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Special Report: Tech transfer and the COVID-19 pandemic

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Technology Transfer Tactics ™

Special Report: Tech transfer and the COVID-19 pandemic

TTOs respond to urgent pandemic needs with 'war time' licensing

When a scientist at the University of Dayton Research Institute (UDRI) in Ohio developed software that detects the COVID-19 virus in seconds using an X-ray, the tech transfer leaders knew they couldn't wait the usual months or years to get it to market. Instead, they had it licensed in two and a half days and on the market in just seven.

Barath Narayanan, associate research scientist at the UDRI School of Engineering, developed software that is 98% accurate using an algorithm to search for markings on X-rays indicating whether or not virus is present, according to software development company Blue Eye Soft, which licensed the innovation quickly from the institute.

The lightning fast journey from concept to market was in dramatic contrast to the typical process at UDRI and every other institution, says **Mathew Willenbrink,** director of technology partnerships at the University of Dayton and UDRI. Narayanan contacted Willenbrink soon after the pandemic took hold to say that he had been altering some of his usual research in using algorithms to detect disease in an effort to address COVID-19.

He had posted on his blog about that research, and Blue Eye Soft contacted him directly to express interest in licensing the new software. Willenbrink facilitated a Zoom meeting with the researcher and leaders at Blue Eye Soft, who inquired about the school's process for licensing and how fast it could be done. Soon, discussions ensued in another Zoom meeting with the

What's inside ...

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inventor, the director of the incubator where he worked, the incubator's outside counsel, Willenbrink, and Blue Eye Soft's representatives.

"We hashed it out over three or four hours to settle on a price, including some money back for the school of engineering, making sure the inventors were taken care of, and some buyout clauses," he explains. "It was a somewhat complex negotiation, but I could tell that Blue Eye Soft was very, very driven. And since it was a technology that could potentially help with the epidemic, I pretty much dropped everything I was doing to make this happen."

Streamlined process

UDRI skipped some of its formal processes for expediency. Instead of the usual invention disclosure process, Willenbrink just asked questions relevant to the disclosure to get the description of the invention.

"There were a couple issues in negotiation where we just agreed to have a gentleman's agreement, since the CEO of Blue Eye Soft was a University of Dayton alumnus and we had a great deal of trust in each other," Willenbrink says. "That smoothed out some of the things that would have taken longer negotiations and a more thorough vetting of each side. We dropped some of our internal measures that addressed how things will operate and how people will be treated, and we could do that only because there was mutual trust and respect."

Blue Eye Soft had a working prototype of the software online within a day of the license.

"They got the code and got it up on a web site to start using it to diagnose pictures so they could get FDA approval and funding," Willenbrink says. "They're now beyond a working prototype, have some extra funding, and are seeking approval to

treat. We expect very soon to be able to see this tool doing diagnostic work, which is pretty exciting within a month."

Why not always?

Willenbrink was ready for the inevitable question to follow: If this license could be done so quickly, why can't that be the standard process? He says it would not always be possible or appropriate to skip some of the standard steps in vetting and negotiation, and delays often do not come from the university side.

"I was also able to drop everything to get this done so that reviews were complete in a matter of hours instead of days," he explains. "The normal way for both sides when we're not motivated by a national crisis is that we review things and send it to them, they review it and make changes, sending it back to us in a week, and the process goes on. On my end at least I could probably do all of our licensing agreements that quickly if I only focused on that one agreement with 100% of my time."

This also was one of the first licenses completed since the University of Dayton put all of its licenses online, he says. The availability of the licenses to anyone and the transparency sped up the process, he says.

Willenbrink also found value in running some processes in parallel. He was obtaining approvals at the university while negotiations were still going on with Blue Eye Soft, rather than waiting for all the negotiations to be completed first.

"I saw how quickly the process can move if you review things very, very quickly and get back to motivated people," he says. "When you have a lot of momentum with motivated parties, you do everything you can to do keep that momentum up. It doesn't take much for one party to lose steam and

motivation, so you have to stoke those fires and keep them hot."

Face shields fast-tracked at Columbia

Columbia University in New York City also was successful in rapid licensing for an invention that could be of immediate help in the pandemic, says **Orin Herskowitz**, executive director of Columbia Technology Ventures.

"Under the best of circumstances, our life saving and life improving technology might help someone in eight to 15 years," he says. "That's kind of the definition of most tech transfer outcomes: moving potentially great products into the world a decade from now."

In the midst of a pandemic however, those timelines just don't work. At Columbia, researchers quickly developed a new design for face shields that could help alleviate the critical shortage of personal protective equipment for healthcare workers. Engineers called Herskowitz in late March to notify him of their new design, eager to get it in the hands of users as soon as possible.

"They had gotten together to figure out how to mass manufacture these face shields, and they realized quickly that their first idea, 3-D printing, wasn't going to work. Hospitals need so many thousands of these every day at every hospital, and you just can't 3-D print at that scale," he says. "So they came up with a design that is on a flat piece of clear plastic that has origami-like folds."

A clinician can unfold it and put it together in three seconds, Herskowitz explains, and since it's a flat piece of plastic it can be cut quickly with traditional die-cut manufacturing. That makes it possible to manufacture on a large scale using commonly available equipment.

"I got the call on this on a Saturday, and by Sunday we were having conversations with two different contract manufacturers," he says. "New York Presbyterian Hospital, one of New York's largest hospital systems, had seen the design and liked it. They tested them in the hospital on Sunday and told us they wanted them as fast as we could get them there."

Fast contracts, fast licenses

Within seven days Columbia had contracts with two manufacturers scheduled to deliver more than a million units to New York hospitals, Herskowitz says. Before those deliveries could be made, the Columbia School of Engineering delivered 8,000 units it had manufactured with its own water jet in the Columbia Engineering maker space.

"We wanted to get these face masks out as quickly as possible, so we set up a click licensing site and distributed them for free," he says. "We used a license that our general counsel's office put together in about 12 hours, which basically says, 'You can use it how you want, just please don't sue us.'"

The streamlined licensing agreement makes clear that Columbia is making no claims about efficacy. Links to the click license forms and descriptions of the face shield products are available online at https://techventures.columbia.edu/face-shield-designs-columbia-engineers. In addition, *TTT* readers can access two versions of the license agreement -- one for small entities and one for large entities -- at https://techtransfercentral.com/ttt420.

Columbia had to quickly research manufacturers and distribution options, in addition to making the product known to hospital purchasing managers. The product also had to be tested with multiple groups of clinicians.

"We in the tech transfer office were involved all along the way, but much of it [involved] things we had never done before," he explains. "We're not the only university moving quickly like this, perhaps just among the first due to NYC's crisis. Every tech transfer office in the country is now engaged in the same conversations about how to make these inventions available as soon as possible."

No-cost negotiations

The fast deployment was possible only because some typical steps were eliminated or greatly streamlined, Herskowitz explains. First, there is usually a long conversation about money with most tech transfer projects, and in this case Columbia decided to make the product available for free. That eliminated what would have been a lengthy delay in actually making the items available, he says. The university's general counsel office also moved quickly. Concerns about liability typically slow down any product in the healthcare arena, he notes.

Clear communication about the dire need for the product was key to getting the general counsel's office comfortable with this fast approach, Herskowitz says. One of the things that helped was involving them as early as possible, he says.

"Once the attorneys realized the life and death situation we were facing, the legal flexibility and creativity they displayed was outstanding. Everyone recognized this was not a peace time license; this was a war time license," he says. "Every hour of delay because we didn't expedite something was going to be, in this case, two or three thousand patient-clinician interactions per hospital that were done without proper equipment."

Design process vs. speed to market

Columbia had to balance perfecting designs against trying to get the designs to market as quickly as possible. Normally, one would generate a series of designs, obtain feedback on them, make improvements, and repeat that process over and over until an optimal design is determined. Some faculty members were focused on that classical design process and reluctant to skip any steps, Herskowitz says.

"But we had other faculty members who heard directly from purchasing managers at hospitals, including one who said if we couldn't get him something within a few days he was going to order a bunch of swim goggles off Amazon for their doctors," Herskowitz says. "Some engineers were conceding that perfect design principles could not be the most important thing at this moment. We just needed to get a product to market fast, and then continue to improve upon it later. We were building the airplane while flying it."

The engineering school had enlisted faculty members and students to produce the masks as quickly as possible, until the contracted manufacturers could take over, but a problem occurred when one of the teams thought they could speed production by using laser cutting instead of water jets. They didn't realize that heat from the laser cutting changed the consistency of the plastic so much that when clinicians opened the box of face shields, the product cracked in their hands.

"The engineers had to go back and figure out what had happened, then go to the in-house manufacturing teams and make sure they were all following the same process that yielded the best results," he says. "These were all things that the tech transfer office is not used to being involved with. We don't operate on these time scales at all, and with this much involvement in some of the details of the work. It's been a huge learning experience for us."

Herskowitz says the successful deployment of what has been dubbed FaceShieldOne is a testament to how well the Columbia University community pulled together in a time of need, but also how his counterparts at other schools were eager to help.

"It's been fascinating to go from 10 years to market to seven days to market, and realize you can do that. Without the university community, none of this would have been possible," Herskowitz says. "I contacted my peers at Duke, Partners, Cleveland Clinic, and others, and later on I was trading information back and forth with other AUTM members to get tips and see what others are doing with licensing and other issues. It is an enormous privilege to work in a community that is this open to collaboration and sharing, especially in a crisis."

Contact Willenbrink at 937-229-3469; contact Herskowitz at oh2120@columbia.edu. ▶

Coronavirus brings challenges and changes to TTO operations

University researchers and tech transfer leaders have pivoted to prioritize research related to COVID-19, with streamlined licensing and pledges to make technology available free of charge during a time of crisis.

There can still be a need for close oversight of partnerships and licensing, however, and there is some concern about well-intentioned efforts to speed technology to market could undermine some principles of tech transfer.

The COVID-19 outbreak quickly changed the nature of research at the University of Michigan, says **Bryce Pilz**, director of licensing in the Office of Technology Transfer there. The university wound down all non-pandemic related research as COVID-19 work quickly spun up.

"That involves everything from researchers pivoting their research to focus on COVID-19, to collaborations that formed very rapidly in an expedited manner. Companies were reaching out to ask if they could use one of our facilities or they could work with some of our top scientists on high priority projects," Pilz says. "The technology coming out

of this includes antivirals and vaccines, as well as many ventilator-related projects. Those include new ways to use ventilators on multiple patients, ways to build ventilators with available equipment, 3-D printed masks and shields, and a great deal of software for diagnostics and prioritizing patients when resources are limited."

For some physical items, the university has adapted with fast licenses that can make some of that research available to manufacturers and users rapidly, with documents available on its online portal that specify the technology is early stage, has not been fully validated, and does not have FDA approval.

Oversight still needed

However, there is still a need for careful oversight of licensing in some areas, Pilz notes.

"There are things like antivirals in which it does matters who you give it to because there is going to be a ton of work done by that other party and there are things they could do to make it difficult for anyone to bring it to market," Pilz explains. "We're being told by experts and investors that even with relaxed regulatory approvals, it is still the case that anyone generating negative data for a potential therapeutic is going to make it hard to bring that to market, so we still have a responsibility to make sure the people we're partnering with know what they're doing and are the right people to partner with."

That means the university is scrambling to put together the oversight and connections necessary to ensure those partnerships are sound, and to do it in the most expedited way possible, Pilz says.

"The document you use to effect that transaction is the easiest of all the problems. We can pretty quickly put together a document that allows them to use the technology, and our policy across the board is to allow anything for COVID-19 to be used free of charge and without additional hurdles," he says. "But the actual transaction, the licensing, is the easy part -- it's the end result of a lot of coordination of resources and development of resources when it involves something like a potential therapeutic."

Dual use IP challenging

One challenge is dealing with technology that is dual use, including applications in addressing COVID-19, Pilz says. The university may want to make the technology available for use in addressing the pandemic, but without giving up rights to its potential in curing cancer, for instance.

In those cases, the university provides a more detailed and restrictive license that makes the technology available to address COVID-19 in a specific time frame. "The license and exclusivity are limited to that particular use, with restrictions that we might place on a face mask or something like that [which] we're also trying to make available as fast as possible," Pilz says.

Lining up resources

Along with its commercialization and licensing work, the University of Michigan TTO has been busy matching companies and philanthropists eager to help address the pandemic with the right resources in the university community.

"We work to play matchmaker but also to create a system so that we can understand, categorize, and prioritize all these resources coming in. Related to that is all the requests for research, and we have a process for people who want to perform COVID-19 research, making sure they are qualified before we grant them access to our facilities with limited bandwidth," Pilz says. "This is new to our office. We're as equipped as anyone to handle it, but that's not something that has been part of our basic operation and now has become critically important to what we do."

Pilz expects TTOs to carry forth some of the lessons from the pandemic response, such as his university's improved focus on matchmaking, brought on by the sudden onslaught of queries and opportunities.

"Tech transfer was always a complicated activity in which you're bringing together a number of people from very different skill sets, and that got even more complicated in the last few weeks," Pilz says. "As hard as it's been, it's also been fulfilling to see the great human spirit from everyone at the university rising to the challenge to try to help out."

Marketing can continue

The University of Georgia is continuing to market and encourage inquiries from potential partners during the crisis. The university's tech transfer office recently sent a reminder to innovators and partners assuring them that it is offering its full suite of services during the pandemic, pointing out it uses an IP database, market analysis tools, and communication platforms that are cloud-based.

Challenges continued from p. 53

"If you are a UGA innovator, perhaps this time provides an opportunity to submit a new invention disclosure. We will conduct our full IP evaluation and market assessment and meet with you virtually to receive your feedback and move forward with protecting your discovery," the letter says. "Or maybe you are ready to explore your idea for a start-up company. Our start-up program and team are ready to assist you."

A strong online presence makes it possible to continue operations when working remotely, says **Derek Eberhart**, PhD, associate vice president for research and executive director of UGA's Innovation Gateway. "Most universities are scaling back research at this time, but we've seen a real increase in work related to COVID-19, particularly with our Center for Vaccines and Immunology, so we've been working to facilitate MTAs and sponsored research agreements," Eberhart says. "Anything related to coronavirus goes to the front of queue for agreement execution."

Partners easier to reach

UGA is still maintaining its deal flow, actively executing license agreements unrelated to COVID-19. A large portion of its portfolio is in the agricultural space, and the pandemic fell in a busy time of year for that sector, with people trying to get cultivars licensed before planting time, Eberhart explains.

Tech transfer leaders also are trying to take advantage of the fact that so many people are at home now and more accessible.

"A lot of our industry partners are not traveling as much now, so we are trying to be available to them if there are things we might be available to help with. We're reaching out to our start-ups and trying to be proactive with some customer discovery," Eberhart says. "Those people who are not directly involved with any kind of COVID-19 response are at home like the rest of us, and it can be a good time to chat and explore opportunities, see if there's a need that we can help address for them."

Pledges urge free IP

Part of the tech transfer community's response to the pandemic has been to offer the free use of technology that can offer immediate benefit, with some major universities signing on to pledges that they will not let the pursuit of profit stand in the

way of helping fight COVID-19. One initiative, the Open COVID Pledge, calls on universities and companies to "free up intellectual property (IP) to spur development of treatments and cures for COVID-19, now spreading rapidly through the world."

The creators of the pledge say it is "a practical and moral imperative that every tool we have at our disposal be applied to develop and deploy technologies on a massive scale without impediment. We therefore pledge to make our intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease." (The sign up for the pledge is online at https://opencovidpledge.org/)

The pledge and a license agreement specific to the COVID-19 outbreak were developed by a group of lawyers, including **Jorge L. Contreras**, presidential scholar and professor of law at the S.J. Quinney College of Law at the University of Utah in Salt Lake City.

"We put together what we think is a lightweight, very easy to implement pledge with a license that allows IP holders to commit their IP, with patents and copyright, to anyone who wants to use it to address COVID-19 during the duration of the pandemic and for a year after," Contreras says. "It is a temporary, emergency measure, not meant to give away their IP permanently. It's meant to open some doors and remove barriers to groups who want to work fast on all the different types of technology issues related to the pandemic."

The immediate response was positive, Contreras says. Intel, Mozilla, and Creative Commons were among the first companies to adopt the pledge.

Some skepticism on pledges

Harvard University also announced its commitment to the COVID-19 Technology Access Framework, a similar agreement that allows the use of non-exclusive and royalty-free licenses of IP for fighting COVID-19. Stanford, MIT, and Yale have also signed on. Harvard's Office of Technology Development describes the framework as a set of technology licensing principles designed to "incentivize and allow for the most broad and equitable access to university innovations."

However, such pledges were met with skepticism by **Marc Sedam**, vice provost for innovation and new ventures at the University of New Hampshire. In a communication to AUTM members, Sedam wondered if the well-intentioned

pledges might prove detrimental in the long run.

"While this is a noble and valuable effort, the few [pledges] I've seen have made inference of reducing the cost of the eventual solution as one of the ways to improve access. The challenge presented by this language is that it inadvertently connects IP and licensing with the price of the solution -- a narrative that AUTM has fought to correct since the inception of Bayh-Dole," he wrote.

The pledges may inadvertently "be used as a direct hit on Bayh-Dole," he wrote. "University innovation is an accelerant for commercial solutions, not a hindrance. If asked, I will recommend that UNH not sign these pledges and am working with AUTM leadership and others around the country on a possible solution that upholds everyone's desire to pitch in and respond to the pandemic under substantially similar principles to what's been proposed but avoids this potential pitfall."

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Special Report: Tech transfer and the COVID-19 pandemic

TTOs adapt to remote work but still learning on the fly

Leading TTOs from across the country shared their experiences in the COVID-19 crisis during the recent free webinar "Managing TTO Operations During the COVID-19 Pandemic and Planning for Future Disruptions," provided by Tech Transfer Central. *(To get the on-demand video and/or print transcript of the program, register at https://tinyurl.com/ts78s3n.)*

The common theme among the presenters was that prior emergency planning brought tremendous benefits when it was time to pivot to remote operations, but there still are plenty of adjustments and concessions to be made in the transition to closed laboratories and home-based work.

A survey just prior to the webinar revealed that nearly 100% of tech transfer offices surveyed are now working completely remotely, though a few have someone in the office to receive payments and carry out other essential administrative tasks. The transition to remote work was relatively easy for 52.94% who said they had procedures in place when the time came, but 38.24% said it was more challenging and 8.82% said it was quite difficult to make the change.

The biggest challenges cited in the transition to remote work were communication, computer and other technical issues, meeting deadlines, finding a work/life balance, and interruptions or stoppage of research projects.

Tech transfer leaders found that pivoting in the COVID-19 pandemic was most efficient when there already was a robust continuity plan in place that could be activated for this emergency. The University of Southern California conducts annual continuity planning for a wide range of possible emergency scenarios, and leaders there began proactive planning for COVID-19 in January, says **Lisa Andaleon**, MA, director of operations and finance with the USC Stevens Center for Innovation in Los Angeles.

"Last year we had our first FEMA emergency training with all the senior business officers, who are like the COOs of the schools and departments," she says. "In January our emergency planning team called together a meeting of all our senior business officers and operations people to talk about how they were beginning to plan for COVID. They said we wanted to be proactive and not reactive."

The emergency planning team explained that the university already was looking for housing in case students had to be quarantined, as well contingency plans for international programs and other travel-related issues. That first meeting was followed by six or seven meetings every week to advance the university's emergency plan, and then mandatory testing of online learning platforms began in early March.

Each department also was testing its business continuity plan. "At USC Stevens we had already started making sure we could work remotely, and by March 13 we got the notice from the school that we all had to work remotely," Andaleon says. "We were pretty much ready for that. Maybe it was serendipity, but USC had purchased a thousand Zoom licenses last fall, and Slack as well, to get everyone at the university on the same page as far as that type of technology."

Emory goes remote

At Emory University in Atlanta, a similar experience was unfolding. The university was executing

its emergency plans for moving all operations off site and shifting to remote technology like Zoom and Skype, says **Linda Kesselring,** MBA, RTTP, operations director with the Emory Office of Technology Transfer.

"You all may be tired of Zoom and the various backgrounds that people come up with during your meetings, but at Emory we were lucky because the university allowed us to take computer equipment home," she says. "People were allowed to take their laptops, their monitors, their docking stations, whatever they liked. We actually had someone ask to take their chair. It was all fine, and you just filled out a form so that at some point we knew where everything went."

Kesselring and her colleagues also learned to utilize the full capabilities of the university phone system, which is a voice-over-IP (VoIP) system. It includes an app that will mirror the employee's office line to a cell phone, so that when you dial out the call appears to come from the Emory office number. That provides the proper caller ID to the other person and avoids the caller having to give out his or her personal phone number.

They also took steps to ensure each staff member has the proper permission for firewalls, virtual private networks, and other technology protections, which may require supervisor signoffs or contact with the IT department. Access to the tech transfer databases was critical for working remotely, Kesselring says.

"Can they be accessed with a simple internet connection, or does it have to go through various security measures? Are those permissions in place?" she poses. "Is your database vendor-hosted? In our case, our main databases is vendor-hosted, and so one of the upsides to that is that all of your upgrades and maintenance will continue on its normal schedule, supporting your offices without any sort of extra time and attention from you."

Emory's TTO has a second database that is not vendor-hosted, and it was scheduled for an upgrade during the early weeks of the pandemic shutdown. Emory's IT department had to try to handle the upgrade remotely.

"They stepped up, but unfortunately something still went wrong and we had to call that upgrade off. We're still in the process of diagnosing what we are going to do next and when," Kesselring says. "We had wanted to get that database on a web platform even though it's not ven-dor-hosted, and obviously that caught up to us in this situation."

Online storage vital

Portals also proved important, allowing faculty to submit disclosures, MTAs, or other paperwork electronically. The Emory portal also allowed oversight of those documents to be transferred easily from one staff member to another if, for instance, the original employee became ill, she explains.

The widespread use of electronic documentation can make data more available when working remotely, but the type of storage and the number of different storage sites can make a difference, Kesselring says. Network drives have different types of security privileges, whereas staff can get to cloud storage with a simple internet connection, she notes.

"Our director challenged me two years ago to figure out how few places I could store electronic information for our staff, saying he wanted use to try for one even though he knew we couldn't get to just one," she says. "So we were in the process of retiring network drives and were very close to the end of that process when all of this happened. With some scrambling at the last minute, we completed getting all the files into Box Drive for the staff."

Cloud storage systems like Box Drive allow for more granular permissions than a network drive, so Kesselring says the investment in time to transition from network drives can pay off.

Staff management issues

For staff management, Kesselring says Emory leaders found that they could repurpose existing policies on telecommuting that might previously have been employed when people needed to be home temporarily with a sick child or parent, or when employees wanted to split hours.

Emory also had to assess how student workers could continue to contribute to the tech transfer operation. They may not have the same permissions and access to technology, but in Emory's case most of their students were able to continue working.

Electronic signatures become more important when working remotely, and Emory had been fortunate enough to adopt DocuSign about a year before the pandemic. The TTO already had vetted the use of electronic signatures and so was able to roll out the use of DocuSign more broadly once the program pivoted to remote operations.

Generic e-mail addresses also proved useful for Emory. The tech transfer office had created some recently to direct common business functions like CDAs, MTAs, progress reports, and legal invoices to a specific mailbox for that purpose, rather than to a specific person.

"These are in our templates, on our forms, on our web site. What's really nice about them is that they are a true mailbox, so you can access them right from our Outlook client, give multiple staff access to them, and send e-mail from that mailbox," Kesselring explains. "It also makes us less dependent on postal mail because everything can come in directly to those mailboxes."

"There were also simple, everyday things that we didn't fully think about until we started leaving campus. What do you do about mail and packages?" Kesselring says. "For part of that you have to wait on other offices on campus to make their decisions. In our case … mail would be delivered to everyone on campus one day a week, and we have someone going into our office picking up those checks."

Keeping meeting schedules

Emory's tech transfer program is maintaining workflow by continuing all internal meetings through videoconferencing, even ramping up the frequency of some to account for the lack of office drop-ins and chitchat at the coffee machine. Kesselring also recommends regular check-ins with people outside the tech transfer office, including licensees, start-ups, and legal counsel. Tech transfer staff also continuing to pull and share key metrics, and so far there has been no noticeable drop-in activity or productivity, Kesselring says.

"There's a lot of functions in the office where everything is business as usual. Post-license compliance, marketing -- all those folks are doing their normal thing," Kesselring says.

Even simple things like the office refrigerator can become an issue, Kesselring says. She and her staff realized that food had been left in the fridge when everyone left campus and that it would be a mess when they returned, so they arranged for one of the employees visiting the office to throw everything away.

Communication is especially important with remote operations, and that includes keeping stake-holders abreast of activity, Kesselring says. At Emory, and probably at most universities, this responsibility falls not on tech transfer leaders but on the senior vice president for research.

The Emory SVP holds a campus-wide faculty videoconference every week, called "Friday at Four." It's a 30-minute presentation followed by a 30-minute question and answer session. Topics typically include maintaining research continuity and productivity, human subjects accrual, and animal research. The SVP also sends a weekly e-mail to faculty and a web page with key resources (http://www.ora.emory.edu/COVID/index.html).

At USC, the SVP also created a central web site for resources with information such as deadlines for grant funding, research integrity, and IRB access. Andaleon says in January the licensing associates also began sending an e-mail to each of their assigned faculty members every other week.

"It's a lot of work for them. They weren't happy when we first rolled this out," she says. "It's their entire docket they have with each of their faculty, so that's any licensing agreements in negotiation, where they are with patent prosecution. They also meet with their faculty members to give them live updates, which they're doing by Zoom now."

Faculty innovation may suffer

Faculty innovation may take a serious hit during an emergency that necessitates remote operations, notes **Neil Veloso**, MBA, executive director of Brown Technology Innovations at Brown University in Providence, RI. The move to online teaching, an increased clinical load, and laboratory shutdowns can all make it difficult for faculty to continue pursuing research and tech transfer, he says. Veloso and his colleagues at Brown are studying the effect on invention disclosures.

"There are two competing schools of thought, with one saying the lack of data will slow down disclosures and the other saying simply that the time away from the lab will give them time to reflect and get more disclosures on the books," he says. "For TTOs where it's budget season and you're looking to allocate your patent budget for new disclosures, trying to answer this question now would be very important."

The pandemic has put a new emphasis on engineering innovation, Veloso says, so TTOs could see more disclosures in that area. Other COVID-related

disclosures that are more clinical could have the effect of drawing researchers away from cancer and other research, he says.

Brown's working relationships with vendors are largely dictated by their ability to communicate through telework technology, Veloso says. Law firms tend to have good telework capabilities, so work with them is largely unaffected, but consulting work that requires on-site activity has ended, he says.

So has an entire slate of in-person events, as is the case countrywide. And plans for the future are sketchy at best. "We do continue to plan for fall events like inventor night and networking opportunities, but at least at an operational level we are really looking to avoid non-refundable down payments just in case our shutdown lasts into the future."

As researchers have shifted their focus to tackling COVID-19, the Brown TTO is shifting into support mode. "We have been heavily engaged with identifying researchers with COVID-related work and will respond to new funding initiatives as part of the stimulus package or industry sponsors as well," he says. "We've found that COVID-related work can be broad-based, spanning the entire university from life sciences to engineering and, of course, public health."

Amended agreements and deadlines

Industry research sponsors have needed amended agreements and revised deadlines because of the pandemic, Veloso says.

"Rather than simply end an agreement, what we've done within the TTO is to try to continue conceptual research, literature searches, all sort of the back office research activity that won't require a lab," he says.

Veloso notes that the pandemic has given his TTO an opportunity to reach out to industry sponsors and government resources to identify new COVID-related RFPs, and to utilize state-owned resources, like 3-D printers and other manufacturing equipment.

At USC, when the vice president for research started an internal fund to look for COVID-19 related research at the university, the executive director of the USC Stevens Center for Innovation volunteered $100,000 to the effort. "Our vice president of research was thrilled that we could do that, and the

last I heard they were up to close to a million dollars in internal funds to fund COVID research," Andaleon says.

Brown so far has not seen COVID-related effects on diligence milestones, but Veloso says he does expect to see an impact soon on diligence, clinical trial milestones, and existing royalty streams. MTAs are still at a steady level but Veloso says the continued lab closures are likely to cause a slowdown, possibly mitigated by a rise in COVID-related MTAs.

Kesselring notes that Emory is seeing some researchers preparing for the reopening of their labs.

"Faculty are preparing for restarting, putting various materials in place in their labs and trying to be ready to hit the ground running when we restart," Kesselring says. "We've started to have an internal discussion about whether we should be reaching out to some of our start-up companies because patent reimbursement can be a challenge for some of them and we're considering doing something a little more proactive for them. We haven't quite figured out the answer for that but we've started the conversation."

At USC, the TTO recently sent an e-mail to all of its licensees who will owe license income such as annual royalties or milestone payments between March 30 and June 30, the university's fiscal year end, noting that if they are experiencing hardship the university will extend the due date to September 30. For patent reimbursement, Andaleon says USC told licensees that they need to collect the funds but will accept a payment plan if necessary. A few licensees requested a payment plan, she says.

Watching for impact

Veloso says at Brown there has been no effect so far on term sheet or draft agreements in negotiation, and no appreciable effect on IP licensing. Tangible material licensing from repositories is continuing, but Veloso says he expects some effect on material licensing that comes direct from labs, especially if the lab shutdown continues for much longer.

Veloso also has heard anecdotal evidence of investors facing difficulties in performing due diligence without face-to-face meetings.

If there is a silver lining, Veloso says Brown's TTO is able to focus more on prospective, early-

stage marketing. "We've actually seen an increase in our operational tempo on the marketing side. I think the whole crisis has given our office a little bit of breathing room to focus on our existing, unlicensed portfolio," he says. "We've seen an uptick in venture engagement and a continued interest in new technology."

Contact Andaleon at 213-740-7249 or andaleon@usc.edu; Kesselring at 404-727-3857 or lkessel@emory.edu; and Veloso at 401-863-1585 or neil_veloso@brown.edu.

The on-demand video and print transcript for the free webinar "Managing TTO Operations During the COVID-19 Pandemic and Planning for Future Disruptions" provided by Tech Transfer Central is available after registering at https://tinyurl.com/ts78s3n. ▶

Take step to avoid patent-killing 'pre-print' disclosures

Careful, albeit enthusiastic, inventors have always been guarded about sharing any aspects of their innovations. They follow rules about public disclosures and publishing, and leverage the time-tested patent protection process. But in the academic world, where publishing is paramount to tenure and career advancement, there is always the risk that a public disclosure will eliminate the innovator's -- and their university's -- ability to protect an invention.

As TTOs know, the publishing date is significant. So is understanding what publishing means in the 21st century. And with the advent of automatic or "pre-print" publishing being used by some online platforms and publishers, the risk of public disclosure -- and loss of patent rights -- is trickier than ever.

Felicia Metz, JD, associate director of the Office of Technology at the University of Maryland, reminds us that "if you publish first and go later to the Patent Office, that will be prior art against your application. You get that one-year grace period for an inventor's own publication, but that's in the U.S. The risk is that public disclosure activities within one year of a patent filing can compromise your patent rights or you can lose them altogether." Outside the U.S., once an invention has been publicly disclosed, inventors have minimal or even zero shot at patent protection.

What is publishing?

As with other aspects of our lives, the Internet seems to offer as many wonderous never-before-contemplated advantages as it does potential ways to get into trouble. Easily granting public access to just about anything, including a patentable idea, is just one of them. One thing the web has changed is that a description of an invention doesn't need to appear in a "publicly distributed paper journal" to constitute a "printed publication" for the purposes of the Patent Act. Not all academic inventors get this, putting themselves and their universities at risk in terms of patent protection. The "pre-print" trend makes this even harder to police for TTOs.

Companies, universities, non-profits, government agencies, societies, and associations have created myriad free distribution services that provide open-access file-sharing archives comprising many millions of scholarly articles in virtually all fields of science and technology.

Inventors often use these services to post "pre-prints" of their manuscripts, not realizing they are "publishing" in the eyes of patent offices. Many platforms use some form of the letters "rxiv," for "archives," in their titles, such as arXiv.org operated by Cornell University; bioRxiv and medRxiv operated by Cold Spring Harbor Lab; ChemRxiv operated by chemical societies in the U.S., U.K. and Germany; PsyArXiv operated by the Center for Open Science; SportRxiv, a community-based repository led by a steering committee comprising professionals from the U.K., U.S. and Canada; and viXra, created by a physicist to compete with "dominant" arXiv. There are many others, from Google Scholar to Microsoft Academic Search, and OpenDOAR operated by UK not-for-profit Jisc; CiteSeer^{X} out of Penn State University; and ResearchGate, a Berlin-based commercial social network.

Fast and easy public sharing is the primary mission of these sites. For example, bioRxiv (pronounced "bio-archive") is a free online archive and distribution service for unpublished pre-prints in the life sciences. "By posting pre-prints on bioRxiv," the service says, "authors are able to

make their findings immediately available to the scientific community and receive feedback on draft manuscripts before they are submitted to journals." The site makes it clear: "Articles are not peer-reviewed, edited, or typeset before being posted online."

The Directory of Open Access Journals, launched in 2003 at Lund University in Sweden, lists 14,469 journals and 4.8 million articles from 133 countries. "DOAJ's mission is to increase the visibility, accessibility, reputation, usage and impact of quality, peer-reviewed, open access scholarly research journals globally, regardless of discipline, geography or language," the site explains.

Elsevier ScienceDirect, the leading platform of peer-reviewed literature, has more than 1.2 million articles from 250 full open-access publications. ScienceDirect overall has 16 million articles from 2,500 journals.

The perils of not getting it right

Journals and open access sites often post articles online before they appear in print which, not all inventors realize, starts the clock ticking under patent law.

Unfortunately, as we detailed in the January 2020 issue of *Technology Transfer Tactics* (page 5), a pair of inventors at Albert Einstein College of Medicine and the school itself paid a steep price for not knowing online access was considered publishing. They drafted a manuscript about an exciting and potentially lucrative new genetic testing technology, which was accepted for publication in the journal *Clinical Genetics*. A preview of the article appeared online in December 2011.

What the inventors called a "final" version was published electronically in January 2012 and in print in March 2012. The inventors told their attorneys about the print publication, but did not mention -- and say the law firm was negligent for not asking them -- about the earlier online publication dates. Because the patent application was filed more than a year after the appearance of the first online version of the article, the Patent Office rejected the patent application. The result, they said, was the loss of potentially tens of millions of dollars and a pending lawsuit against the firm that handled its application.

More recently, according to a source who requested anonymity, a group of prolific inventors actively posted their pre-prints to one of the file-sharing sites and, while they did not lose patent protection in the U.S., they did lose international rights.

It's critically important that academic inventors keep their innovation offices in the loop no matter what form of publishing is used, and it's critical that TTOs educate researchers about the potential perils of pre-print disclosures.

As Metz noted, "we're not here to stop them from publishing, but to get research out and to file patent applications." Universities need to face this communications challenge so inventors are telling TTOs or venture development teams what they are doing -- not to hinder their work but to protect it *and* share it, she stresses. Metz says best practices include holding regular internal talks with inventors about intellectual property, speaking to classes, and holding faculty workshops.

When in doubt ...

Metz says the message her office conveys is a simple one: "When in doubt, contact us -- even if the university might not own an invention.

"We used to say," Metz continues, "'Let us know when your manuscript is accepted.' Now we ask for it right away and will file a provisional patent application first."

Metz reports that her office is also proactive in looking for possible disclosures that may not be brought to their attention. She says they set up automatic alerts based on key words relating to the type of work the university's teams are undertaking, as well as the names of their inventors, to see if any of their innovating students or faculty are writing articles, being quoted, or giving presentations.

Teamwork and relationships key

TTT also contacted the University of Pennsylvania's Penn Center of Innovation for their insights. The center's formal language puts their approach this way: "Penn and [the Penn Center for Innovation] are strongly dedicated to protecting academic freedom and ensuring that faculty and researchers are able to freely publish and disseminate the fruits of their scholarship and research activities. However, since valuable patent rights

may be affected or even destroyed by any public disclosure activities, it is best to submit an invention disclosure well in advance of communicating or disclosing your invention to people outside the Penn community."

Executive Director of Licensing **Benjamin C. Dibling,** PhD, and Chief Operations Officer **Jennifer E. Langenberger** say part of the key to successful prevention is about working well as a team.

"The best way to mitigate the risk associated with an unexpected public disclosure as a result of pre-publication is by cultivating strong relationships with faculty and our other customers at Penn," they said in an e-mailed response to our inquiry. "Our business development team works directly with specific departments and individual inventors to build strong relationships that include education around public disclosures and emphasizing the benefits of proactive communication with our office. Ideally faculty will be in regular communication with their business development lead and will contact our office before submitting a publication. We can then ask the faculty whether they anticipate there being a pre-publication upon acceptance of the manuscript. If this is unknown, we can always confirm with the journal. If there's any uncertainly as to whether a pre-publication may occur, we always have the option of filing a patent application at the time of manuscript submission, and we would likely employ this strategy for technologies of high commercial potential."

Of course, sharing manuscripts online is just one method of disclosure. Inventors can also disclose by:

• Writing research proposals and applying for grants.

• Discussing inventions with third parties at industry or academic events.

• Presenting at conferences or giving lectures.

• Writing abstracts and articles.

• Writing or publishing a thesis or dissertation

• Creating informational posters.

• Writing website descriptions.

Tips for researchers and TTOs

In communicating to your researchers, Metz and the PCI team say the guidance you provide is not complicated, but it is important to work hard at making an impression and gaining their assistance by focusing on these points:

1. Notify, notify, notify. Alert your technology or innovation office as early as possible, and certainly before uttering a word to a third party, writing about your invention, sharing any descriptions with any websites, or publicly discussing it.

2. When in doubt, See # 1. There is no downside to bringing your innovation team into the loop. The downside to not doing so can be crushingly severe.

3. Consult the guidelines. Find, familiarize, and check your university's publishing information and best practices resources, often available on your institution's website.

4. Participate in training opportunities. Take advantage of educational sessions or workshops your university offers on protecting intellectual property.

For TTOs and IP professionals, the experts outlined these steps to take in ensuring your researchers don't inadvertently place their own innovations in danger of losing patent protection, including through pre-print disclosures:

Educate, educate, educate. Hold faculty workshops, conduct internal IP seminars for students, and display or distribute informational posters and infographics.

Strengthen disclosure forms. Emphasize the importance of notifying the tech transfer office before making any other disclosures.

Set up automated subject-matter alerts. Get notified when articles appear online dealing with the type of work your teams are undertaking.

Search your inventors by name. Frequently search the web to see if researchers on your team are writing articles, being quoted, or giving presentations.

Publish your publishing guidance. Provide clear, current, and easy-to-follow instructions for your inventors on your website and whatever other distribution methods you use.

Nurture your internal relationships. Work with faculty and inventors as part of a team so when the time comes they will be more likely to keep you in the loop.

Confirm schedules with journals. If there is any doubt about when an article or manuscript might be pre-released online, contact the relevant journal.

Contact Metz at 301-405-2797 or fametz@umd.edu; Dibling at 215-898-9272 or bdibling@upenn.edu; and Langenberger at 215-573-4508 or langenbe@upenn.edu. ▶

U Cincinnati opens its pre-accelerator program to other institutions

The University of Cincinnati has opened its pre-accelerator, Venture Lab, to not only start-ups formed out of UC, but also those from Wright State University, Xavier University, the University of Dayton and Cincinnati State Technical and Community College. Venture Lab was founded in 2018.

The new program, which claims to be "a first-of-its-kind partnership in the Midwest," enables start-ups from the other schools to apply to the seven-week pre-accelerator, which includes access to a number of EIRs.

Venture Lab, which is housed at UC's 1819 Innovation Hub, has helped generate a record 400% increase in start-ups spun out of UC in its first year, and a 1,000% increase to date. More than a dozen Venture Lab graduate have attracted funding -- a total of more than $1.4 million from grants and UC investments. It graduated its latest cohort in February -- its eighth class.

Fulfilling its mission

There were a number of reasons why opening up the program to outside institutions made sense, says **David Adams,** UC's chief innovation officer. "One of the things that is really important to us is that we take seriously the fact that we're a Carnegie Level 1 research institution -- and one of only two public universities in the state," he says. "As a public institution we feel very strongly that we have a responsibilityto help ensure [other] organizations' success. As we got better putting teams through this, we felt we had a good process and wondered if there were other colleges and universities that did not have their own resources and could benefit from ours."

Initial discussions with the other institutions began last fall, he relates. By having their start-up teams at UC's pre-accelerator, he notes, they would not only have access to the EIRs, but also to CincyTech, a public-private seed-stage investor.

"We felt we had a process that worked well; we had over 100 teams, and we had the EIRs," Adams says, adding that he saw this as an opportunity to strengthen the larger ecosystem of the region.

When it comes to attracting support for start-ups, he asserts, location and proximity matter. "Having more teams with more start-ups being generated gives us the opportunity to attract individuals and organizations from outside Cincinnati into the area," Adams notes. "If a VC is thinking about coming to the Midwest, they have trouble because of the volume of deals. If we do all of this in pockets, it's hard for someone to come and make five stops. So, the question was how to create more opportunities for entrepreneurs in a single location -- how do we leverage this engine we're created?"

The first step, he continues, was to start with other universities -- to be entrepreneurial and innovative, "and then see what other opportunities there might be." He adds that this leverage will work in both directions. "It's leverage not just for the university, but for the community," he asserts. "If we have a strong community, we have a strong university."

Range of resources

The seven-week program offers broad support, Adams says. "First, we walk them through the basics; you have an idea -- let's figure out if it's marketable," he explains. "The EIR network brings external expertise we do not have. CincyTech brings the capital and other levels of expertise in specific fields, and they have their own set of EIRs as well. They help with the due diligence; they bring the institutional expertise to help these companies be vetted as well."

There are also service providers such as legal and accounting firms, which are not under contract but will come to the community and engage with these start-ups. "Virtually everyone who comes through this program is a student or a faculty member; they've never started a business," Adams notes. "So, we ask: How can we surround you with resources that can help you evaluate your idea? If it's marketable, how can we help you accelerate it? It would be good if we could be masters of it all but none of us are, so how can we help you along your journey so at least you have a presentable idea, a business concept you can take to the community?"

Michael Arens, CEO and co-Founder of Clean Earth Rovers, LLC, and part of an undergraduate team from Xavier University that was the first non-UC team to graduate from the Venture Lab program, is an enthusiastic supporter. "The program is really fun," he says. "You go once a week for two hours; you get about an hour's worth of teaching

and then you meet with mentors or EIRs. They help you go over what was taught in the hour-long period, and they help you model and format your business idea."

Arens says teams earn the right to participate through an online application. "You describe your idea, what problem you're solving, the solution you're creating, and how you'll bring value to market in doing so," he says.

The process, he continues, is "a very effective way to look at your idea clearly -- to model and talk about it so that others understand it." Meeting with the EIRs, he adds, helped the most. "Every week we met with different ones," he recalls. "For seven weeks you're constantly meeting different people with different insights. Then, there's a week focused on customer discovery, which is really big too. It teaches you how to go out to customers and get those interviews. That's something start-ups fail to do."

Arens' company is "pre-seed," he notes. Their project at Venture Lab involved the Ocean Rover Cleaning Apparatus (ORCA), which is focused on solving the growing problem of oceanic plastic pollution. "We've been incorporated for about year; we're in the prototype phase," he adds. "We're using the money from UC to start the prototyping and we have a small-scale model we hope to sell by the start of summer."

And how are the "visiting" universities expected to compensate UC for its generosity? Adams says they are asked for nothing in return. "We have the capacity to do this, and we have not asked them to put anything towards this," he says. "We do not want to create unnecessary friction or gates to prevent participation. We the have space here, and the resources. If there is interest by faculty or students, we want to make it available to you."

The only thing Arens would change, he says, is for participants to spend more time at Venture Lab. "I really enjoyed the amount of time we spent; I think having maybe another hour each week would add to the experience," he suggests.

Value of model

For Arens, there is no doubt about the worth of this model. "When implemented, it has absolutely been a benefit in terms of real-world experiences," he asserts. "It increases the start-up culture at the university level. A lot of students

with a lot of different ideas do not know how to implement them or where to go, and they just write it off. Having an outlet to be part of to bring this idea to life is really important -- especially at the university level."

And what about the fact that UC has opened Venture Lab up to other institutions? "I think it's really good for student innovation and entrepreneurship," he offers. "It's something I've encouraged and even played with the idea with some people and professors at Xavier -- to have a program like that here. Having something open where there's a resource to [all] universities is really important -- and really good -- especially for Ohio and the start-up community here."

But doesn't this create more competition for UC start-ups in terms of access to school resources? "One of the charges I give my team is that they have to *increase* capacity," Adams responds. "Look at Steve Case and *The Rise of the Rest*; we have to accelerate for Cincinnati and be a conduit and create more visibility for entrepre-

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U Cincinnati continued from p. 63

neurs bringing things to life. Hopefully we'll engage not just students and faculty but a community with resources. If we strengthen the region, we will continue to have a strong university -- and all strong universities; we're all in this together. So, we're nearly at capacity, but I've already charged my team for the upcoming fiscal year on how to increase it."

If you think about the pace of change that we're all seeing, he continues, "the ability to partner in new and creative ways makes us stronger as a university, a city, and it will continue to create opportunities to collaborate with others like businesses and community partners."

UC, he adds, has also strengthened its support of student entrepreneurship through a revamping of its IP policies in order to further accelerate the number of teams coming out. "There are friction points, inhibitors that prevent students from staking things out," he notes. "Now, students own their own IP. And if you're a faculty member, you can also have exclusive rights to the IP."

With just the second outside cohort coming through the program, Adams recognizes it's too early to claim success. However, he says, "we're excited one group came through, and we want to celebrate their success. Plus, we've seen a dramatic increase in the number of start-ups coming through the university in general."

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Coming in future issues...

What to do about "zombie" start-ups • TTO strikes sweet deal with law firm for dedicated attorney • More on adapting to the new pandemic realities • Oregon schools make pact for co-owned IP