

Technology Transfer Tactics™

The monthly advisor on best practices in technology transfer

Court ruling undermines sovereign immunity, puts university patents at risk

State universities are now in a weaker position when protecting patents from inter partes review (IPR) petitions, after the Federal Circuit court ruled that sovereign immunity does not apply in patent challenges. The ruling could require some universities to reassess their patent enforcement strategies and brace for significantly higher costs from increased IPRs.

The case in question involves the University of Minnesota (UMN), which has argued that its patents could not be subject to IPR proceedings because, as an arm of the state, its patents were protected by sovereign immunity, which in many circumstances prevent suing a state. The court said no in a rather forceful way, ripping this defense strategy from state universities across the country.

Some observers say this decision is another step in the road toward an anti-patent bias in the U.S. courts, but the legitimacy of that criticism depends on your perspective, says **Edward H. Rice**, JD, principal with the Miller Canfield law firm in Chicago.

"I can understand where patent owners are feeling under increasing pressure because of the IPR and other patent office procedures but also Supreme Court and district court rulings that, for instance, make it easier to collect attorney fees in unsuccessful cases," Rice says. "That provides some disincentive and makes you think twice about bringing a case if you might have to pay the other side's fees."

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TechTransferCentral.com/TTT

about patent trolls and frivolous patent infringement lawsuits, Rice says, but the UMN case and other recent rulings may signal that they have gone too far and are undermining the value of patents.

"I think there may be some overreaction, with anti-patent sentiment swinging the pendulum too far against the patent owner," Rice says. "It may swing back in the other direction some day, but I think there is some validity to the notion that rulings and laws in the past five to 10 years have swung more often than not against the patent owner."

Court says no to UMN

In the closely watched case, the Federal Circuit ruled that sovereign immunity does not apply to several IPR petitions filed against UMN-owned patents. (The ruling is available online at <http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/18-1559.Opinion.6-14-2019.pdf>.)

The court's reasoning was based in part on a 2018 decision in *Saint Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc.*, which addressed whether tribal sovereign immunity would shield tribe-owned patents from IPR proceedings. The court in that case determined that "tribal sovereign immunity cannot be asserted in IPRs." (That case is available online at <http://www.cafc.uscourts.gov/node/23647>.) The Saint Regis tribe petitioned the U.S. Supreme Court for review, but the court denied the petition for certiorari in April 2019.

The challenge was clouded somewhat by the fact that drug company Allergan, in an attempt to shield its patents from IPR, had paid a fee to the tribe and transferred title to its patents, essential-

ly using sovereign immunity as a patent protection tool for a for-profit company.

However, the Federal Circuit court in the UMN case determined that "the differences between tribal and state sovereign immunity do not warrant a departure from the reasoning in Saint Regis." The court went on to say that with regard to the Saint Regis decision, "this reasoning applies equally to states as it does to tribes.... As we held in Saint Regis, IPR is properly viewed as an agency's reconsideration of a previous patent grant that is aided by information supplied by a third party, and state sovereign immunity does not bar these proceedings."

Undermining Congress' intent?

The court additionally noted that if sovereign immunity were used to avoid IPR proceedings against patents obtained by a sovereign, states may be incentivized to make arrangements that effectively lend that sovereign immunity to parties that were never intended to benefit from that protection -- as was attempted by Allergan.

Allowing that would undermine the intent of Congress to provide a post-grant administrative proceeding for the assessment of patent validity, the court said.

"They said there really was no material difference between the Saint Regis tribal case and the Minnesota case. Although the nature of tribal sovereign immunity is different in some ways from state sovereign immunity, the principles applied there also apply equally here," Rice explains. "I think they very deliberately put themselves in line with that case because *certiorari* was denied in that case. There were a lot of *amici* briefs filed in support of the tribe trying to get a

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Technology Transfer Tactics™ (ISSN 1940-1663) is published monthly by 2Market Information, Inc., 1992 Westminster Way, Atlanta, GA 30307 USA

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POSTMASTER: Send address changes to Technology Transfer Tactics, 1992 Westminster Way, Atlanta, GA 30307 USA.

CEO and Publisher: David Schwartz Marketing Director: Connie Austin Graphics and Web: Jason Norris

Subscriber Services: Valeasia Walker Events and Distance Learning: Debi Melillo

Subscription rates: USA, USA possessions and Canada, one year (12 issues): \$697. Other international subscriptions: \$747. Back issues: \$65 each. Technology Transfer Tactics™ is completely independent, and not connected with or controlled by any government agency, organization or society, consultancy, contractor, or vendor. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other forms of professional advice are offered for general guidance only; competent counsel should be sought for specific situations.

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rehearing, multiple briefs from states saying the circuit court has to reconsider the decision because it could apply to states too, and that would be a terrible thing.”

The U.S. Patent and Trademark Office -- and in particular the Patent Trial and Appeal Board -- has been criticized in the past as being anti-patent because it has tended to support petitioners in IPR claims, finding a large percentage of the patents invalid, Rice notes. PTAB has been referred to by some observers as a “patent death squad.” Knowing that, defendants have latched on to prior art invalidity claims as the favored defense against patent infringement, he says.

State universities have used sovereign immunity to force patent infringement defendants to actually go through litigation of their claims rather than derailing it with an IPR, Rice explains.

‘Like a government-brought action’

The UMN decision negates any advantage that U.S. public universities had in protecting their patents from IPR challenges -- an advantage that some had argued could bring higher royalty rates and more licenses given the extra level of protection.

“The decision basically takes the position that it doesn’t matter who owns the patent because the nature of the IPR is akin to the federal government bringing the action. A private party is the petitioner and triggers the action, but in an IPR proceeding the commissioner has to make a decision to go forward or not,” Rice says. “The Federal Circuit framed the issue by saying that the IPR proceeding is really like a government-brought action to reconsider something the agency has done. It’s as if it’s a fight between the government and the patent owner, not between two private parties.”

To drive home that point, the judges filed a supplemental statement. That is unusual, Rice says, because ordinarily if there is an alternative ground for supporting the opinion the court will put it in the opinion itself or a subset of the judges will offer it in a concurring opinion.

“This was unusual because all three judges signed off on this supplemental views statement, making the distinction between *personam* jurisdiction, in which the court is exerting its power over an individual, and *in rem* jurisdiction, in

which the court is exerting its power over the property and not necessarily the individual,” Rice explains. “I think it did that to drive home the point the primary focus of the opinion was on the notion that the IPR is akin to a case brought by the United States, which is not subject to sovereign immunity.”

Not all settled law

However, the nature of intellectual property rights, namely whether it is *in rem*, *in personam*, or something else, is not settled law, notes **Jingjing Ye**, JD, partner with the Culhane Meadows law firm in Dallas, TX.

“We can only guess why the panel provided the non-binding additional view. But in any event, it hints at the personal beliefs of those Federal Circuit Court judges regarding the nature of patent rights,” she says.

Ye notes that the 11th Amendment under which sovereign immunity is claimed has been robustly upheld by other courts. The interpretation of the 11th Amendment by the Federal Circuit in this case amounts to an erosion of this strong immunity, she says.

“A Supreme Court review of the case is often triggered by a split in circuit; however, due to the Federal Circuit’s exclusive patent subject matter jurisdiction, this wouldn’t be a factor here,” Ye says. “Therefore, we will watch if a backlash forms in the aftermath of the case. If it does, the Supreme Court might get interested in reviewing the case, which also holds true for Congressional intervention.”

Costs will increase

State universities should anticipate an increase in costs to defend their patents in IPRs, says **Emer L. Simic**, JD, partner with the Green, Griffith & Borg-Breen law firm in Chicago. An IPR is less expensive than litigation but is still a significant expense, she notes.

A typical IPR can cost the university between \$500,000 and \$1.5 million, Simic says. At the same time, the fact that state university patents are now subject to IPRs could potentially decrease the value of university-held patent portfolios, she says.

“In IPRs, there is not an assumption of the validity of patents; rather, you only have to

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show it is more likely than not that the claims were unpatentable. In district court there is a presumption of validity and you have to show by clear and convincing evidence that the claims are unpatentable," she says. "This case puts an end to the idea that you can monetize sovereign immunity. To the extent that patents have been assigned to universities with the idea that they can use sovereign immunity to defend them, that will no longer be the case and so that could mean a decrease in revenue for universities."

Simic points out that states still have sovereign immunity for patent litigation in general, just not with regard to IPRs. For example, if a party brings an action in district court claiming a patent is invalid -- and the state had not sued that party -- then the university would be able to move for dismissal on the grounds of sovereign immunity, she explains.

Supreme Court could review

The Supreme Court could review the UMN case, even though it declined to review the Saint Regis case, Simic says. There are differences between the sovereign immunity invoked by the Indian tribe and that claimed by the state universities, and that could be enough to convince the Court that a new legal issue needs to be addressed, she says.

In the meantime, Simic says state universities should brace for increased patent challenges.

"This opens a world of additional patents that may be subject to challenge. Patent challengers and companies in the pharmaceutical industry, for example, who are concerned about freedom to operate may want to do a deep dive into the patents currently owned by state research institutions," Simic says. "You don't need to have standing to petition for IPR, so you could strategically target certain patents prior to developing your product and see if you can take them down in advance. You do have to have standing in district court, so an IPR is this lower bar for bringing action, and that can be quite helpful for patent challengers."

The impact of the UMN case falls only on state universities, Rice notes, because no one questions that private universities patents are subject to IPR challenges. State universities are

now essentially on the same footing when it comes to patent protection, Rice says.

"As a practical matter, it is going to mostly affect those universities that are active in asserting their patent portfolios, both in building their patent portfolios and enforcing them," Rice says. "The IPR proceeding is used primarily reactively, as a defense when a party is sued in district court. If someone tries to sue me for patent infringement and I think I have a good validity defense, I can try to short circuit the process by going to the patent office right away and filing an IPR petition."

If the patent office grants the IPR petition, the defendant can go to the court and ask that the patent infringement proceedings be held up until the patent office has ruled.

"The patent office's decision on IPR proceedings is relatively quick relative to district court proceedings, so the most common result today in most courts is that the court generally grants those stay motions," Rice says. "You can stop the litigation in its tracks and go over to the patent office to try to knock out the patents. State universities [could] rely on sovereign immunity from IPRs to block this strategy, but now that has changed."

Consider IPRs in strategy

State universities will have to factor the IPR defense strategy more heavily into their patent enforcement plans, Rice says.

"You may lose the claims more quickly. If there is a significant risk of IPR, that's a disincentive to file a lawsuit," Rice says. "It's not only a defense that will foil your claim against this one defendant, but if you lose your patent validity through the IPR, you lose your rights to exclude anybody. If you think your patent is vulnerable, IPR can be a real threat."

On the other hand, sophisticated players can evaluate their risk of losing in an IPR and factor that in. The mere fact that a state university is subject to IPRs now doesn't mean they should avoid patent enforcement, Rice says, as long as they are reasonably confident that the patent can withstand scrutiny.

"If you're confident your patents can survive, this shouldn't deter you," Rice says.

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NYU's Future Labs blazes path for scalable start-ups and exits-by-acquisition

New York University's Future Labs has been churning out one start-up after another, and it just crossed the threshold of 20 exits via acquisition -- an astounding record of financial success that many TTOs would like to emulate. So how do they do it? The answer involves carefully selecting start-ups to back with the greatest chance for success and monitoring their progress carefully. It also helps that the incubator's main goal is not to cultivate IP from NYU.

Operating under the auspices of NYU's Tandon School of Engineering, Future Labs is a network of start-up business hubs that includes the Data, Urban, Digital, and Veterans Future Labs. The network has seen 23 start-ups acquired since Future Labs was launched in 2009 with funding from the New York City Economic Development Corporation.

Revenues derived from acquisitions of these start-ups total more than \$530 million, and the buyers include well-known tech giants like Uber, Google and Twitter. Examples include Geometric Intelligence, which was acquired in 2017 by Uber to become the base of its artificial intelligence laboratory, and Vetterly, which was bought by Adecco Group for a reported \$100 million. Twitter acquired another Future Labs company, TapCommerce, in 2014. More recently, MINDBODY acquired Bowtie.ai, an artificial intelligence-driven virtual receptionist for appointment-based businesses, marking the 20th acquisition for Future Labs. Three more start-ups were acquired soon after.

Future Labs released an economic impact study in 2018 that found the combined programs and member companies supported 3,201 jobs in New York State, with a total impact on New York City's economy of just over \$4 billion. Future Labs comprise the largest university-affiliated start-up ecosystem in New York City, with its companies and graduates now valued at \$1 billion, the study found.

An economic development winner

Future Labs was born just as New York City was coming out of a financial crisis, explains **Kurt H. Becker**, NYU Tandon vice dean for research, innovation and entrepreneurship, and a professor of

applied physics. City leaders, led by former mayor Michael Bloomberg, decided the city had missed the high tech train that had produced so much development in other communities, Becker says. They decided they wanted to make New York City a preferred place for start-ups and entrepreneurs, he says.

Bloomberg used the city's Economic Development Corporation to funnel money into economic incubators, with Future Labs as the first to launch.

"We started as an incubator that served primarily fairly early stage start-ups. Over the years we have developed this into a model where our core program is a two-year seed-to-series A program that is highly curated with a lot of handholding," Becker says. "We also are extremely selective in who gets in, and in the last two years we have aligned the technology verticals we support with the research strength of the university."

One of the key reasons for the success of Future Labs is the close association with a major research university, Becker says. Start-ups can draw on student interns, and there are faculty engineers in residence who work with the start-ups, sometimes using case studies created by the start-ups for their courses, he says.

"This connection between the university and Future Labs is extraordinarily beneficial to the academic side but it also provides assets to the start-ups that you will not find in many other co-working spaces," Becker says. "We went out to get corporate sponsorships, legal services, public relations support, pitch coaching. Anyone who gets into Future Labs has a curated package of benefits and support services that they can draw on."

Trial by fire

Those benefits don't come easily though. The Future Labs participants are expected to perform while in the program and earn the right to stay. Rather than admitting them for the full two-year program, Future Labs admits participants for six month terms and evaluates their progress at the end of the term to see if they have satisfied technical and business milestones, Becker says.

Future Labs also offers a virtual six-month program that caters to earlier stage start-ups, including some that are just in the process of forming. These participants go through a six-month "boot camp" with the hopes that in the end they will qualify for the two-year program.

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Even with the close association with NYU, a unique aspect of Future Labs is that it was not created to serve NYU students and faculty, notes **Steve Kuyan**, managing director of NYU Tandon Future Labs. Only about 20% of Future Labs companies are commercializing IP owned by NYU, with the rest working with technology not affiliated with the university.

"If you look at the way most incubators work with universities, their primary focus is helping student and faculty member ventures. When we first launched in 2009 there was not a tremendous amount of entrepreneurial activity at NYU, or at universities around the world. We were just starting to see the initial phases of universities starting to adopt concentrations and entrepreneurial competitions that would encourage students and faculty members to build their own ventures," Kuyan says. "There was some success with net revenue, but there wasn't that much success in start-ups. So it was at that point that we decided our focus would not all be on students and faculty members."

Companies founded by students and faculty members represent only a small part of the entire entrepreneurship ecosystem at a university, Kuyan says. By expanding the focus, Future Labs is able to bring in companies that don't have any affiliation with the university but could benefit from NYU resources.

"Our goal was encouraging entrepreneurial culture change within and outside the university, not incubating a small percentage of faculty and students who want to start their own companies," Kuyan says. "That is important when selecting companies for the program because it allows us to leverage the resources of the university, like interns and faculty members, which most programs like ours don't have the reach to capture for their program."

The students and faculty of NYU benefit from their association with these entrepreneurial companies, Kuyan says. Future Labs typically recruits companies that are in burgeoning markets, so NYU students and faculty have the opportunity to work with fast-growth organizations working on cutting edge technology.

"We can connect our students, faculty, and research institutions with the start-ups that have the highest potential," Kuyan says. "We select those companies based on the industry trends that we foresee over the next two to five years."

Acquisition not the main goal

Despite its incredible record of exits through acquisition, Kuyan says selling to a larger company is not the primary focus of Future Labs. The goal of the two-year program is get the company to a point where it is scalable and sustainable, he says.

"Scalable so they're growing consistently and not being stagnant in their growth, and sustainable so that they can pay their rent, pay their employees, and stand on their own two feet," Kuyan says. "Those kinds of companies end up attracting more investment dollars and more companies that are looking to acquire start-ups in their space. A company that is scalable, sustainable, and making money is a very attractive target."

The New York City investment market leans heavily on revenue when evaluating companies, so Future Labs does too. "We're very adamant that our companies be revenue generating," Kuyan says. "We look pretty heavily to companies that are able to generate dollars in the early stages and then get customers on board as early as possible."

Becker notes that in addition to the long string of acquisitions, Future Labs has other success stories with companies that went out and generated a lot of financing. "The acquisitions were companies that were still in our program. Once the companies graduate and leave our program, some of them are acquired but many of them have gone on to series B and series C funding, and they have grown substantially," Becker says.

That success is partly due to the way Future Labs targets slightly later stage companies than the typical incubator program, Kuyan says. "The most important reason for that is that seed to series A is the stage at which companies define product market fit and then identify the business model they're going to be operating under, so that when they invest more dollars into their business model it returns a net positive on the other side of that equation," Kuyan says. "The acquisitions are all the result of us trying to institutionalize the model of incubation and push companies to revenue generation, testing their business model off multiple iterations, and constantly getting their product out the door."

Oversight of company progress

Future Labs acts almost like a board of oversight for the participants, Kuyan says, constantly asking about revenue projections and other key

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issues. "Having this external resource like Future Labs monitoring these milestones makes the company accountable to the milestones for someone else," Kuyan says. "That feedback loop has to accelerate their entry to the marketplace and their growth."

Becker notes that Future Labs has become an attractive platform for companies from around the world, with participants from Germany, the Netherlands, Denmark, Israel, and other countries.

The staffing for Future Labs comes from the start-up community rather than the university, Kuyan notes. "Other universities could replicate what we're doing, but they would need a commitment from the university to provide seed funding and probably also funding from the local government," Becker says. "As long as you have a strong research university that is willing to work closely with these companies and not just look at them as a source of revenue but as making a contribution to the local economy, it can be duplicated."

Kuyan notes that NYU was incubating student and faculty start-ups for five years before forming Future Labs, so the current model is the result of 15 years of experience.

"In talking with other incubators across the state, the lesson seems to be that you should identify a unique model that serves your ecosystem and find out how you can leverage the resources at your university so that you start to benefit the ecosystem and the university," Kuyan says. "It is very important for the university to be present in the start-up ecosystem and for the ecosystem to be able to tap into those resources that the university offers. Ultimately the success of a start-up depends on what resources they can get access to as quickly as possible."

Paraphrasing former Speaker of the House Tip O'Neill's belief that all politics is local, Becker says: "All entrepreneurship and incubation is local."

"You really have to take into account the local environment. You can't take something that works in one place and just transfer it to another place," he observes. "Patience also is an important lesson. The economic impact from Future Labs for the first few years was almost negligible and began to take off exponentially after year four or five. So anyone who gets into this game really has to have staying power."

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Commercialization fellowships help get more innovations off the shelf

Editor's note: This is the first of a two-part series on commercialization-focused fellowship programs. While this installment focuses on preparing and nurturing postdoc fellows for start-ups, next month look for Part 2 focusing on fellowships designed to recruit and train TTO staff.

Many good ideas are born in university labs. However, the road from an idea to commercialization is fraught with many pitfalls. In some cases, a valuable idea may languish in a lab for lack of an available entrepreneurial scientist to take it further. To help overcome that gap, a number of universities are creating commercialization fellowship programs.

Two excellent examples can be found at Cornell University and the University of Memphis. The program at Cornell is simply called the Commercialization Fellowship, while the program at the Memphis is branded as Patents2Products. These programs each have different goals and out-

comes. However, the result is similar: innovations that otherwise would have gone nowhere are picked up, examined, and sometimes end up as the basis for a start-up company. The Commercialization Fellowship Program is for PhD students at Cornell's engineering school. The Patents2Products program hires postdocs who want to spin out a company but are unable to do so due to such obstacles as having a family to support, needing health insurance, and not having the financial security to take a risk with a start-up.

How the programs work

Dr. Jasbir Dhaliwal, executive vice president for research and innovation at U Memphis, recognized that universities are underutilizing postdocs in commercialization and innovation. He came up with a solution that was a win both for the postdocs and the university. "Trying to set up a science-based company is very risky. So, why don't we hire him or her as a postdoc and give them the two years to get the patent [better refined] for commercialization? At

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the same time, they can work here as employees, they have full health benefits, and they have a postdoc salary. So, they get personal financial security while they're spinning out the company."

Dhaliwal partnered with Epicenter, a Memphis-based entrepreneurial organization. Epicenter contributed more than half a million dollars to the program. With that support, Dhaliwal has hired five postdocs who have experience in areas needed to get U Memphis patents ready for the market. The school provides access to the technologies and puts them in touch with Memphis-based venture capitalists.

Dhaliwal is also happy to work with postdocs from other institutions who want to spin out a company with their own technology. In those cases, "I find a faculty member who can work with them to guide them," he says. "The program is geared towards commercializing our own technology, but we will work with anyone who wants to come to Memphis and partner with my faculty. We know all the angel investors in town, and we can make them accessible to any invention that comes out of our labs."

The Commercialization Fellowship at Cornell is a six-month program open to engineering PhD students. It is a rigorous, multi-step program that begins by evaluating technologies for commercialization potential. The length of the program is a critical element. "Having a period of months where you can give a PhD candidate an opportunity to remove themselves from the day to day of their lab work and provide some focus while they're still continuing their PhD is important," says **Tom Schryver**, the program's director and executive director of Cornell's Center for Regional Economic Advancement. "These are people who have extraordinarily busy lives with very, very high expectations from their PIs and advisors. So, if you don't give them a little bit of elbow room, you're not going to get the same outcome."

The multi-step approach is another valuable aspect of the program. During the first few weeks of the program, fellows work on market identification. Then, they participate in the national I-Corps Program, where they generate a business model and validate the technology. During the last three months, the fellows are matched up with a team of MBA students. The fellows work with the teams to finalize business plans and to develop investor pitch materials.

There are distinct benefits to teaming the fellows with the MBA students, notes Schryver. "One [benefit] is, it broadens the exposure of the technologies to more students. So, we get more impact on the whole program. When it comes to figuring out market sizing analysis, [which] financial model we would use to raise money, or what is the right way to position that particular product or service, MBA students can be very helpful in that."

Schryver is very intentional in holding off the introduction of MBA students until the second half of the program. "What I've seen in the past is that when you connect technologists and business people at the very beginning, the business people say, 'that's great, I guess I'm the leader' and then they'll just start taking charge. And the technologists say, 'I guess business stuff isn't for me.' And [the team] starts off [with] a lack of connection between the two domains. The MBAs don't learn enough about technology space, and the technologists don't learn about the business space. So, we onramp the technologists [first] to think about the business model in a structured way. By the time they start connecting with the MBAs, the technologists have more power to be leaders of these projects and can work with the MBAs on more of a teamwork footing."

The Commercialization Fellowship Program has an intellectual property thread woven throughout. "We're with them in the application process through the completion of their project," notes **Patrick Govang**, director of innovation partnerships at the Cornell's Center for Technology Licensing. "There are several meetings that each candidate fellow has with the intellectual property officer. When we're working with the fellow student, we spend a bit more time making sure that we're fully clarifying the intellectual property protection process, the decision points that we're looking at in terms of filing decisions, and how broadly or not we protect it. We're there to support them as they're going through their discovery process and exploring the viability of that technology in the marketplace and applying the I-Corps learning template."

As does the Patents2Products program, the Cornell program removes financial burdens from its participants. "It is a paid fellowship," reports Schryver. "We're helping cover their stipend, and we're helping cover their tuition." This financial arrangement also creates some breathing room for the postdoc's principal investigator, because it

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removes the financial burden of paying the post-doc. Schryver notes that the savings encourage PIs to be more open to allowing the fellows to have time outside the lab.

Program goals

While both programs generate start-ups, that is not the primary goal of the Commercialization Fellowship Program. "It's important that we focus on the learning of the student," Schryver emphasizes. "[A fellow can be] a great candidate who we think is working on an interesting technology. We all agree [that we] can't wait to see what happens. Sometimes, we get to the end of the six months and [the fellow says], 'Gosh, guys, I thought this was a cool technology. My advisor is awesome. We're moving the needle. We spent six months to get all the right things, and it just turns out there isn't a market there.' It's important that that's an okay answer, because if we're telling everybody, 'Hey, this is all about starting start-ups,' that person could feel like they failed when, in fact, they might have learned a ton, and they may have added a ton of value by identifying a technology that isn't ready for commercialization," he comments.

"When we get to the end of the six months, we hope that each one of these candidates is much better prepared to have a high impact on a non-academic career path," Schryver adds.

And that appears to be happening with increasing frequency, with a number of fellows who have graduated from the program becoming start-up CEOs. "They've got funding to do that through a variety of programs, and we're very proud of that," Schryver says.

Other fellows have gone on to industry careers. "We have a few great examples of fellows that have gone on to jobs that they didn't even know would have been available to them," Schryver points out. "But they essentially networked their way in by having gone through a commercialization program. Those are direct impacts [of the program]. There is a broader sense of what is possible."

One current fellow has expressed interest in working in a technology transfer office. "That was an outcome we hadn't expected or thought of, but this would be good preparation for [a TTO role]," Schryver notes.

Though the program prioritizes educational goals over business creation goals, its results have

been a boon to the campus start-up scene. "I believe that by this program being here, there will be more start-ups than there would have been had this program not been here," Schryver asserts. "That's a rising tide. It lifts all boats to the benefit of this ecosystem. But we don't want fellows to feel like that's their obligation."

And Govang sees the fellows program as giving the school's tech transfer efforts a boost as well. "The experience is great because it helps us put together some strategic thinking around the technology," he says. "[We see] where the students are going to move forward with that technology. We've got a great network of incubators and programming that is there to help them carry the idea forward and start to find financing to commercialize that idea."

Adds Schryver, "For [the fellows] that do go on and create start-ups, they wind up being better licensees. So we work closely with [the Center for Technology Licensing]. I consider them a key partner."

Memphis focuses on start-ups

For Patents2Products, accelerating the commercialization of U Memphis intellectual property and creating spin-out companies are the primary goals. Dhaliwal expects to spin out six companies in the first year. The goal is for every patent assigned to a fellow to result in a start-up or other commercialization path.

"That's our goal," said Dhaliwal. "But because we'll be setting up a company fairly quickly, let's say after one and a half years of further development of the patent, the patent becomes more valuable. If at that point a company with an equity fund comes in and says they'd like to buy our product, we'll do that too. But the point is to invest in our work full-stop so that the patent portfolio becomes more valuable for the commercial market case." Assuming all goes as planned, the program will have a six-person cohort every year going forward, resulting in six new spin-out companies each year.

The Patents2Products program is a joint project of the university and Epicenter, whose focus among other priorities is to launch new programs where there are gaps in entrepreneurship. "The Patents2Products program fits firmly [within] the 'fill a gap' [mandate] ... by having a designed program specifically oriented to entrepreneurial post-

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docs to encourage innovation,” comments **Leslie Lynn Smith**, president and CEO of Epicenter. “[Dr. Dhaliwal] is the type of partner that we love to work with because our goal is to elevate an entrepreneurial movement that produces 500 companies over a decade and supports 1,000 entrepreneurs. We can’t do that without dozens of partners.”

Benefits to the university

The Commercialization Fellowship Program has produced an uptick in new start-up teams coming together, and an associated influx of both SBIR funds and private capital. Another benefit is that a broader message is reaching faculty, postdocs, and PhDs. Schryver notes that they are thinking more about what is possible in terms of research commercialization and beginning to think of entrepreneurship as something they could do, too.

The program is also drawing the interest of non-engineering PhD candidates. “That’s led us to connect those people to other programs,” reports Schryver. “We don’t have anything in other schools that’s quite like what we have in engineering, but at least we can start connecting these other PhD candidates to programs like the I-Corps as [a place where] they can go to get help with commercialization.”

The Patents2Products program offers its postdocs the opportunity to learn from each other, working side by side in the university’s CommuniTech Research Park, where undergraduates and master’s students will also be working. A faculty advisor is appointed for each of these postdocs as well, so they will be working in labs where they will be interacting with the other PhD students. “That’s a great mixture for innovation,” said Dhaliwal. “It moves basic science forward much faster. At the same time, the faculty member and the doctorate and master’s student working in the lab learn to understand the commercial dimension of their science.”

Program challenges

Both Dhaliwal and Schryver cited recruiting participants to their respective programs as their biggest challenge. “My biggest challenge is to find the right postdoc who wants to spin a company out,” said Dhaliwal. “You get all these postdoc applications to sift through to find postdocs with

the entrepreneurial fire in their belly. That is a work of art, not an exact science.” Many of the applicants to the Patents2Products program, notes Dhaliwal, are traditional postdocs who are not a good fit for the program.

Advertising is also a challenge for Patents2Products. “You have to be very careful about where you market and what messaging you’re marketing,” Dhaliwal observes. “You tend to go to traditional places like the Chronicle [of Higher Education], or a similar outlet. But sometimes only traditional postdocs go to that location. In the second round, [we’re writing to] the PhD coordinators of the top 20 schools that work in the area in which we have the patent.”

Dhaliwal has also changed his messaging. He avoids saying that he wants a postdoc who will do entrepreneurial work. Instead, he says he wants an entrepreneurial postdoc who wants to work on an exciting project. “Because it’s such a new concept to a lot of people, the messaging has to be just right,” said Dhaliwal.

Another change in his marketing approach is that, rather than inviting postdocs to apply, he is asking them to call him to discuss the opportunity. This method is a quick way for Dhaliwal and the candidate to decide if the program and the postdoc sense a good fit.

At Cornell Engineering, a large number of PhD candidates have expressed interest in the Commercialization Fellows Program. But actual applicants have been harder to come by. “It’s a pretty big leap from [expressing interest] to saying, ‘I’m going to go ask my advisor if I can spend six months doing this fellowship,’” says Schryver. “We assumed we had an awesome product, and the world would beat a path to our door.”

To combat that hesitancy, Schryver is having more one-on-one meetings, departmental meetings, and meetings with PIs whom he knows have people on their teams who are interested in commercialization. “We try to prime the pump a little bit earlier,” he says.

The more personal approach also increases the diversity of the cohorts. General invitations, he’s observed, tend to garner more responses from non-minorities. “There’s got to be a little bit more of a conscious inviting-in for women and under-represented minorities, and that’s a priority for us going forward.”

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Legal Consult



UK court decision highlights need for U.S. patent reform

By Brian Amos and Alan D Miller
Amster Rothstein & Ebenstein LLP

Short take: A recent UK court ruling that a European patent on a groundbreaking invention is valid and infringed contrasts with a U.S. court invalidating a similar patent as not patent eligible. This disconnect between jurisdictions highlights the importance of current efforts to fix U.S. patent law.

In 2012, in one of a series of cases of judge-made law limiting inventions that could be patented, the U.S. Supreme Court in *Mayo*¹ effectively limited patentable methods in the field of medical diagnostics under Section 101 of the U.S. patent code. Some in the patent community considered the wording of the *Mayo* decision somewhat of a blunderbuss, scattering shot in a wide arc, perhaps beyond the lines intended by the Court. The decision also set the stage for dramatically divergent outcomes for medical diagnostic patent applications in the U.S. and Europe.²

Following an uproar among stakeholders unable to protect inventions in which they had invested, and from the patent community over uncertainty as to what actually constituted patent-eligible subject matter following *Mayo* and other cases, notably *Alice*,³ the U.S. Congress has recently begun to consider reforming the statute (35 U.S.C. §101) that governs what is actually patentable. To this end, a draft text⁴ has been released by a group of U.S. Senators for a new Section 101 which proposes, in part, the following:

Section 100:

(k) The term “useful” means any invention or discovery that provides specific and practical utility in any field of technology through human intervention.

Section 101:

(a) Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(b) Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation.”

The proposal addresses the need to add a definition for the word “useful.” This underlines the fact that, even though the current Section 101 does in fact state “[w]hoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor,” a series of Supreme Court decisions has snipped out whole fields of processes as not patentable *per se*, regardless of how useful, new and inventive they may be.

Case illustrates need for change

One U.S. patent case illustrated the dilemma faced by patent holders. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,⁵ an inventor of a new and undeniably useful process could not in fact ultimately have a patent. To be clear, a patent on the invention was obtained,⁶ but that was several years before the *Mayo* decision. The patent covered a method for performing a non-invasive prenatal fetal diagnosis by using a maternal blood sample. The USPTO issued the patent in 2001 on this new, inventive and useful process, which was conceived by researchers at the preeminent University of Oxford. The patent was subsequently assigned to a diagnostics corporation (Sequenom, Inc.). Importantly, the patented method was not invasive to the fetus and, by using cell-free fetal DNA, it could use a non-cellular portion of maternal blood which in the past had simply been discarded.

This new diagnostic method was acknowledged by a Federal Circuit judge as a “ground-breaking” invention. During the case, an expert witness stated that “nobody thought that fetal cell-free DNA would be present” in the maternal plasma. In the lower court’s opinion it was even noted that the UK’s Royal Society characterized the invention as “a paradigm shift in non-invasive prenatal diagnosis.”

One might think that the inventors of this highly useful and surprising new process should be entitled to a U.S. patent given the language of the patent statute. But when the Assignee tried to assert the

patent in court against a commercial company that was making money using the invention without permission, the Federal Circuit was bound by the *Mayo* decision and affirmed a lower court finding that the claims of the patent were not directed to patent-eligible subject matter and were therefore invalid. Moreover, the U.S. Supreme Court, whose decision had led to this situation in the lower courts, declined a request to consider the case, effectively ending the patentee's rights. *Ariosa* (a subsidiary of the multinational corporation Roche) was free to commercially continue using the process that the University of Oxford had invented.

A dramatic contrast

Now, in the UK, in dramatic contrast to the U.S. outcome, the High Court of England & Wales has come to a very different decision on *Ariosa's* commercial use of Sequenom's patented invention. While *Ariosa* argued that Sequenom's European Patent No. 1,524,321 covering diagnostic procedures should be excluded from patentability, as they argued in the U.S., the High Court disagreed.⁷

The upshot of the opposite decisions in the U.S. and the UK is that the invention is protected for a limited amount of time in the UK, which ultimately benefited Oxford University and its faculty innovators, but in the U.S. any corporation can commercially exploit the invention for their own profit without recompense to those who invented it.

While a starkly different outcome for inventor's rights in the U.S. and Europe is not a surprise in 2019, this recent UK case is a timely reminder given the proposed legislation being discussed in the U.S. Congress. As a former director of the USPTO testified in June 2019 to the U.S. Senate Committee: "[O]ur current patent eligibility law truly is a mess," adding that "current U.S. law governing patent eligibility puts us behind China and Europe in life sciences and information technology -- two critical technical areas for national competitiveness."⁹

One piece of the language proposed by Congress is unusual in statutory terms, and might reflect frustration at the Supreme Court's muddying of "bright line" rules that the CAFC had put in place. The CAFC was widely credited with unifying and consolidating U.S. patent law, providing bright line rules, and was well-respected. The Supreme Court, necessarily being a generalist court in its role as court of last appeal for all federal court cases, had nevertheless chosen to overturn a number of CAFC decisions.

Former CAFC Chief Judge Michel spoke for many when he stated, "[t]he Supreme Court has made it clear that they have no interest in clarity at all. Every single review of the Federal Circuit in the last decade and a half has cut against clarity."⁸ So it is perhaps no surprise that the proposed language currently being discussed includes the following text:

"The provisions of section 101 shall be construed in favor of eligibility. No implicit or other judicially created exceptions to subject matter eligibility, including 'abstract ideas,' 'laws of nature,' or 'natural phenomena,' shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated."

In other words, the exceptions to patentability are set forth in the statute, and making new categories of unpatentable subject matter is Congress's job, not the court's.

The proposed language also attempts to fix more of the muddying of requirements for patentability introduced by the Supreme Court's decision language in *Mayo*. For decades, the questions of novelty, obviousness, enablement/written description, and patent eligibility had each been considered separately, and the case law had grown up around that. In *Mayo*, the Supreme Court blurred boundaries by introducing the concept of novelty (asking whether the invention was routine and/or conventional) into the question of subject matter eligibility. To staunch this bleeding of one concept into another, the following language has been proposed:

"The eligibility of a claimed invention under section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102 [novelty], 103 [obviousness], or 112 [enablement, written description and clarity] of this title."

Points and counterpoints

The proposed legislation is not without its critics. A coalition letter by the American Civil Liberties Union (ACLU) and others opposes the proposed legislation on grounds that it allegedly would permit patenting of human genes.¹⁰ Arguments against

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the always emotive charge of “patenting humans” include the fact that the human genome has been sequenced¹¹ and one cannot obtain a patent on a composition of matter that is itself not new.

In addition, the ACLU has asserted that a revamped statute would “prevent discovery of new treatments for diseases.” In counterpoint to this, proponents of the legislative fix point to patent coverage as actually incentivizing research, not disincentivizing it. This is part of the traditional balancing of the competing interests of the inventor and the public¹² where the inventors are rewarded for the fruits of their labor with a time-limited monopoly (which they can sell or license to others), and the public ultimately obtains the whole invention.

Away from the biotech/medical arenas, the Electronic Frontier Foundation has also criticized the proposed legislation, stating that it would create a field day for patent trolls with abstract software patents.¹³ Again, however, despite these concerns, future inventions will still need to be both new and non-obvious in order to be patented.

Support for new law

In the other camp, a group of 72 companies and trade associations has supported the proposed legislation.¹⁴ They emphasize that the reforms to Section 101 would stimulate the private sector to invest in innovation, economic development, and job growth. More recently, all 12 judges on the Federal Circuit felt that an Athena Diagnostic test for an autoimmune disease should be patent eligible, but the CAFC declined a request to hear an appeal *en banc* because of the judges’ differing views on whether the *Mayo* decision required the invalidation of Athena’s patent. The judges called for Congress or the Supreme Court to clarify the law.¹⁵

For those currently in limbo as to the patentability of their inventions, the growing Congressional recognition of the need to impart clarity as to what constitutes patent-eligible subject matter is encouraging. In practical terms, applicants who have U.S. patent applications that are subject to rejection based on patent-ineligible subject matter under 35 U.S.C. §101 may want to keep such applications pending until legislation based on the current proposals is enacted and the U.S. Patent Office and/or federal courts have provided guidance as to their interpretation of such legislation.

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ACKNOWLEDGEMENTS:

The views expressed herein are those of the authors and do not necessarily represent those of Amster Rothstein & Ebenstein LLP or its clients. Nothing in this article is to be construed as legal advice or as a substitute for legal advice.

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Expanding faculty connections

UGA launches digital images and artwork licensing program

Patented and patentable technologies may “rule the roost” in tech transfer, but that doesn’t mean universities are ignoring other creative forms of innovation that may be desirable to licensees and could represent potential new revenues -- not to mention the chance to get more faculty involved in commercialization activity. A good example can be found at Innovation Gateway, the TTO at the University of Georgia, which recently announced

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that “more than 300 unique and beautiful images emerging from university research are now available for public benefit.” The digital images and artwork are currently being made available to license through Zenfolio and Flintbox.

The images run a broad gamut, from microscopy to cultures, from flowers to crystals. Other categories include nature/wildlife; landscape; fine art; agriculture; biology; chemistry; and physics. “We decided to determine what additional IP was available out there,” shares **Gennaro Gama**, senior licensing manager, who adds that he was looking for “non-traditional materials.”

While the program was officially started late last year, the website was just launched in June. Generating additional revenue, Gama emphasizes, was not the primary driver behind the site. “Our purpose,” he explains, “is to engage researchers that do not develop patentable materials. Our thought was, let’s engage them -- to bring to this environment individuals who have never worked with us before.”

As with many innovative ideas, this one came from a clear illustration of an unmet need. Gama recalls that several years ago a faculty member approached his team with a handful of images and wanted to know if they could do something with them. “This was their first -- and only -- disclosure,” he notes.

At the time, he continues, “there was nothing we could do; we did not know much about his field, either. It sat there for several years until we said, let’s expand these and look at what else is out there.”

Getting started

The first step was to find and gather visual materials that, according to UGA’s promotional material, “captures the essence of innovation at UGA.” Gama looked around the university website, as well as its publications, and identified researchers who were potential sources of digital innovations. “We did in-reach, met with them and discussed the program,” he says.

The researchers were “very curious and very receptive,” says Gama. “Of those in the initial batch, five or six went on board right away.” Many of the images, he notes, are what he calls “art of science,” or “art of STEM.”

“They come from the labs, and several authors have actually received awards for them,” he says.

The cost of licensing depends mainly on the

intended use of the images. “For re-use of images in publications, we have academic and non-academic fees,” Gama explains. “For-profit use generally ranges between \$50 and \$70 per use, and it’s \$0 to \$20 for non-profit.” There are exceptions, however. For example, “for polarized light microscopy you could pay a small license fee to us,” says Gama (a quick search of the site found one charge of \$500 for commercial use). Part of the revenue from the license fees can accrue to the inventor under the university’s IP policy, as it addresses copyrights. “We have created specific cases for authors,” Gama adds. “When we receive revenue from a license or web site, we identify the situation and can send funds to the author.”

Searching for purchasers

While emphasizing that the amount of money generated by these licenses “is not really important,” Gama says his team is nonetheless seeking to expand the universe of potential users. For example, he says, “we are probing what might be attractive for the common man or lay person in terms of abstract art. We think some could be suitable for home décor, for instance -- especially because in our hallways we have decorations made by some of the images, and they’re beautiful. We have some computer drawings for bedding, comforters, and they look very good. We also offer those images for publication purposes.”

The overall message, he continues, is “we are trying to really engage new folks, and expand the activity of the department. I know there are universities that have much more developed [creative works] programs, like the University of Wisconsin and the University of New Hampshire, that are very profitable.”

One interesting proposition involves a small copyright-based company in UGA’s hometown of Athens, GA, called Very Good Puzzle, which makes puzzles out of local artwork. “They specialize in local artists, and low-tech-based economic development activity,” Gama explains. “Their boxes [packaging the puzzle pieces] actually contain explanations of the artwork and a short biography of the author.”

In this business arrangement, Innovation Gateway will use some of these puzzle images as a platform for explaining what it does; the boxes will explain both the images and, for the benefit of the general population, the relevance of that

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research. "We have a license with Very Good Puzzle, and they expect to launch the products sometime next year," says Gama.

What's more, Gama adds, he does not intend for this to be a one-off opportunity. "We are also in discussion with other local companies to develop products as well," he says.

Contact Gama at 706-583-8088 or gjg@uga.edu. ►

Should your TTO have its own dedicated grant writer?

Usually, grant writers are situated in a sponsored research office. But at Indiana University the Innovation & Commercialization Office, the school's TTO, has a grant writer of its own.

"I'm not aware of another tech transfer office that has a grant writer dedicated to the office," says **Bill Brizzard**, PhD, former executive director of the ICO. "It is something relatively new for us that we're trying. Indiana University does, of course, have support in place for more typical research grants, but we're trying to fill a niche in having brought on a grant writer to focus on commercialization grants," adds Brizzard, who resigned in May.

The ICO is part of the Office of the Vice Chancellor of Research (OVCR). Prior to July of 2017, technology commercialization at Indiana University was managed by an affiliate organization, the Indiana University Research and Technology Corporation (IURTC). In July of 2017, the commercialization staff transitioned into the university and now focuses entirely on start-ups. The IURTC uses the services of a contract grant writer focused exclusively on the SBIR and STTR grant applications.

The ICO's grant writer, **Amie Frame**, MPH, CCRP, handles non-SBIR/STTR grant applications. "It's often a challenge to find funding for early stage discoveries," Brizzard comments. "Federal research grants fund research but generally don't fund further development and prototyping that's necessary for commercialization. One of the goals in bringing Amie on is to try to find additional support for further technology development as well as to more generally seek out research funding opportunities to enhance the research base of our faculty inventors."

Proactive outreach

Frame proactively reaches out to faculty to encourage them to apply for grants that can be used to advance their inventions. "We have regular meetings where I sit with the tech managers and I get a

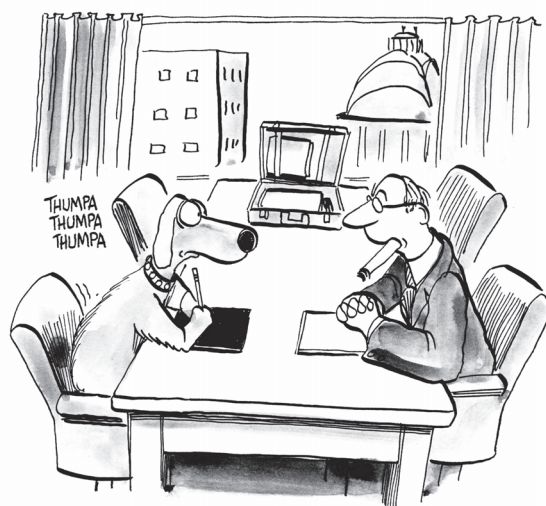
good idea of what researchers are doing on campus and what is new," she says. "I take that opportunity to reach out to the investigator to see if they're interested in grant applications, or if they're already currently working on one and how I can assist with that."

As Frame explains, her role as a grant writer is to identify which applications researchers should pursue and to help them navigate the grant submission. She sits with the researcher and explains what is required for the application package. "Each agency has their own guidelines for their applications, and those change often," Frame notes. "It helps to have someone who is an expert in the application process to guide them."

Frame constructs a development timeline with two major sections. The first guides her review of the application. She requests certain pieces of information at certain times so that she can review them in a timely manner and give feedback to the researcher. In the second section, she creates a list of the required application components and highlights some of the details specific to the funding opportunity announcement that are sometimes overlooked. "The agency application guidelines are lengthy, some hundreds of pages

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License to Laugh



*"As a negotiator he had ice in his veins,
but his tail betrayed him."*

Grant writer continued from p. 127

long,” Frame points out. “My familiarity with the agencies and their guidelines facilitates the process.”

She focuses on finding grant opportunities at federal agencies, such as the National Institutes of Health, the National Science Foundation, and the Department of Defense, that also have SBIR/STTR funding opportunities because it's likely that they will have other grants available that are not SBIR/STTR-specific.

A faculty relations plus

Brizzard notes that having a grant writer in the office has not only brought in new funding, it's also nurtured positive relationships with research faculty. Frame, who came on board in late in November, is actively reaching out to let researchers know she is a resource for them.

“We view this as an expanded service offering from a commercialization office with the intent of helping to build or improve relations with existing inventors and to possibly help us add additional donors and spread awareness of the commercialization process,” says Brizzard.

Based on the success of the IURTC's contractor dedicated to SBIRs and STTRs, Brizzard expects Frame's focus within the commercialization office will yield similar benefits. “I think all tech transfer offices should consider offering something like this,” he says.

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