed by one of the universities. Clearly, that is not a good thing. The CREATE Act attempts to fix this problem by allowing two parties who have signed a JRA not to use such “secret prior art” (that is, e-mails, telephone conversations) against one party’s patents. Unfortunately, JRAs are built around the scope of work being performed, so it isn’t possible

Box 1 Reasons for the rise in IP importance

The academic world is very different from that of 20 or even 10 years ago. Here are some reasons why:

- The passage of the Bayh-Dole Act in 1980. This legislation allowed universities to own the patents generated from federally funded research. Most universities had scant technology transfer operations before Bayh-Dole and had to hire staff. As in any new profession, the number of skilled practitioners was small at first. However, over a 20-plus-year period several ‘generations’ of true professionals have been trained. Simply put: there are now a fair number of technology transfer professionals who know what they are doing.
- The technology bubble of the late 1990s. For better or worse, the ‘irrational exuberance’ caused scientists, technology transfer professionals and venture capitalists to speculate about what was possible, and form startup companies. Although the bubble popped, the spirit remains.
- The explosion in the size of federal research funding. My institution is primarily a US National Institutes of Health grantee and our research budget has grown from ~\$85 million when I joined in 1998 to ~\$200 million in 2007. This has led to roughly twice as many inventions and patents. It is a higher-volume activity than it was just 10 years ago and thus more visible.
- The need for universities to find new sources of revenue as they try to grow and remain competitive in attracting and retaining top students and faculty. Where else is the money to come from?

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Box 2 Dos and don'ts of laboratory notebooks

- Do use a notebook that is bound.
- Do write legibly in permanent ink.
- Do date all pages unambiguously using month, day and year.
- Do explain experiments in as much detail as possible.
- Do attach graphs, charts, gels and other data to the notebook with glue and explain their significance in writing.
- Do sign and date each page.
- Do have each page witnessed.
- Don't rip pages out. Never, ever remove pages.
- Don't erase. Correct errors by drawing a single line through the mistake. Initial and date the correction.
- Don't skip pages.

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to simply enter a one-size-fits-all blanket JRA. Most technology transfer offices are not any happier about this extra paperwork than scientists are, but the good news is that it is possible to create a JRA that can be reused for almost all circumstances. This also is a great time to touch base with the technology transfer office on the status of your research. Sometimes it is a good idea to file a patent application before beginning the collaboration to clearly lay down what is yours. Your technology transfer office can help you with this.

Another important point to note is that the scientists cannot make any determination about who is the inventor before a patent filing. I have seen numerous semi-formal 'collaboration' documents prepared by the scientists that state that "all inventions will be jointly owned." This is appropriate for authorship, but not for inventorship. I cannot emphasize that enough: inventorship on patents is a matter of patent law and must be determined by a patent attorney. In fact, patents that improperly include or exclude people from the list of inventors are likely to be invalid.

During the collaboration

Perhaps the most important thing to do during the collaboration from an IP standpoint is to keep a proper laboratory notebook (**Box 2**). The laboratory notebook is the seminal document for determining who is the inventor and for establishing an invention's conception date. It's my impression that quality notebooks are becoming a lost art in academia and it seems many records are kept in scientists' e-mail folders. That is convenient, but it's not very helpful from an IP standpoint. There are newer, electronic laboratory notebook products that claim to timestamp entries, but they have not yet been certified in court for documenting the date of invention for a patent. Until that day,

the old standby, the bound paper notebook, is the way to go. A well-maintained laboratory notebook comes in very handy if there later is a dispute about IP. A proper laboratory notebook can defuse a situation in which a collaborator attempts to leave you off a patent that you should be an inventor on, and prevents an invention that is 100% yours from being filed as a joint patent application.

Here's another tip: keep your technology transfer office informed of planned publications. The publication of your ideas (unless you filed a patent application first) means the loss of patent rights outside the US and sets the clock ticking on a one-year grace period to file your US patent application. There is proposed legislation that will eliminate the grace period and require even US patent applications to be filed before publication. This applies not only to manuscripts and abstracts, but also to theses written about the work by graduate students in your collaborator's laboratory. Federal grants also count as publications as of the date of the award letter. It's always good to let the technology transfer office know that you have received a fundable score on a grant application.

Obviously, your collaborator could have different publication needs and goals, and these might cause you difficulty in patenting your invention. Consider a collaboration between a chemistry laboratory at one university and an animal researcher at another school. The chemistry laboratory can publish as soon as the synthesis of a new compound is nailed down. However, the universities' technology transfer offices will likely be reluctant to file patent applications until the new compounds have at least demonstrated some efficacy *in vitro*. The difficulty is that if the chemistry manuscript contains a phrase in the discussion section that the compounds "may have utility as a pharmaceutical agent or pesticide"—even

though there are zero data in the publication to support the claim—the animal researchers who later try to patent the compounds as a pharmaceutical agent may have the initial publication used against their application. This is a thorny situation because the animal researcher clearly shouldn't ask his collaborator not to publish.

The possible solution: it is not unreasonable for the animal researcher to ask the chemist to refrain from making the "pharmaceutical and pesticide" claims. Such a statement without data to support it adds little to the manuscript and potentially steals the animal researcher's thunder when he or she publishes *in vitro* findings.

So, you have an invention

The first step to take after invention is to discuss it with your collaborator. Once you and your collaborator agree that you have something worthwhile, you should both disclose the invention to your respective technology transfer offices. These offices vary on whether they will accept another school's invention disclosure forms (an internal document for informing the technology transfer office of your invention). Personally, I don't care so long as it contains the proper information, but some offices insist on proper procedure, especially at larger schools.

Once the technology transfer offices have the paperwork, several discussions then proceed out of the scientists' view. The technology transfer offices confer about basic questions, such as, "Is this invention worthwhile?" If the answer is "no," then the remainder of this article becomes moot. But if it is worthwhile, the technology transfer offices will begin to work on an interinstitutional agreement (IIA). IIAs are documents that specify how the joint invention will be commercialized. At its most basic, the IIA is an agreement that neither party will license out the rights in the joint patent independently.

The two sides also should decide which university will 'lead'—or, have the primary contact with the patent attorney, pay the bills, conduct the marketing, negotiate the license agreements, receive the money from the licensee and manage the disbursement to the other school. The decision is based on many things—which university has an established technology transfer office, for instance, or which technology transfer office has more experience licensing inventions in the technical field, or which technology transfer office portfolio complements the new invention—and it is usually clear at a glance which university should lead. In the rare cases where there isn't agreement, the universities could elect not to name a lead and allow both universities to try to find a licensee.

One of the most exasperating experiences for a faculty member is having two technology transfer offices squabble over patent expenses or the division of future licensing revenues. At the end of the day, it is a negotiation and each party's only true power is to refuse to sign a deal with the other university. For some inventions, not having the two universities working together is the kiss of death and the universities tend to reach agreement. For other inventions, it matters less if the universities work together and in those cases most technology transfer offices refuse to compromise.

There are quite a few moving parts on the money side (**Box 3**). If you want to successfully commercialize the technology, finding two technology transfer offices that can work together is as important as finding scientists who can collaborate well. In the US, technology transfer is a small field of ~2,000 professionals, and we all know each other, but we don't necessarily all like each other. I love to get new inventions involving Baylor College of Medicine in Houston (BCM). The BCM technology transfer office has worked well with my office in the past and I've found them to be professional, competent and enjoyable to do business with. On the other hand, there are other technology transfer offices that are so exasperatingly incompetent that I will not waste my time or my institution's money attempting to work with them. Commercializing a joint invention is tricky and both technology transfer offices need to be pretty sharp to pull it off.

The last major topic of discussion is about what rights the trailing university will have to sit at the license-negotiations table. If the technology transfer offices trust each other and have worked well before, there are likely to be no problems. However, if they have worked poorly together in the past, then the trailing university probably wants a full seat at the table. That is a messy and slow situation in which the universities must agree among themselves before signing anything with a company. Consider a situation

Box 3 The cost of inventing

Unfortunately, whenever money is involved, there will be disagreements. The money related issues that technology transfer offices argue about tend to fall into three categories.

- **Patent expenses.** It's often thought that the lead institution should bear 100% of the patent expenses. After all, it is 'in charge' and has direct contact with the patent attorneys. Paying 100% of expenses will likely inspire the institution to find a licensee quickly. Furthermore, it isn't doing anything it wouldn't do if the invention was 100% owned by them. Others suggest that because the two sides will share revenues, it isn't fair for one to cover 100% of the expense but get only a fraction of the return. And, those people argue, the institute is doing things it wouldn't do if it owned the invention outright—namely, exerting 100% of the effort to license the technology, but sharing revenues.
- **Management fee.** The customary request is 15% of revenue capped at a lifetime maximum of \$50,000. Again, some feel the lead school isn't doing anything that it wouldn't be doing otherwise, so there is no reason for a management fee. Others say there are too many things the lead school has to do—copying the partner on patent correspondence, sending reports, answering questions from the trailing university's inventor, dealing with criticism for not finding a licensee, disbursing money to the other university—for there to be no fee. Keep in mind that the administrative tasks last for ~20 years.
- **Licensing revenues.** Benevolent folk feel that revenues should be shared 50/50, or perhaps based on the number of inventors or the significance of the inventors. More aggressive people retch at this thought. They typically think that revenues should be shared in the same ratio that expenses are shared, although that perhaps lessens the potential return to an inventor with a poverty-stricken technology transfer office that cannot pay anything.

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in which one university has an acknowledged top ten technology transfer program and the other doesn't really have a technology transfer operation at all. Does the less experienced university trust the experienced university to do a good job and look after both universities' interests? Or, do they become concerned that the experienced university will cut a better deal for itself? I have seen both cases. In all cases, there is a trade-off to be made between allowing the trailing university to have a voice, and the speed with which a license can be negotiated.

Still, collaboration is important in biotech research and if your goal is to effectively

commercialize technologies, you need to remember two vital things. One, keep excellent records, and two, involve your technology transfer office early and often, and stay engaged with them throughout the process. By doing those things, you can get the most out of your research collaborations.

COMPETING INTERESTS STATEMENT

The author declares no competing financial interests.

1. <<http://www.law.emory.edu/fedcircuit/aug97/96-1550.html>>
2. <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=publ453.108.pdf>