TECHNOLOGY MANAGEMENT AND SPONSORED RESEARCH
Q AND A (10/43)

The Q&A herein are excerpts from "Technology Commercialization Manual. Strategy, Tactics, and Economics for Business Success." (www.tclearningcenter.com). Notation after each heading reflects the (# of excerpts/total Q&A).

The Q&A are for information only. Seek legal or accounting advice for specific situations.

1. Material Transfer Agreement (MTA) rights - A company wants a MTA for a compound that grants them an exclusive, royalty free license under any rights resulting from the use of the sample. They have assured you that no inventions will result from the study, although results must of course be sent to the company and the agreement grants the company the sole right to determine whether and where patent protection will be sought. You dislike the language, and are concerned about the possibility of the company deciding there is patentable subject matter (despite the assurances of the investigator), but your supervisor (who is also the lab director for the post-doc requesting the materials) says sign it unless there is a legal impediment to doing so. What would your concerns be if accepting such terms, given Bayh-Dole or any other law or regulation?

The response to this query depends on these questions: Who is paying for the research and experimentation? What obligations are there to the sponsor?

The financial terms of this type of an agreement are not limited by anything except what the market will bear. Upfront fees vary from a few thousand to tens of thousands. Royalties are in the 5-15% range.

Companies usually do not pay royalties for unpatented biological materials unless they are an integral part of a product. Most biological materials are used as a research tool to help develop a product and are licensed for a one-time payment plus modest annual maintenance fees. The exceptions are licenses under programs that some drug companies have started to obtain exclusive rights to patented biological materials. These companies will pay royalties are usually no more than 2%.

Some organizations prefer to use a biological materials license agreement instead of a material transfer agreement. The two agreements are similar, but the biomaterials license agreement often extends its rights to progeny and mutations resulting from the use of the biological material. However, there are MTAs that do not extend their reach to progeny or mutations. It depends on what the parties are willing to agree to.

If it is the federal govt., then free dissemination of research results (especially tangible products) emanating from a federal grant is a major issue and exclusive rights run counter to that.

If the sponsor is a private entity, then check the sponsorship agreement before signing anything that would create a conflict. If you inadvertently double license, you will be sued.

There is the entire issue of fairness. If a mere donor of materials demands rights that normally are reserved for a full research sponsor, then where is the fairness? Offer a non-exclusive royalty free license for research purposes only and then negotiate from there.

It all comes down to need and greed. If you need the material from the company so much that you are willing to forego compensation of any type, then signing the MTA might be in the best interest of the researcher (provided they realize what they give up in the process). Companies that want royalty-free grant backs say they need them to protect against royalty stacking if the final product uses a combination of patented technologies developed with multiple partners who receive materials under MTAs.

You may want to ask the company if it was their intent to profit from the university-invented patent and share none of the benefit. If they said yes, you may either be dealing with a greedy, stupid, or posturing negotiator. The way it usually fell out was the offer of either a non

royalty-bearing nonexclusive grant back license or an option for an exclusive royalty-bearing grant back license. If the company is motivated by greed, then admit that you are too, and propose a way for them to financially compensate you that does not produce royalty stacking. Although this is usually too complex for an MTA you could ask if they would be willing to fund research or pay a one-time milestone payment. Companies act rationally by offering no compensation at first, because some people are willing to sign this type of agreement.

You might also want to have a senior level university person call a senior level person at the company. Embarrassment can sometimes help.

Lastly, remember that the company may have no real incentive to provide materials that are not on their terms if the material is their crown jewel and they really do not want others working on it.

MTA's can be the bane of academic's existence. The company cannot have a wholly exclusive license if government funds the research; government gets a royalty free, non-exclusive. Also, there is something inherently wrong with a party who does nothing but supply material, albeit valuable/costly/inventive stuff, getting all the rights in an invention made using it + inventor's expertise + other unique reagents + taxpayer dollars (and/or private dollars meant for research).

MTAs are means by which one can transfer proprietary material to another party without transferring any proprietary rights. There are several forms of MTAs, one of which is when payment is exacted to cover the costs of providing the material. If you were to charge much above the cost, then you may run the risk of establishing a first sale bar date if you have not filed a patent application for the material. Universities as well as nonprofit research organizations and commercial companies use material transfer agreements to control their downstream rights to the materials and may legally charge something for the materials as long as it is not excessive and is intended to cover their cost.

Bailment Another form of MTA that can be used is the Bailment Agreement which is used for proprietary material which is not likely to be patented because it is a biological material which will be used as a research tool leading to development usually of diagnostic kits within a year or two and then the products from its use will then be subject to a royalty under the bailment agreement.

The financial terms of this type of an agreement are not limited by anything except what the market will bear. Up front fees vary from a few thousand to 10s of thousands. Royalties are in the 5-15% range.

Bailment is an exception to university policy in that it requires that a trade secret be maintained, i.e., limited access to the biological material.

A bailment requires the recipient to exercise a certain degree of care over the transferred material but at least the same degree of care that they would exercise over their own material of a similar nature. Some universities prefer to use a biological materials license agreement instead of a material transfer agreement.

Agreements with bailments for unpatented, published biological materials can be enacted. Bailments do not always deal with proprietary objects. For example, you are creating a bailment when you park your car in a public parking lot for a fee or take your cleaning to a dry cleaner.

When material is accepted by a University and it is subject to a bailment agreement there may need to be an exception to University policy, to maintain as trade secret. You are addressing the degree to which to which the recipient must comply. It is also the responsibility of the university to also restrict its distribution. It may require a sign-off of a university official to make the exception to policy regarding publication restriction and maintenance of what amounts to a trade secret.

Fees/Price. MTA's terms are usually in the range of $2K-25K up front plus a 5-7% royalty on kits that were produced using biological material transferred under such agreements.

If biological materials are used as a part of the product a royalty is appropriate. Many fee-based MTAs or biological materials licenses are for drug targets used to screen candidate compounds. The drug targets are only used for R&D and not part of a product or used to develop a product so companies will not pay a royalty. The exceptions are those companies that have programs to grant exclusive licenses for patented drug targets. However, only unique patented targets pass their screens.

2. What kind of terms are being received for biomaterials agreements?

- Unpatented cDNA clones: $3,000 - 10,000
- Unpatented cell lines, including hybridomas: $5,000 - 10,000 plus an annual maintenance fee of $3,000-5,000.
- Patented cell lines with unique properties used for drug screening: $30,000 - $50,000 plus an annual maintenance fee of $5,000-$10,000.

Some pharmaceutical companies have announced programs where they will pay much greater fees for patented biological materials used as drug targets. They will pay upfront payments of $50,000-100,000 milestone payments based on drug development, and a 1-2% royalty on sales. The challenge is having a drug target pass their initial screens

3. A large corporation contends that the reporting requirements under 37 CFR 401 provide for certain cases where inventions resulting from government sponsored research do not need to be reported, hence are not subject to the royalty-free, non-exclusive license to the federal government. The contention is based on 37 CFR 401.1.2b, which states, in part: "In accordance with 35 U.S.C. 212, no scholarship, fellowship, grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to 37 CFR 401.1 inventions made by the awardee." The belief is that the value of the invention is diminished by the government having any rights to the technology. The academic institution feels strongly that all publications, patent applications, etc. note the federal sponsorship clearly and that this clause is relevant. What would you recommend for the academic organization? If a patent application was filed containing federally-funded claims and some non-federally funded claims, how would you promulgate this in the application?

One can sustain the position that while students may not be obligated under their "own" funding, if the student chooses to work on a project that uses federal funding obtained by their mentor/principal investigator, then the public is paying for that specific research at least in part, and the student's potential inventions are subject to obligations under 37 CFR 401. The student is funded to learn how to do research, but when h/she chooses a project, they also implicitly agree to obligations that cover funding of that project, because otherwise they would be unable to do it.

If you think about them clearly, you will see that the government rights are truly limited, and any effect they might ever have on the revenue stream would hit the licensor's revenue stream more than the licensee's. The greatest issue for companies in the 37 CFR 401 requirements is the substantial manufacture in the U.S. for U.S. markets requirement, but even that can be legitimately handled when the circumstances justify it.

4. A university has a large Federal cooperative agreement, the intent of which is to assist a major U.S. industry sector, of interest to the agency. About 1/3 of the funds get subcontracted to private companies in the industry (by RFP) for R & D; many of the subs require software development. An administrator wants to reserve - for the university - rights to IP developed by the private companies under the subcontracts. Subcontracted R & D sometimes involves creation of derivatives of software already developed and owned by the companies. In most cases there is no co-inventor at the university. Would the

requirement be disadvantageous in contract negotiations between the university and private industry?

This is overreaching and can be inequitable to the subcontractors. However, if the software would be a "subject invention" as defined in 37 CFR 401.2(d), it may also be unlawful. 37 USC 401.14(g) states that subcontracts of federal funds must flow down rights in subcontractor inventions to the subcontractor; and further states, "The contractor will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions."

If the software is a derivative of IP owned and developed by the companies the U may be able to negotiate some rights in the developed software. But it seems that the U is engaging contract workers and not workers for hire. The contract workers are only obliged to present the work product to the contracting agent with a limited license for specific use by the contractor. There may be some royalty owed to the software creator who has developed a derivative, but that act should not obligate the creator to give up all rights in favor of a contract. Further if there is no U contribution, save the contract admin., it certainly is not a engaging a worker for hire and does not provide any technical supervision creating a U contribution to the work done under contract. It might be best for the outside provider to avoid doing business with the U. Does the administrator have an idea about what would be done with rights if obtained?

Federal funding doesn't necessarily provide a "blanket" claim to a third party's IP. Two points:

1. Look at the federal grant and review what IP rights are granted. DARPA and ATP programs often give the company full and total IP rights (for foreground inventions). Other programs vary and the specific working arrangement, like a CRADAs, give the private sector limited rights. Background IP lies with the originator in all cases. However, reduction to practice on an existing invention(s) may transfer rights to the company if they reduce it to practice. Thus, read what the contract language is contained in the federal grant.
2. Most (a generalization) federal grants say "you can keep what you develop". Thus, if a company or university invents something then they may be able own it.

The university will generally own no IP if they only provide "pass through" funding and do no work. No company is going to subcontract (with you) if they will lose IP rights to their main products, which may be modified with federal funding. Thus, on software, I think you may have problems. Even if the university has ownership of the derivative work, any user would have to employ the main software, making a sale for the company, so this is a tricky situation especially if the software is more application orientated than shrink wrapped. If you are creating a consortium, then the IP will end up being shared by the consortium.

5. Does receipt of federal funding for a grant proposal count as a publication giving rise to a bar against future foreign filing? Also, would the publication date be the date of submission or the date of funding grant and subsequent publication. Second, does the submission of the proposal itself constitute an offer to sell, again giving rise to a bar against subsequent foreign filing and beginning the one -year U.S. clock?

The proposal itself may not be enabling and the funding request is not a proposal to sell the innovation but a request for funds. However, if experiments are described in such a clear and concise manner as to enable someone skilled in the art to which the invention pertains to make and use it the description might be considered enabling and be considered to be in the public domain. This would be especially true if the conception as disclosed was subsequently reduced to practice.

For that reason, and others, the provisional patent application process was created. This allows University researchers to file their grant proposal as a provisional application at a lower cost and preserve for one year their rights to pursue full patent protection later."

Funded proposals are not necessarily published but abstracts often are. An abstract is "accessible to the public" on the date of publication because it can be retrieved by a FOIA request. If the proposal when submitted identified specific sections regarded by the applicant as proprietary to the applicant, those sections can be redacted under FOIA (but that may not happen, given the high likelihood of a clerical oversight). So, if in fact someone does obtain an unredacted copy of the application under FOIA (whether or not he should have received it), that event could be held against the international patent if it is challenged. On or before the public is notified of the funding of a grant application, an abstract of the application is published electronically, and that will stand as prior art against the international patent. The argument that such disclosures are not enabling may not cut any ice in foreign jurisdictions because the enablement requirement is not a factor in patentability in the same sense as it is in the U.S. Submission of a grant application does not create an "on sale" bar unless by some peculiar circumstance the application has embedded within it an "offer" to make available to the granting institution an actual product that would embody the invention disclosed in the application. One thing to bear in mind is that there is no duty of disclosure to any patent office in any foreign jurisdiction. It is up to challenger to discover the prior art.

More patent-savvy faculty members will consider protection at the time they're developing the grant application. They've already conceived of the invention and perhaps have some confirmatory data; the grant is intended to get enough data to publish, which is usually more than is needed to get a patent). Ask grants administration personnel to provide a copy of the abstracts for all applications at the time they're submitted. In theory, you can contact the investigators before the grant is awarded. Time will be a key consideration.

As far as reduction to practice, the courts have consistently held that conception is the be-all and end-all of inventing; reduction to practice is only important inasmuch as it leads to a refinement in the conception. The act of filing a patent application constitutes "constructive" reduction to practice, which is sufficient under the law (provided, of course, that the application teaches how to complete the job). Filing a provisional would similarly constitute constructive reduction to practice. Conception of the complete and operative embodiment of the invention would constitute conception. Filing a provisional or utility patent application constitutes a constructive reduction to practice if it meets the requirements of Section 112. For mechanical and certain electronic inventions it may be possible to describe the invention so that it meets Section 112 requirements without an actual reduction to practice. However, the PTO has taken the position that the chemical (and biological) arts are unpredictable. For these arts, the patent application must contain actual data. Many journal articles and research reports do not provide enough data or experimental details to meet the burden of Section 112.

Advanced Technology Program (ATP). To add some further clarification or complexity, the authorizing statutes for some federal R&D programs, such as the ATP, explicitly exempt them from FOIA.

Cooperative research and development agreement (CRADA). CRADA data are legislatively protected for a period of 5 years after creation, and is treated by the National Laboratory as "confidential", is not released, and is not subject to FOIA until the 5-year period expires.

Proprietary information provided under a CRADA is protected not only by the CRADA statute but, more importantly, the Federal Trade Secrets Act. The Trade Secrets Act makes it a criminal offense for Federal employees to release defined proprietary information - the definition being very broad. Furthermore, the new FOIA legislation does not include a CRADA because a CRADA is not, by law a "funding" vehicle.

6. It is a standard requirement in an institutions clinical trial agreement that companies indemnify the organization for "Use of Study Results". Specifically the company shall defend, indemnify and hold harmless the Institution's, Principal Investigator etc. from any

and all liabilities, claims etc. resulting from the Company's use of the study results. The Institution does include the standard provisions that the study is in accordance to protocol, there is no negligence on the Institution's part, etc.)

The Institution concern is that after studying a sample of 200 women who take the test drug and no adverse effects observed the drug goes to market, or the Company uses the results in a publication stating the results the population takes the drug and adverse effects occur. Those who have taken the drug, not only sue the company but those involved in the clinical trial.

However, the Company has indicated they no longer, although they have in the past, will indemnify for "use of results". They state that other universities and medical centers have agreed to forgo "use of results". They feel that the phrase is "use of results" is too broad and needs to be more definitive for them to accept. Questions are:

a. Is "use of results" as important and should it be included in clinical trial agreements?

b. Are there other potential problems which might occur if such indemnification is not obtained?

Insist on indemnification for use of results for clinical trials. The Institution has no control over what the company may do with results and Institution should not be held liable for what may happen.

7. What is the SBIR Program?

The Small Business Innovation Research (SBIR) Program is a highly competitive three-phase award system which provides qualified small business concerns with opportunities to propose innovative ideas that meet the specific research and research and development needs of the Federal Government.

8. What are the three phases of the SBIR Program?

Phase I is a feasibility study to evaluate the scientific and technical merit of an idea. Awards are for periods of up to six months in amounts up to $100,000.

Phase II is to expand on the results of and further pursue the development of Phase I. Awards are for periods of up to two years in amounts up to $750,000.

Phase III is for the commercialization of the results of Phase II and requires the use of private sector or non-SBIR Federal funding.

9. Do you have to be a Phase I awardee in order to be considered for Phase II of a project?

Yes.

10. What is the small business size standard for purposes of the SBIR Program?

A small business concern for purposes of award of any funding agreement under the SBIR Program is one which, including its affiliates, has a number of employees not exceeding 500.