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University Start-Up Patent Licensing Tactics

Biotech Round Table Discussion

Several recent developments in the patent laws have profound implications for academic research and research tool patent licensing. In *Madey v. Duke University*, the Federal Circuit severely limited the experimental-use exemption from patent infringement previously believed to be available to university researchers.

Infringement exemptions based on FDA-related activities have also been narrowed by recent decisions, such as *Integra v. Merck*, with respect to the use of patented research tools.

Finally, cases such as *University of Rochester v. GD Searle* have clarified the stringent requirements for the enablement of claims to discoveries made with research tools. These developments have implications for start-up licensing strategies affecting further

research and commercialization in the life sciences, biotechnology, and pharmaceutical industries.

Pre-Licensing



William L. Warren, J.D.

William L. Warren, J.D.—What proportion of your university's inventions are licensed to faculty-affiliated start-up companies versus larger established companies, and how much does

prelicensing play a role in the decision to file for a patent?

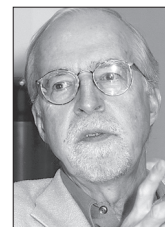
Michael G. Gabridge, Ph.D.—In my experience, maybe only one out of a hundred invention disclosures really merits a start-up company. Our license activities at the Medical College of Georgia (MCG) are probably only in the 15 or 20 percent range for start-up companies and other early-stage companies

combined.

The majority of our licenses are with larger entities. As far as the patent-filing strategy, one has to be very careful what to proceed with. At the MCG we ask three questions: is it quality science, is it likely to be patentable, and is it going to be marketable?

If we don't answer yes to all three questions, we'll walk away. We're a little bit strict on filing standards, but we don't require a license to be in hand to go forward. If our best guess is we think the science is credible, patentable, and marketable, we will go forward with a patent application.

Todd Sherer, Ph.D.—Of Emory's licensees, less than ten



Michael G. Gabridge, Ph.D.



Todd Sherer, Ph.D.

percent are start-ups.

With all the licensing deals we do over the course of a year, 10 to 15 percent of those are going to be licensed to a start-up or a spinout company, and the remainder then are licensed to a more established entity.

Certainly the time we spend negotiating and working with our start-up companies is inversely related to the number of completed deals. We don't require that commercial licensing interest be expressed before deciding to file a patent application. We make a lot of patent filings and then initiate the license marketing once the research has had a chance to evolve.

Supporting Start-Ups

Warren—From the perspective of the start-up entrepreneur, what can universities do to support their associated start-ups, from licensing and incubating to supporting sublicensing proposals?

Clifton A. Baile, Ph.D.—A primary issue that licensing entrepreneurs deal with is the quality of the patenting process initiated at many universities. When I have my choice, I ask the university to prosecute the patents through a qualified law firm and patent attorney who really knows the technical area.

Frequently, the company's patent attorneys can also be responsible directly to the university with full disclosure to both parties. Regardless, getting good disclosures from the inventors and then getting really good patent service are the most important elements for a university to consider initially to increase the licensing potential of its inventions.



Stephen J. Kennedy, Ph.D.

Stephen J. Kennedy, Ph.D.—I have been impressed and pleased with the networking and incubation facilities available at Georgia Tech, which is the system I happen to be most familiar with. But the state has also really been an important resources sponsor through organizations like the Georgia Research Alliance. The infrastructure support is excellent here.

At the licensing level, universities may sometimes have an unrealistic expectation about the terms that a start-up company can afford to license a technology. If the initial licensing terms are not favorable in view of the early stage of development, the license may become punitive to the point that it inhibits the availability to obtain investor financing for the firm.

In our case, **Orthonics** has been successful in obtaining outside private financing post-execution of the university license.

Licensing Relationships

Warren—What kind of suggestions would you give to a start-up company for maintaining a successful licensing relationship with the university?

Dr. Sherer—The answer to that would simply be open communication. If I'm going to be asked to take an equity component instead of cash, which is usually the case in the start-up situation, then we need to understand, just like every other stakeholder in that company, what we're all getting for our respective contributions.

We don't know how to value our stock unless we know what the other investors are getting for their contribution. So purely and simply, open com-

munication is necessary to lay all the facts out on the table and work together to build the company.

Dr. Gabridge—I agree that open communication is the basis for successful licensing negotiations. But I also quickly add that there has to be an attitude of willingness to identify and solve problems.

So we never simply say "no" in a negotiation before or after the license has been cut. I will indicate if I have a problem with any particular language and provide a suggestion on how to get around it. That kind of a mindset helps a lot in both directions.

Patent Law Changes

Warren—Have any of the recent changes in the patent laws led you to consider different research strategies for your start-up companies?

Dr. Baile—I'm very cautious in my start-ups to avoid using anything that we don't have a license to. You must also be careful about what third-party disclosures you're exposed to and how it's confidentially filtered within your new entity.

I've always been concerned about anything that we touched that didn't have appropriate material-transfer contracts in place, and didn't have a license if it was required.

Dr. Kennedy—Certainly the legal developments in the increased level of detail required to enable valid patent claims means we'll pay more attention in the in vivo studies to generate specific supporting data. I'll be working with our legal counsel to consider filing follow-on patent applications for new observations that we make in our research. The ongoing intellectual property strategy has to be a picket-fence patent-defense approach.

Warren—Have these patent law changes caused your technology transfer offices to modify licensing strategies for research tool patents?

Dr. Gabridge—We are seeing some differences in our approach in highly unpredictable fields where we know the patent office is not going to allow a claim just on tissue culture data, for example.

In those cases we're going to wait to file a patent until after we obtain some mouse data or primate data, ideally. It seems like it's going to force us to have our investigators interact more fully. This is a dilemma where investigators have to follow a scheduled grant-application process rather than nimbly performing useful experiments for another researcher.

I think it's going to stack the cards in favor of patents from the private for-profit sector ultimately. However, the university can be flexible in its licensing structure for different success milestones to delay payment of royalties on a licensed research tool.

The issue of reach-through royalties is a difficult one, because you can't charge someone royalties on a product you do not hold a patent to. Therefore, you have to word the license very carefully to make sure that you're getting delayed consideration and not a royalty on something that doesn't belong to you.

Dr. Sherer—My strategy in this situation is to enable the patents right from the beginning. If a novel metabolic pathway can be modulated to have an impact on a disease, we try our best to enable the patent in a way that protects the method of treatment. That requires more testing and data.

If it's a pure biological reagent or a knockout mouse, then we simply license those things as research tools. We deploy

a nonexclusive licensing strategy, usually with a one-time fee, which can be structured in delayed payments staggered out over four or five years to lessen the bite.

Research Funding

Warren—How important is corporate-sponsored research funding relative to government-based funding for development at a start-up company?

Dr. Kennedy—I think outside corporations can be an important source of funds, however, there are some liabilities that go along with that. Orthonics is young, less than a year old, and we have primarily taken advantage of venture financing and government grants. We have had discussions with potential corporate sponsors that we haven't capitalized on yet.

One of the considerations is that taking research money from a large corporation may be an irrevocable step that locks in your development path, and this may be less attractive to other investors. So there's a tradeoff that you have to consider.

Dr. Baile—I think it works both ways because sponsorship can validate the concept or the product if you can get a credible corporate partner. One of my better successes was where we had a corporate research sponsor from the beginning.

It does limit who else you may talk to, but it's very good to have a corporate partner in pocket when you're talking to potential investors in a company, because it gives both a validation and an exit strategy that is more apparent.

In-Licensing

Warren—In view of the elimination of the research exemption from infringement liability at universities under *Madey v. Duke*, have there been increased

demands by other patent owners that your institution pay for a license? Do you think that there needs to be a legislative fix to the problem of research exemptions at the universities?

Dr. Gabridge—The first answer is no, at MCG we have not seen an influx of requests or demands for in-licensing. Secondly, I'm not entirely convinced it's a problem that necessitates legislation to solve. While there might be disagreement among the technology transfer offices as to whether or not this was a cataclysmic event, I think virtually all of them agree that it was the wrong decision.

From the university perspective, if an infringer is a professor at another institution, even in a start-up company there, we probably would not demand a license fee. We would likely require the researcher to recognize our intellectual property rights through publication credit for example. It's better to promote the technology to the university researchers and try to capture the results when potentially licensable to a commercial third party.

Dr. Sherer—There are only a few cases in which Emory has been asked to take a license to conduct our academic research. In one case, the company later modified the licensing strategy based upon academic peer pressure and a concern that it might not be publicly popular to pursue that strategy.

I'm not concerned about it changing the way we do business this year or next year, but I am concerned that over the next 10 to 15 years, we could be looking at an increase in the cost of in-licensing technology at the university as companies continue to look for ways to profit from out-licensing.

Currently, I wouldn't expect to request another university to stop its research or

take a license because of a patent that was issued to the university. I think it is important that university inventions not become an impediment to basic research at the academy, and I also feel that implementing suitable business practices is a responsibility of all institutions.

Put more simply, we have a dual obligation to make our work product and research available to the public as well as try to commercialize it. **GEN**

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Michael G. Gabridge, Ph.D., is associate vp for technology transfer and economic development for the Medical College of Georgia in Augusta.

Todd Sherer, Ph.D., is assistant vp for research and director of the office of technology transfer at Emory University.

Clifton A. Baile, Ph.D., is an eminent scholar in agricultural biotechnology and distinguished professor at the University of Georgia.

Stephen J. Kennedy, Ph.D., is currently president and CEO of Orthonics.