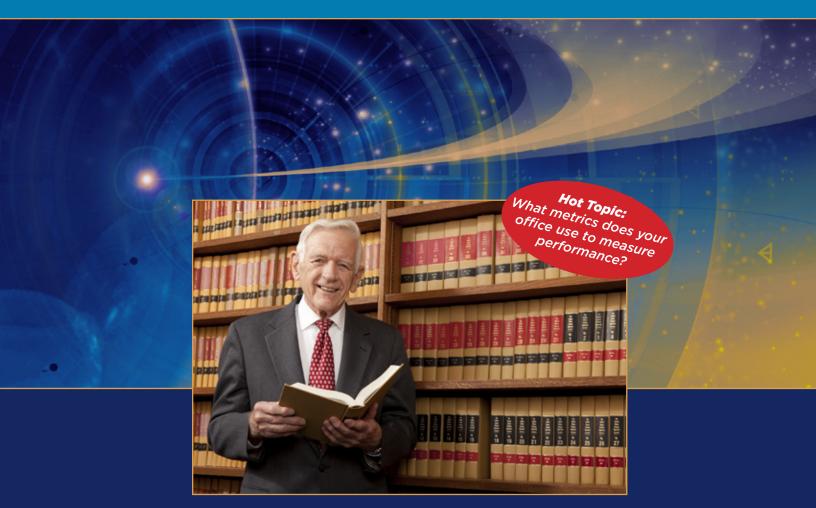
## томогкоw's Technology Transfer

The Journal of the Association of University Technology Managers™



#### Highlights:

- Negotiating against Your Interests?
- The Effects of Patent Agreements on Small-Entity Status
- Commercialization at Emerging Universities
- Comparison of National Innovation Systems in China, Taiwan, and Singapore: Is Bayh-Dole One Size that Fits All?
- And more...



# TOMORROW'S Technology Transfer

#### The Journal of the Association of University Technology Managers™

On the cover:

Pictured on the cover is long-time AUTM member Howard Bremer, JD, in his offices at WARF. Bremer, who joined WARF in 1960 as its first patent counsel, retired in 1988 but for the past two decades has served as emeritus patent counsel and continues his work as the "father of university licensing" by championing the ground-breaking Bayh-Dole legislation that he helped usher into law.



It was for his lifelong work on behalf of Bayh-Dole and university licensing that Bremer was awarded a framed and red-lined copy of the Bayh-Dole Act during the AUTM 2009 Central Region Meeting. To learn more about Bremer and Bayh-Dole, visit the WARF Web site.

Photos courtesy of the Wisconsin Alumni Research Foundation.

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111 Deer Lake Road, Suite 100 Deerfield, IL 60015 USA Phone: +1-847-559-0846 Fax: +1-847-480-9282 E-mail: info@autm.net ISSN: 1946-0619

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### **New Year, New Opportunities**

#### Dear Reader:

Last year forced many of us to look at our organizations and functions in a new light. While such evaluation can be difficult and uncomfortable, it also created opportunity. To start the new year, this issue's pieces reflect the authors' ideas about looking to other technology transfer offices for ideas, but also looking internally to understand the positive aspects that can be enhanced and the opportunities for improvement.

Michael Cohen describes what it means to strive for organizational excellence when our metrics and goals are more complicated and intangible than a for-profit entity's and our top priority is sometimes our licensee's bottom priority. Paul Craane explains the issues that affect entity status when licensing inventions—it's not as clear as we originally thought. AUTM President-Elect Ashley Stevens reviews an enlightening book that describes "the aptitudes necessary to survive and thrive in this brave new world."

Several of this issue's articles are written by academic researchers who study our profession. These researchers use, among other sources, the metrics that AUTM collects. Their analyses give us insight into what we are doing right and where we can improve. The article by Joshua Powers is an example of such an article. He discusses the results of a national study of technology commercialization at universities with smaller programs and offers recommendations for practice.

Three of the articles look at technology transfer from an international perspective. Prabhu Ram describes the changing technological environment in India and explains why U.S. universities should consider partnering with Indian universities and companies. Stephen Chen's article examines Asian research and development policy in industry and universities. Ana Margarida Prado et al. outline opportunities, concerns, and strategies for forming a TTO in Portugal. On the patent front, Nancy Vensko and her co-author discuss the changing standards for patent protection for DNA inventions and how basic research institutions can manage these DNA inventions to enable new health-care treatments and services to reach the public. Hugo Pinto discusses how technology transfer offices intersect the interests of researchers, businesses, and policy-makers and the required skill sets to work with such diverse parties.

The issue closes with the article that will be awarded first place in the AUTM Academic Technology Transfer and Commercialization Graduate Student Literature Review Prize at the AUTM 2010 Annual Meeting<sup>SM</sup>.

Organizations are reflecting on core missions and evaluating how they can reach their true goals. AUTM is no different. For that reason, the AUTM board has decided to place its peer-reviewed journal on hiatus while the board conducts a survey to determine what benefits and services the members of AUTM want most from AUTM.

We urge you to answer the survey and tell the board what resources you value most. Your response to the upcoming survey will guide AUTM's direction for the future. Please direct your suggestions or submissions to AUTM Vice President for Communications Kristin Rencher at rencherk@ohsu.edu. Future publications will be determined by your ideas and requests. After this period of reassessment, we look forward to new growth, in new directions.

Best wishes for a year of prosperity and success.

Kristin Rencher, AUTM Vice President for Communications Oregon Health & Science University Emily Bauer, Features Editor Wisconsin Alumni Research Foundation David Grossman, Research Editor George Mason University



### Organizational Excellence and University Intellectual Property Management Offices:

Without Competition, Is it Necessary to Pursue Excellence, and if Yes, then How?

Michael Alvarez Cohen, MBA

Competition among businesses has perhaps the greatest influence on how businesses operate—in fact, competition is arguably the core incentive for a business organization's pursuit of excellence, as well as its corresponding practices used to motivate employees. Therefore, it's peculiar that university intellectual property offices (UIPOs) perform revenue-generating functions found in the competitive world of business (i.e., marketing, licensing, and managing properties), but UIPOs aren't subject to the competition (and related incentives) of the business world.

This combination of attributes can create a quandary for UIPOs: In the absence of competition, what motivates UIPOs to strive for excellence, constructively assess themselves, and look for opportunities to improve? Maybe the absence of competition makes the pursuit of excellence—and all of the difficulties that go with that pursuit—unnecessary? Maybe good enough is good enough in these organizations, and the way things have been done is the way they should stay?

This combination of attributes can create a quandary for UIPOs: In the absence of competition, what motivates UIPOs to strive for excellence, constructively assess themselves, and look for opportunities to improve? Maybe the absence of competition makes the pursuit of excellence and all of the difficulties that go with that pursuit—unnecessary?

Why pursue excellence? Merely posing the question can shock some UIPO managers and staff—especially those with prior positions at for-profit companies. So it is these provocative questions that are the impetus for this article. In exploring these questions, this article will clarify what organizational excellence means in UIPOs and why it's difficult to pursue in these offices. Then the article will present a case for why (despite those challenges and the absence of competition) UIPOs should strive for excellence and also highlight some advice that UIPOs can use to achieve this goal.

But first, a clarification is in order. This article is not intended as an indictment of UIPOs. Many are well-running operations that are staffed by skilled, ethical, hard-working professionals. For example, the UIPO at the University of California, Berkeley, where I work, has a track record of success that includes spearheading socially responsible licensing, establishing intellectual property (IP) rights agreements with hundreds of startups and large companies, as well as building strong rapport with many faculty. Nevertheless, even (or especially) UIPOs that have been successful need to be vigilant against falling into organizational complacency and mediocrity.

### What Is Organizational Excellence and Why Is it Challenging?

Organizational excellence is a broad concept with many facets, but in the context of this discussion, it's defined as the ongoing process of improvement (including making small refinements as well as big changes) based on rigorously establishing objectives, measuring results, assessing performance, identifying current problems, anticipating future problems, and looking



for opportunities to improve.

While many UIPOs might aspire to achieve excellence in practice, organizational excellence is an ongoing endeavor, and, consequently it's challenging to implement and maintain. These challenges include the following:

- Organizational excellence adds workload to the office—and this work is above and beyond the core functions of a UIPO (i.e., administering disclosures, patenting inventions, completing IP rights agreements, negotiating the IP provisions of research agreements, and managing licensees). Even though UIPO management might shoulder much of the work, organizational excellence also impacts the workload of staff—and as many UIPOs have lean operations, more work can lead to morale problems (as well as a dilution of focus on core functions).
- Organizational excellence results in periodic changes to the office. The world in which UIPOs operate is continually evolving, and, consequently, if UIPOs want to stay in synch with the world, then UIPOs have to change too. But change can be troubling for some UIPO employees that prefer consistency and certainty or have become comfortable with the routine of their office.
- Organizational excellence leads to greater transparency of the office—and with transparency comes the potential for heightened scrutiny and, ultimately, accountability. UIPOs with cultures that aren't accustomed to this level of transparency and accountability might encounter a backlash from some staff.
- Organizational excellence can instigate higher performance expectations—i.e., results and productivity—but without commensurately higher compensation levels. This also might result in disgruntled employees.

Given these challenges, it's easy to understand why it can be difficult to promote organizational excellence without a compelling reason. In the absence of a compelling reason (e.g., looming competition or apparent problems in a UIPO), it's perfectly reasonable for a UIPO's employees to question the purpose of changes—especially additional work. If there's nothing broken with the office, then what is this change trying to fix?

However, while top-down mandates can make the pursuit of excellence more salient within a company, it's the company's competition that fundamentally drives excellence and punishes complacency in the business world.

Proactively addressing these rational sentiments is key to the successful pursuit of organizational excellence because even the staunchest executive mandate and best plans for achieving excellence are likely to fail if the employees involved with implementation don't understand or accept the reasons for the plans.

### Why Pursue Excellence Instead of Complacency?

For-profit organizations (including companies that license IP) have corporate structures in which organizational excellence can be mandated from top-level executives down through middle management. However, while top-down mandates can make the pursuit of excellence more salient within a company, it's the company's competition that fundamentally drives excellence and punishes complacency in the business world. Those businesses that outperform their competitors thrive and enrich their employees (and shareholders, etc). Conversely, those that are overshadowed by their competitors can encounter customer defections, employee reductions, financial problems, and, ultimately shutdown.

Likewise, universities have management structures by which organizational excellence can be mandated from the top-down to UIPOs. However, in contrast to for-profit companies, most UIPOs don't have compe-



tition to motivate them, in that most UIPOs aren't vying with other organizations to manage disclosures from their campus and license the associated IP rights. Moreover, most UIPOs don't have compensation systems that are tightly linked to performance (instead they're often linked to seniority).

Furthermore, many UIPOs are performing adequately in that they don't have any apparent operations problems or urgent financial crises. These conditions can make UIPOs conducive to organizational complacency and mediocrity—even when they are admonished by university leadership to purse excellence.

Note that UIPO management should be cognizant of a potential pitfall when the avoidance of crises is its primary incentive for organizational excellence. This can lead to a risk-averse culture that can dominate decision making such that the organization only pursues improvements that address risks, and, consequently, the organization systematically ignores improvements that leverage opportunities.

So what, if anything, can take the place of competition or a crisis to drive organizational excellence in UIPOs? For well-run UIPOs, sufficient motivation might come from the substantial risks from latent problems and potential crises. These risks include lawsuits by jilted licensees or irate inventors; the loss of key staff; a dramatic unfavorable change in revenues or expenses; or even the development of a reputation problem that is hard to repair and hinders the university's efforts to attract top faculty, students, or companies that sponsor research.

Should a UIPO be proactive or reactive to those plausible large risks? If the former, then the most comprehensive approach for the organization is to adopt the concepts embodied in the pursuit of organizational excellence.

Note that UIPO management should be cognizant of a potential pitfall when the

avoidance of crises is its primary incentive for organizational excellence. This can lead to a risk-averse culture that can dominate decision making such that the organization only pursues improvements that address risks, and, consequently, the organization systematically ignores improvements that leverage opportunities.

However, regardless of the situation, excellence can't be reliably pursued without monitoring key metrics of the organization, and excellence is often hard to implement unless changes are made methodically and progressively.

### How to Pursue Organizational Excellence in a UIPO

Now that a motivation for UIPOs to pursue excellence has been established, let's move to a discussion about how to achieve excellence in the office. There isn't a simple, standard recipe for achieving organizational excellence in a UIPO—as every office is comprised of a unique and evolving mix of attributes, issues, priorities, and people.

However, regardless of the situation, excellence can't be reliably pursued without monitoring key metrics of the organization, and excellence is often hard to implement unless changes are made methodically and progressively. Each of these best practices is highlighted below and followed by examples.

#### MONITORING KEY METRICS

Monitoring key metrics is a fundamental mindset embodied in the pursuit of organizational excellence—because only through measuring a UIPO's activities can it:

- address ignored problems,
- expose latent problems,
- foresee emerging or potential problems (before they become disastrous),
- identify new opportunities, as well as
- make changes and subsequently assess their impact.

Many UIPO managers might think that they know what's happening in their



organization, but some might not reliably know whether their office is—for example, always making justified patent decisions, leveraging all licensing opportunities, consistently establishing reasonable license terms, regularly satisfying the faculty, or currently meeting financial expectations.

Note that most UIPOs are service organizations—not revenue centers—and, accordingly, they perform lots of work that doesn't result in remunerations directly back to the office. Therefore, in measuring metrics, it's important for UIPOs to monitor the key efforts of the office, not just the key results (e.g., income).

Most UIPOs have some data about their operations, but that information might be anecdotal rather than statistically significant, it might be old (i.e., as of the last fiscal yearend) instead of up-to-date, and it might be just data without the context of comparisons to UIPO norms and historical patterns. However, high-performing organizations know that: (1) anecdotal data can be imprecise or even misleading, (2) old data can quickly become irrelevant, and (3) analysis tools are needed to make the raw data useful. Access to comprehensive, upto-date data and analysis is what's necessary to pursue organizational excellence.

Note that most UIPOs are service organizations—not revenue centers—and, accordingly, they perform lots of work that doesn't result in remunerations directly back to the office. Therefore, in measuring metrics, it's important for UIPOs to monitor the key efforts of the office, not just the key results (e.g., income).

#### IMPLEMENTING CHANGES METHODI-CALLY AND PROGRESSIVELY

Change is practically an inherent characteristic in the pursuit (or maintenance) of organizational excellence in UIPOs because the environment in which these offices operate is continually evolving. However, because UIPOs don't have competitors and typically aren't in the midst of a crisis, UIPO staff can be recalcitrant to implementing changes—especially changes that are (a) abrupt and dramatic or (b) oriented to addressing an alleged opportunity instead of solving an acknowledged problem.

Therefore, implementing changes methodically and progressively often facilitates excellence. In this way, feedback can be used to refine recent changes and influence future changes. Because this feedback is important, employees need to be involved in the assessment process, so that they can stay informed as well as provide input. Otherwise, even great strategies can fail during their implementation.

This methodical, iterative approach to improvements can conflict with the sense of urgency that often accompanies the drive for organizational excellence. Consequently, it's challenging to manage the optimal speed of change. Moreover, it's hard to know when change is occurring too quickly—until the change is implemented too quickly and consequently leads to some employee dissatisfaction. This could be metaphorically characterized as the inevitable growing pains of pursuing excellence—and if it's acknowledged as inevitable, then it should not be a surprise and it can be addressed quickly.

#### **Examples**

An example of pursuing organizational excellence through the use of metrics and progressive changes occurred in the UIPO at University of California, Berkeley, over the past few years. In order to maximize service to the campus, as well as office productivity and workload balance, the UIPO needed to identify, track, and analyze activities that it was performing for the campus—beyond the (already tracked) management of invention disclosure cases (that include assessing, patenting, marketing, and licensing IP).

In 2007, the office reflected on its activities and identified the negotiation of the IP provisions of sponsored research agreements as a service to the campus and a



significant load on the office that was not being tracked. Accordingly, the office began tracking "research agreement cases."

In 2008, further reflection revealed that the office was providing a variety of sundry support to the campus at the request of faculty and senior administrators. Examples of these requests range from modifying the IP provisions of employment agreements and faculty consulting agreements to advising on the terms of service and copyright issues of Web sites, manuscripts, digital photos, and art. Therefore, the office began tracking this significant amount of work as "campus cases."

By 2009, metrics from the past two years indicated that the office's quantity of research agreement cases was steadily increasing and projected to overwhelm the workload. As a result, the office made a key change to how research agreements were allocated. Additionally, by 2009, metrics on campus cases enabled the office to provide tangible, compelling evidence to the university that the UIPO was a vital resource to faculty and senior administrators above and beyond its traditional role of managing invention disclosures.

#### Summary

UIPOs operate in a peculiar context that

can make even the best UIPOs susceptible to organizational complacency and mediocrity. The peculiar context is that UIPOs perform conventional revenue-oriented business functions, but they don't have the competition (as well as associated employee rewards and penalties) that for-profit businesses operate under. Consequently, UIPOs don't have the competition-driven motivation to pursue organizational excellence and corresponding improvements.

However, UIPOs contend with a variety of substantial risks. Recognizing the need to proactively and comprehensively manage those risks can be enough of a motivation to pursue excellence. Unfortunately, that type of motivation can result in a risk-averse culture that prioritizes changes to address problems, but ignores improvements to leverage opportunities.

Finally, striving for organizational excellence requires a mindset of monitoring key metrics; and excellence is often best achieved by making progressive changes that allow for iterative feedback and refinements as well as some organizational growing pains.

Michael Alvarez Cohen, MBA, runs the Office of Technology Licensing at the University of California, Berkeley.

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### **Negotiating against Your Interests?** The Effects of Patent Agreements on Small-Entity Status

#### Paul C. Craane, JD

If you are an independent inventor, are associated with a startup, or work in a nonprofit technology transfer office, the attorney who prepared your patent application probably discussed with you whether you should pay the filing fees at the small-entity rate. Given the expense of the application, you undoubtedly were pleased to hear that the U.S. government reduces the filing fees by half for persons and companies entitled to small-entity status.

Unfortunately, qualification for smallentity status can be lost for any of a great number of reasons, the details of which may not have been explained by the attorney. For example, your efforts in finding a commercialization partner to develop, finance, or make and sell your invention could cause you to lose your right to the reduced fees. While proper planning can ameliorate the effect of the increased fees, failure to appreciate the consequences of your actions in the technology transfer process can lead to complete loss of rights in the patent or application.

During the process of filing, prosecuting, and maintaining a patent, the applicant/ patentee will have to pay significant fees to the United States Patent and Trademark Office (USPTO). Application fees are due for filing, search, and examination. During the process, other fees may come due depending on the timing and nature of actions taken. There are also issue fees, payable if the applicant is fortunate enough to convince the USPTO that the invention disclosed and claimed in the application is patentable. After the patent issues, maintenance fees (taxes) are required to prevent the patent from expiring.

Recognizing that there is a governmental interest in making the patent process less expensive for certain groups, Congress authorized the USPTO to establish and maintain a qualification referred to as *small-entity status*.<sup>1</sup> If an applicant/patentee is eligible for small-entity status, many fees payable to the USPTO are reduced by 50 percent. Given the sizable maintenance fees due after grant, small-entity status may end up being worth more than \$5,000 in savings over the life of a single patent.

While proper planning can ameliorate the effect of the increased fees, failure to appreciate the consequences of your actions in the technology transfer process can lead to complete loss of rights in the patent or application.

However, paying a fee at the smallentity rate when the party is not eligible to qualify for small-entity status may render the patent unenforceable.<sup>2</sup> According to the courts, it is not merely sufficient that the fee be paid incorrectly, there must be an intent to deceive the USPTO as well.<sup>3</sup> The intent may be inferred from circumstances, and at least one court has inferred the intent, at least in part, from an attorney's failure to abide by the USPTO's guidance as provided in the Manual of Patent Examining Procedure (MPEP).<sup>4</sup>

So why not just pay the normal fees, regardless of actual eligibility for smallentity status? This is certainly the advice routinely given by Canadian patent practitioners concerning their system, which also provides for a small-entity fee reduction, albeit with different standards but a similar penalty. Certain U.S. practitioners recommend this as well. Given the nature of the penalty, payment of fees at the normal rate, even when the applicant/patentee qualifies as a small entity, may be appropriate in exchange for greater peace of mind.

### How-To

For even a small portfolio of patents, however, the fee reductions may reach tens of thousands of dollars. For institutions such as universities, which routinely qualify for small-entity status, the fee savings may reach the hundreds of thousands, if not millions, of dollars. Given the size of the savings, it is not unreasonable for a client to expect that his or her attorney would be willing to perform the analyses necessary to advise whether the client qualifies.

At the outset, it is important to recognize that small-entity status is determined at least three times during the life of the patent: when the filing fees are paid, when the issue fees are paid, and when the maintenance fees are paid.<sup>5</sup> Consequently, it is possible for fees to be paid at the small-entity rate at one point in time and at the normal rate at another point in time. For example, the filing and issue fees for an application may be paid at the small-entity rate, but the maintenance fees may be paid at the normal rate because of an intervening change in circumstances.

In the first instance, small-entity status is determined according to the identity of the patent owner. To obtain small-entity status, the patent owner must fall within one of three classes: (1) person(s), (2) smallbusiness concerns with fewer than 500 employees, or (3) nonprofit organizations.<sup>6</sup> Persons refers to the inventors or individuals to whom the inventor has transferred rights in the invention.7 Small-business concerns must meet the size standards set by the Small Business Administration, with reference to 13 C.F.R. §§ 121.801 through 121.805. Nonprofit organizations include universities or other institutions of higher education, 501(c)(3) organizations, and nonprofit scientific or educational organizations. Further guidance is provided in the MPEP as to all three categories, although the USPTO will defer to the Small Business Administration on issues involving smallbusiness concerns.

While the patent owner must fall within one of these three classes to qualify for small-entity status, it is possible for a small entity to retain ownership of a patent and still lose small-entity status. As explained in the USPTO rules, a patentee may lose small-entity status if the patentee has assigned, granted, conveyed, or *licensed any rights in the invention* to any person, concern, or organization that would not qualify for small-entity status.<sup>8</sup>

It is important to note that the assignment, grant, conveyance, or license is only of interest to the analysis if it transfers rights to the U.S. patent or application. For example, if an agreement only addresses rights to a foreign patent or application, it is not of interest to the analysis.<sup>9</sup>

Consequently, if the rights to a U.S. patent are transferred to a party that qualifies for small-entity status, but the rights to a foreign counterpart patent are transferred to a non-small-entity, the patent owner still qualifies for small-entity status. If both U.S. and foreign rights are transferred to a non-small-entity, the patent owner is disqualified.

With this guidance, what is the likely effect of a patent license option agreement? Option agreements are frequently used to reserve an exclusive opportunity for a prospective licensee to negotiate with a prospective licensor. In this regard, the wording of the option agreement may be critical, given that there is no single document universally recognized as an option agreement.

While licenses are included in the same list as assignments, grants, and conveyances, do not assume that the rule only extends to *exclusive licenses*. Both the courts and the USPTO have determined that even *nonexclusive licenses* to nonsmall-entities are sufficient to disqualify a patentee from small-entity status.<sup>10</sup>

It is also not necessary that the license be in writing for disqualification to occur. For example, the USPTO has determined that a shop right may cause disqualifi-

### How-To

cation.<sup>11</sup> A shop right is a right (either grounded in principles of estoppel or in the form of an implied license) that permits an employer to use without charge certain inventions of his or her employees without liability for infringement, a right that is nontransferable and extends only to the manufacture and use of the invention.<sup>12</sup> According to the USPTO, even such a nonwritten, limited, implied license can result in disqualification.

On the other hand, certain implied licenses do not appear to disqualify the patentee. In particular, the USPTO has explicitly recognized that implied licenses of use and resale that are attendant to an authorized sale of a product embodying the invention, for example, would not result in disqualification.<sup>13</sup>

Based on this guidance, an argument may be made that so-called shrink-wrap or click-wrap licenses, to the extent that they implicate patent rights, also should not cause disqualification of the patentee. Shrink-wrap or click-wrap licenses are licenses that accompany software, typically involving permissions to use the copyrights and patents that cover the installation and use of the software. Where the terms of such a license extend only to the customer's use of the software, it would appear that this is not the type of license that would cause disqualification.

As further explained in the USPTO rules, a small entity may also lose small-entity status if the small entity has an *obligation* to assign, grant, convey, or license any rights in the invention to any person, concern, or organization that would not qualify for small-entity status.<sup>14</sup>

Unfortunately, the USPTO provides little guidance as to what obligations may fall within the scope of the rule. The single example given in regard to agreements that create obligations of assignment, grant, conveyance, or license is the security agreement. As explained in the MPEP<sup>15</sup> and the rules,<sup>16</sup> a security interest does not involve an obligation to transfer rights except in case of default on the underlying debt. The obligation created by a security interest is not currently enforceable. As such, granting a security interest to a nonsmall-entity does not disqualify the small entity.

With this guidance, what is the likely effect of a patent license option agreement? Option agreements are frequently used to reserve an exclusive opportunity for a prospective licensee to negotiate with a prospective licensor. In this regard, the wording of the option agreement may be critical, given that there is no single document universally recognized as an option agreement.

What is the patent owner to do? Certainly, where the USPTO is clear that small-entity status is lost, such as in the case of nonexclusive licenses or shop rights, the patent owner disregards the USPTO's guidance at its own peril. Where the USPTO is equally clear that small-entity status is preserved, as in the case of security interests, the patent owner may take comfort.

For example, in *Nilssen*,<sup>17</sup> the patent owner argued that an agreement was not a license agreement, but an option agreement wherein the obligation to license had not yet vested. In the agreement, the parties stated that the patent owner will offer and the prospective licensee will take a license agreement in the future, with no royalties accruing until a condition had been satisfied. The Federal Circuit agreed that this language in the agreement was sufficient to disgualify the patent owner from small-entity status. Unfortunately, it is unclear whether the Federal Circuit reached this outcome because the agreement was considered to be a de facto license with a right to future royalties or because the patent owner "reasonably expected to receive a revenue stream" such that an obligation (but no license) existed, having mentioned both in its analysis.

What if the parties reach a modified agreement? For example, the parties

### How-To

might agree to negotiate exclusively for a limited time period, with no mention that the parties will offer and accept anything. Does such an agreement protect the qualification for small-entity status? Case law suggests that the answer is no. That is, the law of certain jurisdictions may imply an obligation to complete the negotiations based on the terms of the option agreement. For example, if the parties have already agreed to key provisions, the parties may be under an implied obligation to complete the negotiations, which obligation may be enforceable in court. In such circumstances, the parties' statement that they will merely exclusively negotiate may not be enough to avoid conflicting with the requirement for maintaining small-entity status.

What is the patent owner to do? Certainly, where the USPTO is clear that smallentity status is lost, such as in the case of nonexclusive licenses or shop rights, the patent owner disregards the USPTO's guidance at its own peril. Where the USPTO is equally clear that small-entity status is preserved, as in the case of security interests, the patent owner may take comfort.

As for the large gray area concerning option agreements and implied licenses, it is important to recognize that there is potential for disqualification and the need for further advice. Given the lack of clarity on these issues and the consequence of unenforceability, it may be prudent to pay at the undiscounted normal rate and accommodate the fee differential in the terms of the agreement. In any event, the patent owner is well-served in recognizing these other perils that such relationships and negotiations may present to its entitlement to maintain its small-entity status.

Paul C. Craane, JD, is a partner with Marshall Gerstein & Borun LLP, Chicago, Illinois.

#### Notes

<sup>1</sup>35 U.S.C. § 41(h) (2009). <sup>2</sup>See, e.g., *Ulead Sys. Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139 (Fed. Cir. 2003); *Nilssen v. Osram Sylvania*, 440 F. Supp. 2d 884 (N.D. Ill. 2006), aff'd 504 F.3d 1223 (Fed. Cir. 2007). <sup>3</sup>Ulead, 351 F.3d at 1146. <sup>4</sup>Outside the Box Innovations LLC v. Travel Caddy Inc., No. 05-2482, slip op. at 40 (D. Ga. Dec. 19, 2008). 537 C.F.R. § 1.27(g) (2009) <sup>6</sup>37 C.F.R. § 1.27(a)(1)-(3) (2009). <sup>7</sup>Under U.S. law, inventors are presumed to be the original owners. See Teets v. Chromalloy Gas Turbine Corp., 83 F.3d 403 (Fed. Cir. 1996). <sup>8</sup>See 37 C.F.R. § 1.27(a)(1)-(3) (2009). <sup>9</sup>Manual of Patent Examining Procedure (MPEP) 509.02 V, at 500-46. <sup>10</sup>See, e.g., Outside the Box Innovations LLC v. *Travel Caddy Inc.*, No. 05-2482, slip op. at 40 (D. Ga. Dec. 19, 2008); MPEP 509.02, at 500-46. <sup>11</sup>MPEP 509.02 V, at 500-45. <sup>12</sup>See McElmurry v. Arkansas Power & Light Co., 995 F.2d 1576 (Fed. Cir. 1993). <sup>13</sup>MPEP 509.02, at 500-46. <sup>14</sup>37 C.F.R. § 1.27(a)(1)-(3) (2009). <sup>15</sup>MPEP 509.02, at 500-46. <sup>16</sup>37 C.F.R. § 1.27(a)(5) (2009).

#### <sup>17</sup>*Nilssen v. Osram Sylvania*, 440 F. Supp. 2d 884 (N.D. Ill. 2006), aff'd 504 F.3d 1223 (Fed. Cir. 2007).

### WHAT DO YOU KNOW?

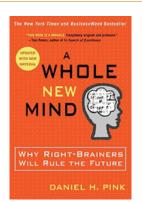
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### **Book Review**



### A Whole New Mind: Why Right-Brainers Will Rule the Future

By Daniel H. Pink

Reviewed by Ashley J. Stevens, D.Phil. (Oxon), CLP

By his own admission, Daniel Pink's last real job was as the chief speechwriter for Vice President Al Gore, a position he held from 1995 to 1997. This is not surprising-I think he looks like a somewhat slimmer version of Gore (though, admittedly, most people look slimmer than Gore, these days). But I digress. Prior to Gore, Pink\* worked as an aide to U.S. Labor Secretary Robert Reich and at a number of other jobs in Washington. You truly wouldn't know from listening to him or reading his books that he was a lawyer-Yale Law, a few years after Bill and Hillary, and, indeed, the dust cover says that, to his lasting joy, he has never practiced law. (So why take on that much debt, I have to ask?)

So clearly, what we have here is an advanced case of, What do you want to be when you grow up? Pink clearly answered this in style: "I want to be famous....Oh, and rich."

So, how do you go from a back-room role behind the camera and microphones, supporting famous pols like Gore and Reich, to being in front of the camera and speaking into the microphones yourself, peddling your own ideas? Well, you come up with a few original observations, put them together, lace them with case studies and interesting tidbits, position your thesis as the next essential savior of American industry, write an entertaining management book, and then wait for the speaking invitations to arrive.

I have the capacity to read about one management book a year. This year, I read *Good to Great* (a) because my university's president promoted the book in a management conference and (b) I was seriously confused by the name of the author—our most prominent faculty member is also named Jim Collins. But I digress.

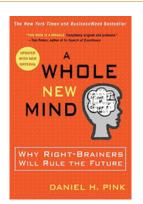
Last year, I read A Whole New Mind, mainly because my friend, Brigitte, who teaches at Buckingham Browne and Nichols in Cambridge, had been assigned (along with the rest of the faculty) to read it over the summer. You have to love a school where the faculty get a summer reading list, too—they're equal opportunity killjoys and don't just ruin their students' summers by having to read a book and write a report. But I digress.

So, Pink makes three observations. He's certainly not the first person to make these three observations. He may not even be the first person to put these three observations together. He may not even be the first person to think through the implications of these three observations. But he is the first person to write an entertaining book analyzing his three thoughts and their consequences.

So, his three observations are three As:

• The overwhelming *abundance* of choice in everyday Western life, which means that products must be continually refined and redefined to stand out and achieve market success. Clearly companies succeed in this, because we overconsume (or at least overpurchase), as evidenced by the fact that self-storage space is a \$17 billion business in the U.S. today, bigger than the movies. This point resonated with me when I counted the shirts in my closet and found I had around 150, not including T-shirts. (The total does include around 30 soccer shirts, 20 referee uniform shirts, and 10 team shirts. Do I really need 3 England

### **Book Review**



shirts? Silly question—of course I do.) But I digress.

- The rise of Asia as an economic power, where very highly trained people can do jobs that were previously the prerogative of people in the developed economies of the West for one-tenth the salary.
- Automation: the increasing sophistication and capability of computers to perform tasks that previously required humans to perform, at an even lower cost than Asia—zero.

These three factors change dramatically how Western economies will work in the future. The thesis of the book is summarized in the introduction.

We are moving from an economy built on logical, linear, computerlike capabilities of the Information Age to an economy and a society built on the inventive, empathic, big picture capabilities of what's rising in its place, the Conceptual Age.

It turns out that these capabilities are housed in the right side of our brains, where as the strictly linear, analytical, logical capabilities are predominantly housed in the left side of our brains, which I find confusing because our hearts are on the left side of our bodies, revolutionaries are left wing, and so forth. But I digress.

The rest of the book is devoted to identifying the aptitudes necessary to survive and thrive in this brave new world. Pink characterizes the necessary mindsets as the six senses of the Conceptual Age:

- Design: This is perhaps self-explanatory. The iPod was not the first MP3-based music storage device—credit the Roxio with that—but it was Apple's superior product design, user interface, and the convenience and pricing of iTunes—design in the grandest sense—that revolutionized the distribution of music.
- *Story*: The ability to tell a story succinctly, engagingly, and attractively is a critical skill set for the right-handed brain.
- Symphony: Pink uses the term sympho-

*ny* for the ability to synthesize different elements and put them together into a complete picture. It frequently requires lots of filling in the gaps. The ability to synthesize like this is a key characteristic of entrepreneurs, who must always operate in a fog of incomplete knowledge and be comfortable doing it.

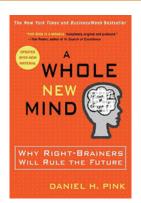
- *Empathy*: Empathy is the ability to put yourself in someone else's place, see what they see, and feel what they feel. Clearly you have to be able to do this to design products that other people will want to buy. It's a key skill in negotiating also.
- Play: This refers not to regular play golf, let's say—but the ability to bring fun into the workplace in a constructive rather than distractive way. Humor is a component of play.
- Meaning: Meaning is a luxury of our abundance. Freed from the necessity to work solely for food and shelter, we spend more and more of our time looking for meaning in our work.

Just as a physical fitness book gives you exercises to follow, so Pink includes assignments—exercises, books to read, things to listen to, places to go. For instance, one of the exercises to develop meaning is to walk a labyrinth (after first understanding the origins of a labyrinth). He gives you Web sites to find a labyrinth near you. My friend used them to find a labyrinth at Boston College and spent a very satisfying three hours walking it and inwardly contemplating.

In the context of the U.S. economy, Pink may not be in time. Recent articles are decrying the fact that, outside of Apple, most U.S. high-technology products are even designed in Asia, not just manufactured and assembled there. We may have outsourced too much of the design and creative infrastructure to be able to reestablish high-technology manufacture.

So what's the relevance of Pink to technology transfer? By definition, we are dealing with new things, things that

### **Book Review**



haven't been seen or done before. The scope for creativity in our work is unlimited. We all need a lot of right-hand brain to be successful in this business. So, even if you heard Pink's talk at the 2009 AUTM Annual Meeting<sup>SM</sup>—and it was one of the best we've ever had—read the book and do the exercises. It'll be fun!

\*Reviewer's note: Daniel Pink is the author of a trio of books on the changing world of work. In addition to *A Whole New Mind*, he has also written *The Adventures of Johnny Bunko: The Last Career Guide You'll Ever Need*, the first American business book in the Japanese comic format known as manga and the only graphic novel ever to become a BusinessWeek bestseller. His first book, *Free Agent Nation: The Future of Working for Yourself*, was a *Washington Post* bestseller. **\** 

AUTM President-Elect Ashley Stevens is the executive director for technology transfer at Boston University and a senior research associate for the Institute for Technology Entrepreneurship and Commercialization at Boston University's School of Management.

### **Hot Topic**

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### Legal Tips



### **To Mark or Not to Mark, that Is the Question** Considerations for Disclosure and Review of Trademarks

Turan P. Odabasi, JD

Trademarks are an important means to protect the names, logos, and other indicia of an institution and can be a useful tool to block any unauthorized commercial associations made with an institution. Trademarks can also be a source of income via licensing and merchandising.

Trademarks protect any word, slogan, symbol, name, sound, color, or any combination of those items used to identify the source of goods or services distributed in commerce. Trademark rights accrue through usage, not registration, but trademark owners frequently register their trademarks with either the federal government or state governments to clarify their ownership and secure certain damages not available to unregistered marks. Whether or not the mark is registered, the owner has the right to exclude others from using its marks or marks that are confusingly similar to the owner's trademarks.

What steps can an institution take to document, review, protect, and enforce its trademarks?

**1. Institute a centralized disclosure process.** Proposed trademarks should be disclosed to the institution for review and prior approval by institutional officials. This process should elicit information regarding the dates, development, and planned uses of the trademark. For trademarks incorporating institutional logos, a set of institutional logo standards should also be implemented. A centralized disclosure process provides documentation of trademarks that have been approved for use.

**2. Develop a review process.** Once disclosed, the trademark should be reviewed to determine whether the time and expense of registration is warranted. Factors to consider regarding federal registration of a trademark include the following:

- Is the trademark central to the mission of the institution? Does the trademark embody the institution's primary logo, slogan, or designation; or is it significant to the institution in some other way?
- Will the trademark be licensed to third parties? This is often the case with marks associated with athletic teams. Such trademarks may present a source of royalty income to an institution and should be registered if licensed.
- Is the trademark related to an institutionally developed technology or a related marketing or branding project?
- Is there a defensive need to obtain registration? If others are using comparable phrases or logos, registration may be prudent to protect the institution's ability to use the trademark.

#### **Resources**

The following articles and Web sites offer more information on this topic:

- The AUTM Technology Transfer Practice Manual, "Trademark Primer," by William Needle, JD: http://www.autm.net/Volume\_1\_TOC.htm
- The United States Patent and Trademark Office: http://www.uspto.gov/
- Trademark Considerations in Naming Your Business or Product by Owen Seitel: http:// www.allbusiness.com/legal/11550325-1.html
- Every Business Should Register its Trademarks by Owen Seitel: http://www.allbusiness.com/technology/software-servicesapplications-markup/11551144-1.html
- Trademark Basics by Lloyd J. Jassin, Esq.: http://www.copylaw.com/new\_articles/ trademrk.html
- Using University Trademarks in Advertising by Jason Bakker: http://www.ypulse.com/ wordpress/wordpress/ypulse-sponsored-postusing-university-trademarks-in-advertising

### Legal Tips



- Will the mark be used in other states?
   Federal registration can only be obtained for trademarks used in "interstate commerce."
- Will use of the mark infringe the rights of a third party? The proposed trademark should be searched for prior uses of similar trademarks with the review and input of institutional counsel.

The options of state registration or enforcement under common law are available if the institution still wishes to protect a trademark without federal registration.

**3. Develop a trademark enforcement strategy.** Consider how the institution will handle unauthorized uses of its trademarks. Failure to take action against the unauthorized use of an institution's trademarks can result in a loss of trademark rights. One practical option is to place the institution's trademarks on a watch service, whereby the institution will be notified of third-party attempts to register similar trademarks.

If an unauthorized use is discovered, the institution may seek to stop the use by enforcing its trademark rights in court. Depending on the situation, however, the institution may consider granting a license to the user instead of litigating the matter. A license agreement would confirm the institution's ownership of the mark and provide for the continued use of the mark in exchange for payment of royalties and/or other consideration.

The manner in which your institution handles these steps will depend on the nature of the institution, the extent of its trademark portfolio, and its resources. Regardless of whether your institution has an entire office devoted to trademark protection, licensing, and enforcement or if a single staff member handles trademark concerns, the key is to establish a process that your institutional community understands and uses. Doing nothing creates significant risk of jeopardizing what may be a very valuable asset—your trademark and image.

Turan Odabasi is associate general counsel at the University of Nebraska in Lincoln.

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### **Embracing the Peacock: Technology Transfer Opportunities in India**

#### Prabhu Ram

In the backdrop of a prolonged economic recession in the United States, most American technology transfer offices have had to face the realities of shrinking licensing and research revenues, drastically reduced endowment funds, hiring freezes, budget cuts, and reduced research investment. Many potential business partners for American universities tightened their budgets. To cope with these changes, technology transfer professionals are increasingly under pressure to perform and show results.

Irrespective of an economic recession or not, a key to enduring organizational success lies in the ability of an organization to adapt—the ability to adapt to changing market conditions, the changing nature of competition, understanding technological advances, and the reality of the interconnected and interdependent global village. One key trend over the past decade is the global shift toward the East, where India and China are taking huge strides in upstream scientific research, with focus on new technology development.

India is the second fastest growing economy of the world. Even in the backdrop of an economic recession, India has sustained its impressive growth. It presents one of the most attractive opportunities for global R&D collaboration and is increasingly becoming the hub of upstream technology development.

Some of the early entrants to India include Cornell University, Stanford University, MIT, and Harvard Medical International, among many others.

Cornell University has a longstanding relationship with India that includes working with the Indian public research system for key interventions in agriculture, life sciences, and biotechnology, and capacity building in ag-biotechnology. Technology transfer has been a key focus, with critical Cornell technologies being absorbed in India.

Stanford University has a partnership with the government of India that aims to train the next generation of medical technology innovators having an interest in inventions and early-stage development of new medical technologies. Many other U.S. universities are entering India with technology transfer and research collaboration partnerships and technology marketing targeted at both the Indian public and private sector. Alongside, India is already home for many innovation-driven global enterprises, with a significant proportion of research and new product development for these enterprises emerging from India. Many of the global corporations have ties with Indian public research organizations for technology development.

So, what makes India an attractive destination for research collaborations and technology transfer? Or, more precisely, why should you be here?

Long known for its prowess in basic research, India has taken active steps over the past decade to create a vibrant innovation-driven ecosystem that would result in innovative product development across disciplines. With a key to boost upstream technology development in the Indian public research system and homegrown enterprises, several initiatives have been established by the government to drive intellectual property (IP) creation and innovation.

One of the key ideas is to establish a network of innovation universities. Alongside India is exploring avenues to fund translational research and create infrastructure and capacity building for upstream technology research in the long term. A bill to



regulate publicly funded research, modeled on the lines of the U.S. Bayh-Dole Act, is pending in the Indian Parliament.

In the past, capability gaps in IP protection, product stewardship, research capacity proved stumbling blocks for doing business in India. Over the past decade, progressive steps have been taken to address these barriers. Increasing investments in education and research have focused on capacity building.

India today presents a myriad of opportunities for U.S. universities and global research institutions in drug discovery and development, software development, nanotechnology, biomaterials, Internet technologies, agricultural seed technologies, drug delivery technologies, biopharmaceuticals, and molecular diagnostics.

So, what specific opportunities are we talking about within these areas?

- Private R&D spending by the Indian industry in biotechnology, IT, and agriculture has increased manifold, with 15 Indian companies finding a place in the top 1,400 global companies by R&D spending in a survey conducted by the Department for Innovation, Universities, and Skills in the UK in 2008. The past decade has seen a huge surge in technology in licensing by Indian enterprises. A U.S. university could tap such licensing opportunities either on its own or by engaging a local partner with expertise in technology transfer to overcome the hurdles and barriers posed by geographies.
- One key hurdle for U.S. universities is the Valley of Death. As we move into the future, it will be increasingly difficult to secure gap funding for the next big innovation. Proof-of-concept validation for early-stage technologies could be accelerated through research collaborations with the Indian public research system and leading Indian universities.
- A third key opportunity is know-how transfer, wherein U.S. technology transfer offices can connect with Indian universities or research institutions in specific

upstream research areas. This could even be in the form of interinstitutional exchange of research personnel, as it's one of the best modes for knowledge transfer. Any IP that is jointly developed could be made available for public-good delivery through the public sector and/or through commercialization by a private enterprise in either partner country.

- India has adopted the consortia approach to tackle the grand challenges in health care, food security and human nutrition, biotechnology, and IT, among others. Some of the approaches adopted are global in nature, involving partnerships between institutions, government, and private sector. Opportunity exists for U.S. universities to engage in such global partnerships.
- Lastly, capacity building in technology transfer continues to be a priority for India, with many collaborative efforts addressing capacity gaps. Some U.S. universities offer in partnership with their Indian universities or other enterprises, tailor-made capacity-building executive education programs.

At a time when the world struggles to find its moorings in a subdued global economic environment, the key is to innovate out of crisis by focusing on new technology development. As India continues to reinvent itself and reshape the world, it is now or never for U.S. universities and research institutions to embrace the emergence of India as a key actor in the global geography of innovation and engage with India.

India, the land of ideas, is the future. And, the future beckons now.



Prabhu Ram is manager, Technology Management Advisory Group, Sathguru Management Consultants based in Hyderabad, India. He can be reached via e-mail at prabhur@sathguru. com.

### **Commercialization at Emerging Universities**

Joshua Powers, PhD

#### Abstract

Much of the research to date on technology commercialization from universities has focused on the activities of large, established research institutions. In recent years, however, smaller regional universities and other comprehensive or specialized institutions have developed patenting and licensing programs. Little is known about their experiences or the nature of the forces impacting their initiation and development. This study reports the results of a national study of technology commercialization at universities with smaller programs and offers recommendations for practice and future research.

#### Introduction

Research universities have been challenged to better engage with their external communities, most notably in efforts to advance regional or national economic development. One way this has been manifested is through technology transfer. While there has been significant growth in technology commercialization, that growth has been substantive among the less research-intensive universities. In 2006, 53 percent could be classified among the top 100 research universities in that year. However, approximately one-third of the universities reporting their technology commercialization activities and infrastructure in 2006 could be defined as a small office, those with three or fewer staff persons devoted to technology commercialization. Approximately one-half of the offices realized ten or fewer patents granted in a given year, many of which are classified as doctoral or master's classified institutions.<sup>1</sup>

Yet, there has been nearly no research conducted on the activities of universities with smaller and less well-developed technology commercialization programs. In light of the large gap in the knowledge base about commercialization at smaller universities and to inform practice, the purpose of this national study was to explore the phenomena at these emerging types of institutions.

A considerable literature has developed around the technology commercialization phenomena at major research universities.<sup>2,3</sup> Yet, there has been nearly no research conducted on the activities of universities with smaller and less welldeveloped technology commercialization programs. In light of the large gap in the knowledge base about commercialization at smaller universities and to inform prac-



Emerging Universities Joshua Powers, PhD tice, the purpose of this national study was to explore the phenomena at these emerging types of institutions.

#### **Conceptual Framework**

Stimulated in part by the Bayh-Dole Act, the opportunities of biotechnology,<sup>4</sup> and resource contraction,<sup>5</sup> business-industry linkages through technology transfer have grown enormously in scale and scope. Prior to 1980, patenting from all U.S. universities was less than 350 per year. Recent figures put that total at 3,255 with more than 190 universities involved in patenting.<sup>1</sup> According to the Association of University Technology Managers (AUTM), licensing activity since 1991 has grown from 1,229 licenses per year to more than 4,000.

Unfortunately, research on technology transfer at institutions other than major research universities is limited. What is known through case studies is that these types of universities sometimes serve important roles in stimulating local or regional economic development. For example, a recent study of technology transfer partnerships found case examples where smaller universities had made a difference in the economic recovery/ growth of a region.

Research on university commercialization has historically been limited, but the rapid growth since 1980 has expanded the knowledge base considerably. Subtopics within the field have ranged from studies of performance differences among universities<sup>6</sup> and processes for transfer such as through startup company formations<sup>7</sup> to the ethical and normative problems that the privatization of science has stimulated.<sup>8</sup>

Unfortunately, research on technology transfer at institutions other than major research universities is limited. What is known through case studies is that these types of universities sometimes serve important roles in stimulating local or regional economic development.

For example, a recent study of tech-

nology transfer partnerships found case examples where smaller universities had made a difference in the economic recovery/growth of a region. Researchers cited the University of Akron with its emphasis on research commercialization to aid the local chemical and polymer industries and Alfred University with its niche support of area glass and ceramics firms among a few other institutions of these sizes and types based on scale of research output.<sup>9</sup>

Yet other research on technology transfer has suggested that new entrants to commercialization may chose to patent technologies that are less likely to be of interest to industry than those patented by veteran institutions. These patent importance studies show that the patents of veteran universities are more likely to receive citations to it by later patents than those of universities newer to patenting.<sup>10</sup> A common explanation for this phenomenon is the importance of organizational and situational learning that within the world of technology commercialization takes time.

Hence, universities with new commercialization programs learn to patent by conducting better technology market valuations, expanding their linkages with industry, and transforming their inventive culture to be more receptive to alternative routes of knowledge dissemination such as patenting and licensing.

This learning period can also be characterized by goal ambiguity as to the means and mechanisms required for contributing to regional economic enhancement. This fact was well-captured in an American Association of State Colleges and Universities report on economic and workforce development:

It was not possible to develop a single definition of economic and workforce development. Since the range of activities that could be included ranged from the fundamental educational mission of a campus through research and service activities designed to be of economic benefit to the local region, to



Emerging Universities Joshua Powers, PhD direct economic benefit to a locale as a major employer; the definition became anything a campus chose to define as an economic development activity.<sup>11</sup>

#### Methodology

One-hundred universities were invited to participate in a 2007–08 national study of technology transfer practice at institutions with smaller programs. Smaller programs were defined as institutions that had at least one but no more than ten patents granted. Forty-one universities participated in the study for a 41 percent return rate. The institutions were geographically spread across the United States with most classified as doctoral/research universities or master's colleges and universities within the Carnegie classification system.

Persons responsible for overseeing the technology transfer program on their campus were asked to complete the survey. This typically meant the technology transfer program director or another officer charged with this responsibility (e.g., director of sponsored programs).

The age of the technology transfer office/program (defined as the year in which .5 FTE or more was devoted to technology transfer activities) in 2007 ranged from 0 to 24 years with a mean age of 9 years (i.e., established in 1999). Just under 60 percent had been established since 2000.

#### Results

#### **TECHNOLOGY TRANSFER FINANCING**

The financing of technology transfer activities on the campus as well as financial performance from licensing activities was one theme emphasis of the survey. Approximately 80 percent of respondents noted that operating expenses exceeded licensing revenues. Of those operating at a net loss, the mean percentage contribution of licensing revenues to operating expenses was 39 percent with a range from 5 percent to 75 percent. Regarding funding sources used to support technology transfer activities, respondents were asked to report their sources of funding and the percentage contribution of each source toward the financing of their programs (Table 1).

The most common source of funding was via an operating budget from the university. Somewhat less frequently cited were licensing revenues, research indirects, and grants. The term *research indirects* refers to funds received through grants and contracts to cover the overhead costs associated with research activities. The other sources of funding were cited much less frequently. In terms of mean contributions toward program funding, research indirects were the largest contributor (67 percent) followed closely by an operating

Funding Source	% of Total Respondents	Mean	Standard Deviation	Range
University operating budget	77%	65%	34%	5-100%
Licensing revenues	51%	34%	23%	0-80%
Research indirects	29%	67%	31%	5-100%
Grants	17%	52%	32%	20-100%
University endowment	6%	18%	16%	6-29%
Research foundation	6%	23%	4%	20-25%
One-time university funds	6%	18%	11%	10-25%
Other	3%	30%	n/a	n/a

#### Table 1: Sources of Funding for Technology Transfer



Emerging Universities Joshua Powers, PhD budget from the university (65 percent). Grants were reported on average to contribute 52 percent of total support with licensing revenues 34 percent. The mean contribution from the other sources was noticeably smaller.

Another financial point of interest was to investigate how long a technology transfer office/program had been supported from sources other than licensing revenue. The data revealed that the mean number of years was 7.8 with a standard deviation of 6.2. Given that the mean age of a technology transfer program was 9 years, this suggests that most institutions have been operating at a net loss for most of their time in operation. Furthermore, an examination of those institutions that reported operating expenses that exceeded licensing revenues, only one experienced a single year where licensing revenues exceeded operating expenses over the lifetime of the office.

#### **GOALS FOR TECHNOLOGY TRANSFER**

A second theme emphasis of the survey focused on technology transfer goal alignment between senior university leadership and survey respondents. The intent of these questions was to investigate the potential impact of goal emphasis on technology transfer office performance. The three goals explored were revenue generation, becoming self-supporting, and establishing an institutional culture of support for commercialization. Table 2 below presents the findings.

The results indicated that a senior-level commitment to institutional culture change

toward commercialization was most strongly felt by survey respondents followed by revenue generation and becoming self-supporting. Regarding how helpful these goals were perceived to be for technology transfer, a commitment to institutional culture change was seen as the most helpful, followed by revenue generation, and then becoming self-supporting.

In terms of the spread of the data, however, the perceived helpfulness of a given goal resulted in a wider range of responses (standard deviations ranging from 1.09 to 1.38) than did the set of questions inquiring of the goal itself (standard deviations of 1.0 to 1.17). This finding suggests that there may be some goal misalignment between senior leadership and technology transfer offices.

The survey also inquired if respondents felt that senior leadership expectations for technology transfer matched what was realistically possible given resource and institutional context constraints. Respondents noted that expectations were somewhat higher than what was realistically possible (mean of 2.54 on a 5-point scale ranging from 1 = expectations are much higher than what is realistically possible to 5 = expectations are much lower than what is realistically possible).

A second set of questions focused on respondent beliefs about senior leadership goal priorities for technology transfer. Nine possible goals were presented. Table 3 presents these goals; the number of times a respondent noted a goal as a first, second, or third priority; and the total number of times that a given goal was noted as a

Table 2: Senior Leadership Goal Emphases and Respondent Perceived Helpfulness for Technology Transfer

Goal	How Strongly Emphasized the Goal Is by Senior University Leadership	How Helpful the Goal Is for Technology Transfer
Revenue generation	3.14 (1.00)	2.91 (1.09)
To become self-supporting	3.62 (1.14)	3.05 (1.37)
Institutional culture change toward com- mercialization	2.51 (1.17)	2.38 (1.38)

Note: Standard deviations are shown in parentheses next to the means. Ratings were on a 5-point scale ranging from 1 = very strong or very helpful to 5 = not at all strong or not at all helpful



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Goal	1 <sup>st</sup> Priority	2 <sup>nd</sup> Priority	3 <sup>rd</sup> Priority	Total Times Selected as a Priority
Generate new revenues	7	5	6	18 (49%)
Facilitate the movement of technologies to industry with revenue returns of less consideration	12	4	4	20 (54%)
To be responsive to the desires of state or federal policy-makers	0	4	3	7 (19%)
Leverage additional R&D resources from industry sources	3	6	6	15 (41%)
Leverage additional R&D resources from federal sources	1	2	3	6 (16%)
Keep up with what other institutions are doing in the arena of technology transfer	0	1	4	5 (14%)
Create more opportunities for relationship building with industry	5	6	7	18 (49%)
Support economic development in the region or state	7	9	7	23 (62%)
Other	3	1	0	4 (11%)

priority at any level. In this last column, the percentage of respondents who noted a given area as a priority is also shown.

The most commonly selected first priority goal of university leaders as perceived by study respondents was facilitating the movement of technologies to industry (12 first-priority selections), followed by generating new revenues and supporting economic development in the region or state, each with seven first-priority selections.

In terms of the total number of times that a particular goal was selected at any of the three priority levels, supporting economic development in the region or state was selected most often followed by facilitating the movement of technologies to industry, generating new revenues, and creating more opportunities for relationship building with industry.

#### **TECHNOLOGY TRANSFER STRATEGY**

A third theme explored in the survey was the strategic orientation that technology transfer programs took in terms of their degree of selectivity in choosing which technologies to patent.

Approximately 50 percent of respondents noted that that they were less selective or not very selective, the latter described as patenting nearly all invention disclosures. Yet, 30 percent of respondents noted that they were very selective or selective in their orientation toward what to patent, suggesting considerable differences in belief regarding how best to pursue commercialization—patenting many or most of what is disclosed versus patenting only those that appear the most promising for licensing.

These results suggest that the primary association (identified as AUTM in 80 percent of the cases) was a major influence, while state policymakers and in-state flagships were influential for only about one-half of the respondents.

#### NORMS OF PRACTICE INFLUENCE ON TECHNOLOGY TRANSFER

A fourth theme of the survey explored norms of practice influence that respondents felt from their primary association, flagship universities in their state, and state policy-makers. An examination of the frequency of rating selection revealed that 74 percent of respondents felt that their primary association had a somewhat strong or very strong influence on technology transfer on their campus. Regarding state flagship institutions, 55 percent felt they had a somewhat or very strong influence on technology transfer on their campus.

Finally, in terms of state policy-makers, 47 percent of respondents felt that this source of norm influence was somewhat or very strong. These results suggest that



Emerging Universities Joshua Powers, PhD the primary association (identified as AUTM in 80 percent of the cases) was a major influence, while state policy-makers and in-state flagships were influential for only about one-half of the respondents.

#### **BENCHMARK INSTITUTIONS**

A fifth theme included in the survey inquired about benchmark institutions of universities of their size and type that they would see as valuable to emulate. Table 4 lists the universities identified by respondents and their frequency of selection.

As noted at the bottom of the table, 13 (32 percent of the 40 respondents) could not identify a benchmark institution that they felt represented a good fit for their program. Furthermore, of the institutions that were listed, many could be considered universities with much larger and resource robust programs and, thus, potential mismatches.

#### TOP CHALLENGES CONFRONTING SMALLER PROGRAMS AND SUCCESSFUL PRACTICES

A final theme explored in the study was the top challenges that respondents confronted as well as best or successful practices that they saw as relevant to their type of institution and program size. The challenges and successful practices that were self-identified were grouped into categories and are shown below with the frequency of response noted in parentheses.

#### Challenges Identified by Respondents

- Education of key institutional stakeholders on the role and purpose of technology transfer
  - Education of scientists/researchers (5)
  - Education of administrators (4)
  - Education of faculty on the mechanics of starting companies (1)

#### **Table 4: Benchmark Institutions**

Universities Identified Two or More Times		
Stanford (8)	Carnegie Mellon (2)	
MIT (5)	Ohio State (2)	
University of Wisconsin (3)	University of Texas (2)	
University of Florida (3)	University of Michigan (2)	
Georgia Tech (3)	University of Virginia (2)	
Arizona State (2)	Virginia Tech (2)	
Boston University (2)	Wake Forest (2)	

Universities Identified Once			
Baylor College of Medicine	Rensselaer Polytechnic Institute	University of Houston	
City of Home/Beckman	Rutgers	University of Illinois	
Cleveland Clinic	Thomas Jefferson University	University of North Dakota	
George Mason University	Tufts University	University of Notre Dame	
Kent State University	University of Alabama, Birmingham	University of Pennsylvania	
Mayo Clinic	University of California, Davis	University of Texas, Southwestern Medical Center	
Michigan State University	University of California, Irvine	University of Texas, Austin	
Michigan Tech	University of California, San Diego	University of Toledo	
North Carolina State	University of Illinois, Chicago	Virginia Commonwealth	
Oregon State	University of North Carolina, Charlotte	Washington University	
Ohio University	University of Akron	Wayne State University	
Purdue University	University of California system	University of California system	

Don't Know (13)



Commercialization at Emerging Universities Joshua Powers, PhD

- 2. Institutionalizing processes and procedures for technology transfer
  - Handling the mechanics of patenting and licensing (5)
  - Objectives from senior administration that are unclear or are unrealistic (4)
  - How best to handle the licensing of early-stage technologies
- 3. Lack of adequate financial resources
  - Funding to initiate projects or advance projects to a licensable state (15)
  - Funding to adequately market patented technologies (7)
  - Personnel pay rates below industry norms (1)
- 4. Lack of adequate human resources
  - Insufficient trained staff to do the work that is needed (10)
  - Lack of access to needed talent to assist in key processes, particularly in early stages (9)
- 5. Other tangible and intangible institutional support
  - Commitment by key institutional for culture change toward commercialization (10)
  - Legal support on intellectual property needs (5)
  - Inadequate research pipeline to support program (3)
  - Institutional or government red tape (3)
  - Inadequate institutional responsiveness to key needs (2)
  - Inadequate recognition of faculty inventors involved in technology transfer (1)
- 6. Additional pressures
  - Expanding role responsibilities (5)
  - Keeping up with demand for services (3)
  - Unrealistic faculty expectations (2)
  - Distractions of copyright management (2)
  - Pressures to push technology too soon to industry (2)

### Successful/Best Practices Identified by Respondents

- Do not know of any best/successful practices (26)
- Involving students such as through project teams or as interns (5)
- Developing a strategic plan for marketing (5)
- Collaborating/partnering with other institutions (4)
- 11. Have processes in place that enable flexibility—all deals are different (3)
- Processes that service the needs of inventors and nurture those relationships (2)
- Clear patent management procedures (2)
- Ongoing assessment of technologies (2)
- 15. Alumni programs for involvement (2)
- 16. Early-stage gap funding (1)
- 17. Faculty recognition events (1)
- Strong relationships with institutional leadership (1)
- 19. Outsourcing paperwork (1)

#### **Study Implications**

To date, much of the research on university technology transfer has focused on the work and experiences of large universities with established programs. Given their scale of operation and the high-profile success stories that have emerged from such institutional settings, literature targeted toward these kinds of institutions is both important and understandable.

Yet, largely absent from the scholarship has been studies of universities with smaller programs, or what some refer to as *emerging institutions*.<sup>9</sup> While their contribution to economic development in comparative terms may be smaller, the pace at which nonflagship state universities and smaller private universities in the United States are ramping up their patenting and licensing enterprises, seeking to find appropriate models to emulate and contributing to regional economic development in particular makes their study both worthy and timely.

This national study of technology trans-



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fer practice at universities with smaller programs revealed a variety of useful findings that inform both practice and future research. The implications of these findings are grouped into three categories that cut across the themes discussed earlier.

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#### TECHNOLOGY TRANSFER FINANCING AND GOAL ALIGNMENT

Given the challenges associated with leveraging typically early-stage patented technologies into revenue streams, it is not surprising that so many institutions have no alternative but to subsidize their technology transfer programs. Of concern, however, is that few appear to have ever realized a licensing income stream that offsets costs of operation over their office's lifetime to date.

The concern is heightened by the fact that at approximately one-half of the universities in the sample, senior leadership appear to value revenue generation as a priority goal, and 35 percent have a moderate to strong desire to see their technology transfer office become selfsupporting. This suggests a need to better educate senior leadership on alternative metrics of success.

Furthermore, it suggests the need to establish realistic timeframes and milestone targets for revenue generation, time periods that may get inappropriately truncated as technology transfer officers feel the pressure from institutional leadership and possibly state policy-makers to deliver on what may be unrealistic financial goals.

#### LACK OF SUCCESSFUL PRACTICE MODELS

One key finding of this study focuses on the lack of clear institutional role models for universities of these sizes and types. The most common answer to the question about benchmark institutions was *don't know*. Furthermore, a number of the institutions that were cited as benchmarks are national leading institutions with large, long-serving programs, ones that may not be the best examples for emulation.

Most of these larger, established institutions have sizeable standalone staffing and resource infrastructures, opportunities that are not realistic for smaller university programs. Smaller programs must rely more on networks, sometimes pooling resources with other institutions and collaborating on program services. Smaller institutions often also have to handle multiple functions within the research enterprise such that at one moment a staff professional is negotiating a license while at the next is assisting a faculty member to submit an National Institutes of Health grant proposal.

Given that there were a number of smaller institutions cited only once by respondents, it suggests a lack of obvious role models for smaller technology transfer programs. A useful future research project would be to conduct case studies of these places to see why they might be seen as a benchmark.

Given that there were a number of smaller institutions cited only once by respondents, it suggests a lack of obvious role models for smaller technology transfer programs. A useful future research project would be to conduct case studies of these places to see why they might be seen as a benchmark.

#### STRATEGIC ORIENTATION TO TECHNOLOGY TRANSFER

The scholarly literature on technology transfer suggests that selectivity may be an important factor in determining the



Emerging Universities Joshua Powers, PhD likelihood of downstream development and, ultimately, product licensing revenues.<sup>12,13</sup> This study discerned that universities of this type were fairly nonselective, with a full 50 percent indicating that they were quite nonselective. For these universities, it appears that they follow a patent-for-numbers approach in the hope that a larger inventory will result in heightened chances that one of the deals will do particularly well and offset the financial investment loses of the others.

Yet, a full 30 percent appeared to take the opposite view, namely, focus on just a few, very promising patents as a way of increasing the chances for marketplace success. Clearly, there is a lack of guiding insight as to which is the better approach and in what circumstances, an experimentation approach with considerably risky consequences.

Furthermore, given that the number of disclosed technologies is likely limited, there may be considerable pressure to patent as a means of evidencing a commitment to economic development, even though a patent may never get licensed. Thus, further scholarship and professional conference discussions that explore this matter more thoroughly would do much to assist universities that are fairly recent to technology transfer practice.

#### Conclusion

Henry Etzkowitz<sup>14</sup> suggested that the current entrepreneurial era for universities is at least as fundamentally paradigm changing as was the birth of the research university model after the Civil War. While large universities have been engaged in this transformation since at least 1980, smaller regional universities and other private institutions are comparatively new to academic entrepreneurship. Given how important these institutions are to their states and regions, scholarship that informs their responsible practice of technology transfer is essential. This study sought to provide a national perspective on this phenomenon and serve as a foundation for follow-on work that benefits both practitioners and scholars.



Joshua Powers is an associate professor and chair of the Department of Educational Leadership, Administration, and Foundations at Indiana State University in Terre Haute. He can be reached via e-mail at jopowers@ indstate.edu.

#### Notes

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<sup>3</sup>F.T. Rothaermel, S.D. Agung, and L. Jiang, "University Entrepreneurship: A Taxonomy

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<sup>5</sup>S. Slaughter and L. Leslie, *Academic Capitalism: Politics, Policies, and the Entrepreneurial University* (Baltimore: Johns-Hopkins University Press, 1997).

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<sup>7</sup>A. Lockett and M. Wright, "Resources, Capabilities, Risk Capital, and the Creation of University Spin-out Companies," *Research Policy* 34 (2005): 1043–1057.

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<sup>11</sup>Committee on Economic and Workforce Development, *Economic and Workforce Development* (Washington, DC: AASCU, 2003): 4.

<sup>12</sup>J. Powers and P. McDougall, "Policy Orientation Effects on Performance with Licensing to Startups and Small Companies, *Research Policy* 34 (2005): 1028–1042.

<sup>13</sup>E.B. Roberts and D.E. Malone, "Policies and Structures for Spinning off New Companies from Research and Development Organizations," *R&D Management 26* (1996): 17–48.

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Comparison of National Innovation Systems in China, Taiwan, and Singapore: Is Bayh-Dole One Size that Fits All?



#### Abstract

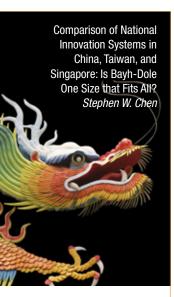
National innovation system (NIS) is an analytical tool to evaluate a country's technological development that focuses on institutional actors creating and diffusing technologies. Examining the policies shaping NIS in China, Taiwan, and Singapore reveals dramatic differences in the types of institutional actors in each country and their roles overseeing and performing research and development (R&D). These differences further exist in universityindustry linkages (UILs).

As an example of contrasting UIL governing transfer of public research assets to the private sector, the operation of each country's Bayh-Dole style legislation is described to illuminate indicators of technology transfer and preview future obstacles. It is finally suggested that legislation implementing innovation policy should be crafted within the context of a country's specific needs.

#### Introduction

One leading approach in analyzing a country's technological development is the concept of national innovation system (NIS). First proposed by economist Christopher Freeman to evaluate Japan's rapid postwar development, NIS focuses on institutional actors (public and private) and their activities (creating, importing, modifying, and diffusing new technologies). Legislation promoting the creation and transfer of technology, such as Bayh-Dole (BD), falls within a narrower slice of NIS that is the university-industry linkage (UIL). A UIL broadly describes how basic research and development activities interact, diffuse, and transfer to the commercial sector. Because NIS varies drastically, it is easy to imagine similarly dramatic variations in UIL.

The following evaluation of NIS in China, Taiwan, and Singapore reveals dramatic



differences in the structure and function of institutional actors overseeing and performing research and development (R&D). Because the role of institutional actors in different countries varies significantly, it is suggested that legislation implementing innovation policy, such as those governing UIL, should be crafted within the context of a country's specific needs.

The first section of this paper analyzes the NIS of China, Taiwan, and Singapore, looking in particular at how they shaped and defined institutional actors. The second section evaluates UIL, using the specific example of BD-style legislation in each country to illuminate existing indicators of technology transfer and preview potential obstacles.

#### National Innovation System (NIS): An Analytical Tool Focused on Institutional Actors' Activities and Interactions

There is no universal definition of NIS, but competing interpretations share the core principle that the function and interactions of actors are significant forces in shaping a nation's scientific and technological development.<sup>1</sup> The Organization for Economic Cooperation and Development (OECD) provides one framework for detailing a country's NIS, suggesting six primary roles for institutional actors. This includes: (1) performing R&D, (2) financing R&D, (3) human resource development, (4) diffusing technology, (5) promoting entrepreneurship, and (6) formulating technology and innovation policy.<sup>2</sup>

This broad definition encompasses everything from administrative agencies coordinating and conducting public research (e.g., the National Institutes of Health), private-sector research enterprises (e.g., Genentech), higher education (e.g., Stanford University), and bridging institutions (e.g., Biotechnology Industry Organization).

Focusing on these specific roles of institutional actors provides a useful analytical tool in characterizing activities beyond rough function-based definitions.

An administrative agency in one country may vary drastically from an analogous agency in another county in terms of function. As an example, the Chinese Academy of Science (CAS) in mainland communist China and Academia Sinica (AS) in nationalist Taiwan are the analogous scientific academies in each country. Both academies serve key roles in governing public research institutes and even share a common origin (with AS being relocated to Taiwan after the 1949 Chinese civil war).

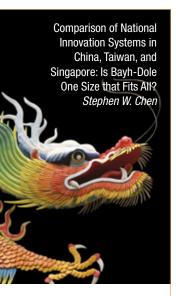
Because the role of institutional actors in different countries varies significantly, it is suggested that legislation implementing innovation policy, such as those governing UIL, should be crafted within the context of a country's specific needs.

However, CAS directly establishes and invests in high-technology enterprises, starting nearly 400 spin-off companies to date.<sup>3</sup> In contrast, AS does not directly foster such private commercialization, but rather, promotes adoption of new technologies by existing private enterprises.<sup>4</sup>

To provide further context in understanding the role of institutional actors in each country, this paper first summarizes the underlying technology policies shaping their creation. A brief discussion of NIS follows, first beginning with China, turning next to Taiwan and Singapore.

#### CHINA: SHIFTING AWAY FROM A LEGACY OF CENTRAL PLANNING, THE RISE AND FALL OF THE UNIVERSITY-RESEARCH ENTERPRISE

After the founding of the People's Republic of China in 1949, research was conducted primarily at specialized public research institutes (RIs), with universities involved in only a limited number of research activities. Adopting the central planning approach of its Northern neighbor, the Soviet Union, the Chinese government was the principal source of science and technology



(S&T) funding. The government allocated specific, defined tasks to RIs through administrative orders, with the majority of science research focused on military-related applications. In contrast, "Universities did undertake research, but their most important priority was pedagogy."<sup>5</sup>

Furthermore, this central planning structure erected a wall, divorcing S&T innovation from industrial activities fixated with production. "As a result of this system, public research institutes had no incentive to understand the needs of enterprises for technology...state-owned enterprises were supposed to concentrate on production activities, without proper incentive systems for innovation..."<sup>6</sup> This artificial decoupling of research and industry eviscerated innovation incentives, causing China to lag behind other Asian nations in technology development.

Nearly ten years after spurring their creation, more than 2,000 UREs were founded with a combined worth of \$3.8 billion.<sup>9</sup>

Establishing Western-style economic reforms in the 1980s was coupled with an emerging emphasis on scientific research and education for economic development. The first of three major policy shifts occurred in 1985 by winnowing away the prior Soviet-style research structure through creation of new incentives. Specifically, RI and university budgets were slashed to spur increased collaboration with industry for alternative funding resources. "For URIs, the only option was to search for alternative source of funds."<sup>7</sup>

In concert with changing the funding landscape, new innovation incentives were offered through adoption of the landmark 1985 Chinese patent law. Together, these initiatives attempted to traverse the gap separating research and industry, providing new types of innovation incentives to spur development of new technologies.

The second step began during the early 1990s, laying the foundation for much

of China's current technology landscape through creation of university and research institute-based enterprises (UREs). "The unique feature of the Chinese NIS is the URI-owned enterprises."<sup>8</sup>

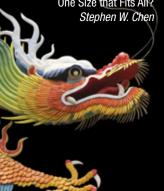
At the initial stages, the Chinese government encouraged not only strong links between universities and emerging enterprises, but direct creation of hightechnology companies. Guidelines for administering UREs were promulgated, and faculty could occupy both teaching roles in a university/RI and research positions in the URE. Nearly ten years after spurring their creation, more than 2,000 UREs were founded with a combined worth of \$3.8 billion.<sup>9</sup>

The third and most recent step, beginning in 2001, shifted the focus away from UREs. Critically, unlike Western spin-off companies, UREs were endowed with substantial control over the mother institutions' assets, including manpower, facilities, research results, and resources.<sup>10</sup>

Earlier reforms bridging research and industry may have reached too far as "[S]ome universities might go bankrupt because of the losses their affiliated firms were suffering."<sup>11</sup> Furthermore, there was increasingly trenchant criticism that UREs were merely importing and adopting technology, rather than innovating. As a result, "The government began to examine the efficiency of UREs in 2001. Since then, a 'delinking' of URIs from their affiliated enterprises has been under way."<sup>12</sup>

Through three major phases, the overall trajectory of Chinese innovation policy has migrated away from central planning, although this further necessitated finetuning of the resource allocation between research and industrial activities. Nevertheless, the Soviet-style central planning legacy remains a pervasive and strong influence on modern Chinese innovation policy. "Each national S&T plan outlines the *main direction* of S&T development... The performers of S&T activities *fulfill the tasks assigned to them from above* and

Comparison of National Innovation Systems in China, Taiwan, and Singapore: Is Bayh-Dole One Size that Fits All? Stephen W. Chen



depend upon official allocations for necessary resources. These performers of S&T activities do not need to suffer the full losses resulting from failure in innovation activities, but nor do they benefit fully from success."<sup>13</sup>

#### TAIWAN: DRIVING POLICY THROUGH CONSENSUS, PROMOTING AUTONOMY OF INSTITUTIONAL ACTORS IN IMPLEMENTATION

After the founding of the Republic of China in 1949, Taiwan's main economic areas were agriculture and exports. However, by the late 1960s, economic policy "relied heavily on labor-intensive manufacturing exports," and there was little or no R&D or innovation policy to speak of.<sup>14</sup> Continuing into the 1970s, R&D activities in both industrial and academic areas remained low. By this time, Taiwan's economy was studded with many small and medium enterprises (SMEs), which were ill-equipped for R&D or had no concept of R&D altogether.<sup>15</sup>

To address the lack of a formal R&D policy, the first National Conference on Science and Technology convened in 1978 and continues to meet every four to five years.<sup>16</sup> Because Taiwan's economy was dominated by SMEs with small R&D capacity, "It was decided that government research organizations should play the role of bridge between academic research and commercialization. This allowed the formation of a preliminary system of industrial innovation."<sup>17</sup> In short, policy-makers sought to make public research assets and resources widely accessible to a variety of existing private businesses.

Due to a generous population of SMEs and the desire to empower them with strong, accessible public research resources, Taiwanese policy-makers drove innovation policy primarily through consensus-building. Rather than orchestrating strong top-down national policy initiatives, relevant actors were tapped to shape national policy initiatives, thereby obtaining significant autonomy in implementing specific approaches.

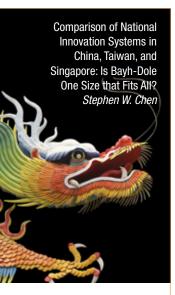
As an example, the National Conference on Science and Technology, "brings together relevant experts from industries, universities, government, and foreign S&T advisers and generates *long-term plans that articulate the basic direction* of national S&T policies." With the larger guideposts in view, the specific execution of these S&T plans "in Taiwan follows principles of integrated planning and decentralized implementation."<sup>18</sup>

Due to a generous population of SMEs and the desire to empower them with strong, accessible public research resources, Taiwanese policy-makers drove innovation policy primarily through consensus-building.

While the Taiwanese consensus-building approach creates variability in executing the overall national innovation policy, two hallmarks are sector-targeting and industrial-clustering. First, was the creation of public research institutes (RIs) and science parks to house RIs alongside private enterprises.<sup>19</sup> In 1973, the Industrial Technology Research Institute (ITRI) was created, focusing on semiconductor chips, computers, and opto-electronic products.<sup>20</sup> One of Asia's first scientific parks, Hsin-Chu Science Park (HSP) was unveiled a few years later in 1980.

Second, was the creation of strong incentives to lure private enterprises to these locations. Enterprises setting up shop in HSP were met "With several adequate incentives including abundant supply of technology and skilled engineers, tax credits, excellent infrastructure, and convenient official services..."<sup>21, 22</sup>

Together, this approach propelled Taiwan to first-rank production volume of desktop computers and notebooks, along with becoming the third largest exporter of computer products, behind only the United States and Japan.<sup>23</sup> With these results in hand, "Taiwan's PRIs continue to play the



role of R&D agencies for Taiwan's SMEs as they have done for decades—to meet their technological and resource insufficiency."<sup>24</sup>

Perhaps due to remarkable successes with ITRI and HSP, Taiwan continues to replicate industrial-clusters for new technologies in different geographical locations.<sup>25, 26</sup> Again, a variety of actors furnish execution details, including SMEs, local county governments, and even city municipalities. As an illustrative example, "[T] he Taiwan *national* innovation system is starting to encompass targeted technology developments within the country's capital, Taipei, *under the control of the city administration.*"<sup>27</sup>

However, merely replicating more industrial clusters across Taiwan has raised concerns about redundancy in R&D efforts, thereby handicapping the overall quality and level of innovation. First, as one commentator noted, "The advantage of one park cannot be easily completely duplicated to other areas. This in turn raises an important policy issue: The science-park development mode may not be implemented without limit."<sup>28</sup>

One additional weakness of this approach was revealed in overexposing Taiwan to global market fluctuations, such as falling demand for computer technologies after implosion of the dot-com bubble. Limiting this exposure has further required a shift in focus from rapidly gaining expertise in foreign technology to creating new technologies.

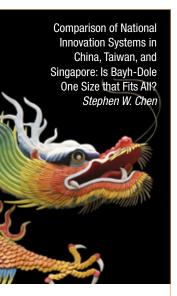
Taiwan's national policy was a sophisticated strategy of fast followership—first beginning with identification of key technologies and later building expertise and capabilities in those technologies.<sup>29</sup> This reliance on foreign technology has meant Taiwan is "extremely dependent on inflows of foreign technologies... and so are easily influenced by global economic fluctuations. Consequently, Taiwan often suffers from the lack of R&D of original pioneering and self-contained technologies."<sup>30</sup> Taken together, Taiwan faces a challenge of climbing up the technology ladder by spurring innovation, but must avoid the track of merely adopting "more of the same" policy approaches that captured initial successes. One strong point of the current approach is that, by allowing a variety of actors to implement the overall national policy, this encourages desirable heterogeneity in execution. Taiwanese policy-makers should continue the decentralized planning approach by embracing input from relevant actors, while also enhancing in-house SME R&D activities.

#### SINGAPORE: ECONOMIC PLANNING ATTRACTING FOREIGN ENTERPRISES AND INVESTMENT, COUPLED WITH HIGHLY FOCUSED INTERVENTION THROUGH STATE-OWNED ENTERPRISES AND RESEARCH INSTITUTES

The Republic of Singapore was founded in 1965 as an island city-state with few natural resources at its disposal. The Singaporean government initially had "little option but to turn decisively outward to export domestically made manufactures."<sup>31</sup> Capitalizing on its strategic location as a historic port of trade, Singapore also eventually developed a thriving professional and financial services center.

At each stage, the hallmark of Singapore development policy has been focused on long-term strategic planning to attract foreign investment, punctuated with decisive government intervention. Innovation policy has followed suit with the government maintaining a strong hand guiding R&D activities, although there are emerging views suggesting the need for a lighter touch.

Among the earliest export domestic manufactures, Singapore moved immediately into electronic and electrical products. One critical enabling factor was not R&D policy, but rather, control of labor costs by leveraging Singapore's specific geography as an island city-state. By closing the nation's borders, managing labor inflow, and regulating wages, the gov-



ernment "pegged wage rises at or below productivity gains [which] was essential in safeguarding this required rate of profit."<sup>32</sup>

Creating a profitable enclave for Western companies further promoted an influx of high foreign investment and foreign enterprises.<sup>33</sup> "[S]ound economic planning and concerted efforts by the government to attract foreign investments were key factors behind its phenomenal growth pace..."<sup>34</sup>

As some commentators have highlighted, strong links with the global marketplace actually favored an overall hands-off approach to allow the Singapore government to act decisively in response to swift global trends, rather than being encumbered by formal planning documents. "Planning in Singapore never involved detailed blueprints, because of the priority accorded to reaction to the international market, impossibility of predicting its course, and need for flexibility to ensure a quick and competitive response."35 Further illustrating this approach is the surprising fact that "[Singapore's] first formal science and technology plan was only implemented in 1991."36

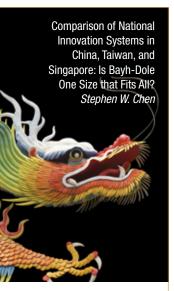
That is not to say that the Singapore government did not strongly promote R&D within its borders during earlier years. Rather, Singapore encouraged R&D through direct funding and creation of incentives in three primary vehicles: foreign enterprises, universities, and state-owned enterprises. "Tax incentives were given to manufacturing companies that undertook R&D in Singapore. The level of public commitment to R&D was confined largely to scientific research in public universities and defense R&D..."37 Furthermore, while educational and manpower training was offered through local institutions, later efforts included overseas training for select workers and grants and subsidies for foreign companies providing specific skills to employees.38

Finally, a variety of state-owned enterprises were created for sectors unattractive to foreign investors. "[T]he Singapore government began as nonstatutory undertakings, a range of enterprises...the government retains a majority holding in profitable and key undertakings like Singapore Airlines and Singapore Telecom."<sup>39</sup> Critically, Singapore "had the advantage that public enterprise began afresh rather than through the nationalization of already loss-making firms."<sup>40</sup>

However, as Singapore approaches a current level of economic development on par with many leading Western nations, the focus is shifting away from attracting foreigners and importing technologies to strengthening local institutions through new technology creation. "Lately, however, there have been concerns that the development strategy that Singapore had adopted for the past few decades may no longer be sufficient...."41 And it is in this context that Singapore's most expansive and decisive innovation policy measures have been deployed. In 1991, the first National Technology Plan was enacted, focusing on the construction of technology infrastructure, further incentives for private sector R&D, and enhanced technical manpower training. This was followed by a second plan in 1996, funding the establishment of thirteen public research institutes in sector-specific areas.42

This brief summary of incentives deployed in each country's NIS highlights that the specific types of incentives varies drastically, but that formulating a proper incentive scheme is a critical balancing act in defining institutional actors and their roles.

Despite these efforts, Singapore is confronted by a somewhat unique challenge of promoting creativity and entrepreneurship within a highly skilled workforce, but one ranking near the bottom in entrepreneurial propensity among developed nations.<sup>43</sup> Addressing this concern, educational policy evolved toward "increasing creativity in schoolchildren," through migration away from exam-based educational assessment



toward encouraging project-based skills systems. Nevertheless, it is necessary for Singapore policy-makers "to change the social and cultural attitudes toward entrepreneurship, acceptance of nonconformity, and tolerance of failure."<sup>44</sup>

As Singapore grapples with obstacles in scaling the technology value-chain, policymakers must balance a remarkably successful model of attracting foreigners to its shores, with an increasingly interventionist approach empowering local institutions. Nevertheless, with the guiding hand of government acting nimbly in response to the country's needs, Singapore may continue to carve a unique path in reaching future successes.

#### COMPARISON OF NIS REVEALS STARK DIFFERENCES IN TYPES OF INSTITU-TIONAL ACTORS AND THEIR ROLES

From this whirlwind tour of NIS, stark differences between each country are apparent. First, the overall policy approach adopted by central government and the *role* of institutional actors in each country is very different. The Chinese government retains a strong central planning structure. In the midst of propelling massive institutional reform, the government must strike an effective balance between research and industrial relationships to eliminate obstacles previously hampering the country's economic development.

In contrast, Singaporean innovation policy has shifted away from being focused intensely on creating attractive incentives for foreign investment and R&D to buttressing these efforts with growing investment in local institutions under the direction of government planners.

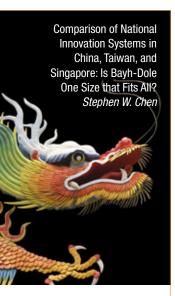
At the furthest end of decentralized planning, the Taiwanese government formulated innovation policy by building consensus and granting significant autonomy to local actors in execution, although emerging limitations in expanding this approach to new technological and territorial areas may require stronger central guidance. Second, the result of each country's NIS has spawned markedly different *types* of institutional actors. The Chinese R&D landscape is populated by universities/research institutes and their closely associated hightechnology enterprises, UREs, while Taiwan possesses many domestic SMEs empowered through broad access to public research resources. Further contrasting these two nations, Singapore is predominated by foreign and state-owned enterprises interfacing with expanding university and research institute resources.

Nevertheless, a common goal is enhancing the efficiency of innovation through creation of new technologies, while reducing mere importation and application of foreign technologies. Proper formulation of incentives is a common theme and appears to be a critical enabling factor in rising up the technology ladder. For example, in China, transformation of RIs was accomplished through funding cutbacks coupled with new opportunities to form UREs.

In Taiwan, a variety of financial, technological, and infrastructure incentives were provided to enterprises setting up shop in science parks and engaging specific technology sectors. In Singapore, strong profit incentives attracted foreign investment, with additional benefits provided to those businesses conducting R&D and manpower training. This brief summary of incentives deployed in each country's NIS highlights that the specific types of incentives varies drastically, but that formulating a proper incentive scheme is a critical balancing act in defining institutional actors and their roles.

#### University-Industry Linkages: The Wide Embrace of Bayh-Dole Style Legislation in Asia

Given that the earlier evaluation of NIS in China, Taiwan, and Singapore reveals dramatic differences in the structure and function of institutional actors, it is remarkable that each nation has nevertheless adopted BD-style legislation as a keystone in its modern innovation policy



governing the diffusion and transfer of public research assets into the private sector. As an illustrative example of university-industry linkages (UIL) in different countries, Bayh-Dole (BD) is particularly attractive because of its widespread adoption around the globe.

As has been noted, "[C]ountries from China and Brazil to Malaysia and South Africa, have passed laws promoting the patenting of publicly funded research..."<sup>45</sup> This wide embrace provides opportunity to compare and contrast the variable impact of BD-style legislation in circumstances composed of divergent cultural, social, political, historical, and economic conditions.

#### THIRTY YEARS OF THE AMERICAN BAYH-DOLE EXPERIENCE SHOWS GOOD SUCCESSES COUPLED WITH NEW OBSTACLES

Prior to Bayh-Dole's adoption in 1980, discoveries in American public research institutes were commercialized in murky legal waters. Specifically, there were few bright-line rules governing ownership of research products originating from public research funding. One of the key roles of BD was clarifying ownership and administrative rules, providing a framework for individual researchers and their universities to patent and license research productsa key step in starting university spin-off companies. In short, American policymakers fashioned a novel incentive scheme to encourage innovation and spur commercial adoption, which is an important formulation in NIS.

Bayh-Dole has been effusively praised for spurring innovation in providing individual researchers and universities with potentially lucrative royalties or with opportunities to privately commercialize their technologies. In 2002, *The Economist* called BD, "possibly the most inspired piece of legislation enacted in America over the past half century."<sup>46</sup>

Routinely highlighted as indicators of BD's success are patent and licensing metrics demonstrating rising numbers of patent application filings, license grants, and royalty revenues. As an example, patent application increased from below 2,000 filings in 1991 to more than 11,000 in 2004. During this same period, royalty income spiked from approximately \$200 million to \$1.4 billion.<sup>47</sup>

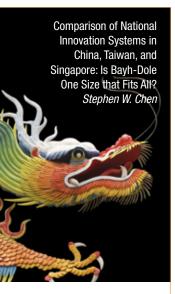
Despite these remarkable numbers, there has been criticism that BD has gone too far in actually erecting new barriers in university-industry research collaborations in the United States. As one commentator recently highlighted, "The broad discretion given to public funded research institutions to patent upstream research raises concern about patent thickets, where numerous patents on a product lead to bargaining breakdowns and can blunt incentives for downstream research and development."<sup>48</sup>

Despite these remarkable numbers, there has been criticism that BD has gone too far in actually erecting new barriers in university-industry research collaborations in the United States.

Furthermore, technology transfer practices in patenting and license negotiations may have "contributed to a change in academic norms regarding open, swift, and disinterested scientific exchange."<sup>49</sup> In short, impressive patent and licensing metrics may mask significant chilling effects on American research and industry relationships.

This criticism that BD may have led to undesirable consequences in creating new barriers provides basis for additional criticism that BD may not be workable in different countries. "[W]ithin the United States, the effects and desirability of the BD Act remain controversial...it is necessary to explore *under what conditions* the U.S. approach to UILs can serve as a useful framework for policy elsewhere."<sup>50</sup>

Among these important conditions necessary for fostering successful BD-style legislation, one commentator has noted that BD's "success" in the United States was highly dependent on the specific nature of actors in American NIS. "[I]t is



unclear whether any of the positive impacts of BD in the U.S. would arise in developing countries following similar legislation, absent the multiagency federal pluralism, the practically oriented universities, and other features of the U.S. research system..."<sup>51</sup>

Considering that there is at least reasonable disagreement about BD's positive impact, the discussion turns to an analysis of BD-style legislation in each country. Evaluating the prospects for success in any given country certainly cannot be conclusive, given that even thirty years of the American experience with BD is still under considerable debate. However, the prior analysis of NIS describing institutional actors in each country provides informative waypoints for evaluating how BD-style legislation could operate in different countries.

#### CHINA'S DE FACTO BAYH-DOLE REGIME

China's version of BD-style legislation was adopted only very recently in 2008, accompanied by a visit by former U.S. Senator Birch Bayh himself.<sup>52</sup> While the legislation enacted a framework for establishing intellectual property rights (IPRs) developed from publicly funded research, the potential role of BD legislation in China is perplexing, considering the expansive powers that Chinese UREs already possess in claiming ownership over public research assets.

If Stanford University researchers had significant control over the university's facilities, research results, and could even adopt the Stanford name for their own private companies, it is hard to imagine they would eagerly embrace a more challenging commercialization model requiring pursuit of private financing to practice entrepreneurial activities.

Unlike an American-style spin-off company where academics may use private capital funds to commercialize an invention, "UREs are usually endowed with the de facto right to exclusively take advantage of the mother institutions' various assets including research outcomes or resources, such as financial resources, physical spaces, manpower, social links, and even the title of the university as a commercial brand."<sup>53</sup> In short, in China "there has long been a de facto Bayh-Dole regime (even before the Chinese patent law was legislated in 1985)."

As provided in the earlier description of China's NIS, the most recent policy focus has been to move away from UREs, which are increasingly seen as merely importing and applying technology, rather than truly innovating. As an example of this delinking of research and industrial relationships, 6,634 UREs existed in 1997, dropping to 5,451 in 2000, and 4,563 in 2004. <sup>54</sup> Perhaps it is envisioned that redefining these relationships will be a new slate of American-style spin-off companies relying on newly adopted BD-style legislation to commercialize promising research technologies through private finance investment.

Nevertheless, it is easy to imagine that Chinese BD legislation is a severely limited tool in redefining the current Chinese R&D landscape. The mere presence of several thousand UREs across China argues strongly that they will remain a significant force in implementing Chinese R&D policy. Stakeholders in the current URE scheme are unlikely to easily relinquish their current roles in exchange for the potentially arduous and risky road of an American-style spin-off company.

If Stanford University researchers had significant control over the university's facilities, research results, and could even adopt the Stanford name for their own private companies, it is hard to imagine they would eagerly embrace a more challenging commercialization model requiring pursuit of private financing to practice entrepreneurial activities. Together, it appears China is embarking on a long campaign in altering the scope and relationship of research and commercialization activities, and BD is only one piece of this massive puzzle.

Comparison of National Innovation Systems in China, Taiwan, and Singapore: Is Bayh-Dole One Size that Fits All? Stephen W. Chen

#### TAIWAN ADOPTED BAYH-DOLE IN LOCKSTEP WITH IP MANPOWER TRAINING, EDUCATION, AND PROMOTION OF TECHNOLOGY ADOPTION

In 1999, Taiwan first adopted BD-style legislation in the "Basic Law on Science and Technology."55 Notably, a multipronged approach was adopted in facilitating and promoting technology transfer practices. First, the government spurred creation of technology transfer offices in universities and RIs by imposing stricter research funding criteria, while encouraging patenting and licensing of technology as an alternative funding resource.<sup>56</sup> Second, for Taiwan's many SMEs, the government fostered competence in "intellectual property management, including aspects, such as law, patent engineering, licensing, and negotiation."57 An example of early success is National Taiwan University's (NTU) growing collection of licensing and royalty fees. Beginning in 2001, NTU collected only about \$100,000 in fees, rising to nearly \$1 million by 2004.58

One evaluation of patenting rates has highlighted that Taiwan "has arguably been the East Asian country that has made the most progress in shifting from imitation to innovation."<sup>59</sup> A significant number of Taiwanese patents arise from Taiwan's leading research institute, ITRI, with more than 3,000 patents.<sup>60</sup>

Further analyzing ITRI's activities, an increasingly critical patent portfolio established learning opportunities for strategic IP management. Rather than simply nurturing a propensity for patenting, ITRI *assigned specific patents to multiple SMEs* to "develop a stronger position in patent negotiations and [they could] take the lead in developing new technologies and setting standards."<sup>61</sup> This hands-on experience in IP portfolio management is "now seen as a key contributor to the enhancement of the country's innovative capacity."<sup>62</sup>

Taken together, the Taiwanese experience with BD, while recent, indicates some good

predictors of future success. If anything is in common with the United States, it is a strong entrepreneurship capacity in the creation of SMEs.

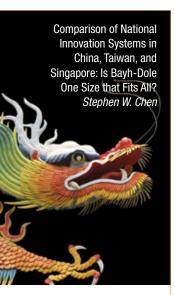
However, this is where any similarities end, as it appears that adoption of BD-style legislation was coupled with dedicated campaigns to further educate and train manpower in IPR management. At least some of this experience was gained through strategic portfolio management at leading RIs, such as ITRI, with precise efforts to strategically position patent portfolios through assignments to specific companies, thereby maximizing IPR benefits.

Thus, while BD-style legislation in Taiwan may prove to be significant in shaping that country's innovation capacity, it is notable that any successes may take on a markedly different path than the American experience.

#### SINGAPORE BAYH-DOLE-STYLE PRACTICE PROMULGATED THROUGH AGENCY RULES HAS LED TO MIXED RESULTS

Singapore promulgates BD-style practice through internal agency rules at leading public research institutes such as the National University of Singapore (NUS) and the Agency for Science, Technology, and Research. As an illustrative example, "Since the early 1990s, NUS has implemented an intellectual property (IP) policy whereby all IP created by NUS staff are assigned to NUS with INTRO [NUS' tech transfer office] tasked to license the IP and distribute any return from commercialization..."<sup>63</sup>

Despite these early pioneering efforts, technology transfer at leading institutions in Singapore, such at NUS, has seen mixed results. As an example, NUS collected \$116,000 in 2001, rising to only \$290,000 in 2003. "[T]he propensity for technological collaborations between universities and private industry was still relatively low and that universities were not highly regarded by industry as an important source of tech-



nology."<sup>64</sup> However, one encouraging result was that prior to 1999, only one issued U.S. patent was jointly owned between private industry and NUS. By 2001, more than 40 percent of patents were jointly owned.

Perhaps taking a cue from the Taiwanese experience, some recent initiatives in Singapore have focused on IP manpower training. Recognizing that "Singapore suffers greatly from a lack of expertise in various fields of IP and technology transfer," policy-makers established an IP educational academy in 2003 to provide professional training in IP management.<sup>65</sup>

Recognizing that Asian nations, including the discussed examples, have diverse development trajectories propelled by markedly different institutional actors is a good first step in crafting effective technology transfer legislation for developing nations.

Together, it appears too early to tell if Singapore's efforts in encouraging technology transfer through adoption of BD-style practices will lead to better and more consistent results in patenting and licensing. However, it appears that the country is at least being informed by the earlier experience in Taiwan, providing IP manpower training with educational programs to promote technology adoption.

#### COMPARISON OF BD-STYLE LEGISLATION SUGGESTS THERE IS NO ONE SIZE FITS ALL

Perhaps the only thing in common between BD legislation in these countries is that they are very recent. China enacted legislation within the past two years and is in the paradoxical position of using modern BD-style incentives to chisel away at an existing regime where public resources are already expansively exploited for commercial use. Taiwan and Singapore are more relevant examples for comparison with the American experience and even these two countries show remarkable differences.

Taiwan can claim some early successes

through rising royalty revenues and patenting rates. However, the illustrative example of ITRI's strategic IP portfolio is remarkable, given that a public research institute strategically assigned patents to private companies to maximize IPR benefits. This is akin to the National Institutes of Health handing off patents to Amgen and Genentech to ward off disfavored competitors or provide them with better leverage in negotiations for standard setting or litigation settlements.

In contrast, Singapore appears to be delivering mixed results, although as described, some initial results are encouraging. Rising numbers of jointly owned university and industry patents are a strong sign of increased collaboration. Unlike the earlier ITRI example, this appears to be a more earnest approach in building relationships (albeit a potentially more challenging one).

However, Singapore may merely be in the earlier stages of patenting, as ITRI only adopted increasingly sophisticated and aggressive IP techniques after amassing more than 3,000 patents, including key technologies to ward off competitors. Further contrasting Singapore is that BDstyle technology transfer is promulgated through agency rules. Again, this is akin to the NIH unilaterally deciding that its technologies can be commercialized under its direction.

Together, it is clear that stark differences existing between each country's NIS further extends into the specific example of UIL governing technology transfer practices. As one leading commentator has noted, "There is a widespread perception that U.S. leadership in industrial innovation owes much to the capacity of its higher education system to provide multiple and dense interlinkages between university research and innovation in enterprises... Unfortunately, very little scholarly research is available to guide policy debates in the Pacific Rim on this important issue...."<sup>66</sup>

Recognizing that Asian nations, includ-

**Comparison of National** Innovation Systems in China, Taiwan, and Singapore: Is Bayh-Dole One Size that Fits All? Stephen W. Chen ing the discussed examples, have diverse development trajectories propelled by markedly different institutional actors is a good first step in crafting effective technology transfer legislation for developing nations.



Stephen W. Chen is a juris doctorate candidate at the University of Washington School of Law. He is a registered patent agent and an incoming associate at Davis Wright Tremaine in its Los Angeles office.

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<sup>3</sup>Kun Chen and Martin Kenney, "Universities/Research Institutes and Regional Innovation Systems: The Cases of Beijing and Shenzen," World Develop*ment* 35 (2006): 1056–1074. <sup>4</sup>Chang and Shih, 532. <sup>5</sup>Chen and Kenney, 1059.

<sup>6</sup>Kazuyuki Motohashi and Xiao Yun, "China's Innova-Linkages," Research Policy 36 (2007): 1251–1260. <sup>7</sup>Chen and Kenney, 1059.

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<sup>56</sup>Ibid,1011.

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Setting up a Technology Transfer Office for a Life Sciences Research Institute in a European Economy: Opportunities and Challenges

Ana Margarida Prado, PhD, David Cristina, PhD, and Tania Bubela, PhD

#### **Abstract**

Research

This paper outlines the opportunities, concerns, and strategies for setting up a technology transfer office (TTO) in a developing European economy, Portugal, at a publicly funded life sciences research institute, the Instituto Gulbenkian de Ciência (IGC). Firstly, it discusses the lessons learned from the North American models of TTO formation and how to best accomplish the translation of science into valuable assets for the benefit of society. Next, is a brief overview of the history and current landscape of technology transfer in Portugal. Finally, the paper looks at the opportunities and challenges in setting up a TTO at the IGC and how the university expects to overcome them.

#### The Role of the Technology Transfer Office

The triple helix model of government, university, and industry relationships brings costs and benefits to all parties and society at large.<sup>1</sup> The benefits include: increased funding for university researchers than would otherwise be available from purely public sources, access to industry research resources, access to industry facilities for academic researchers and vice-versa, and an increased ability for university researchers to address applied research questions of importance to industry, often leveraging public money and resources to do so.

This latter, over the last twenty years, has become central to most science and technology policies related to funding and research agendas, namely that researchers demonstrate the practical application of their work, often for the benefit of industry that is taken as synonymous with societal benefits.<sup>2</sup> The rise of such applied research to address real-world problems has been called Mode 2 science as opposed to Mode 1 or basic science motivated by curiosity.<sup>3</sup>

The costs of the triple helix model and



Setting up a Technology Transfer Office for a Life Sciences Research Institute in a European Economy: Opportunities and Challenges Ana Margarida Prado, PhD, David Cristina, PhD, and Tania Bubela, PhD the shift to Mode 2 knowledge production have been the reduction in basic science, recognizing that many technological innovations are serendipitous consequences of curiosity-based research (e.g., the discovery of penicillin); a loss of long-term vision in research agendas because of the focus on shorter-term solutions to immediate problems; a loss of flexibility to respond to unknown future issues; and the potential, especially in the life sciences, for conflicts of interest that impact negatively on the safety of research subjects, research ethics, and public confidence or trust in scientific and technological innovation.<sup>4</sup>

The dominant institution that has risen to prominence to manage the triple helix of funding and research relationships is the university or institutional technology transfer office (TTO), also known as a university-industry liaison office.<sup>5</sup> TTOs facilitate the mobilization of universitybased research into practical and societal

The AUTM metrics and their equivalents have been criticized as being overly focused on input/ output measures such as number of disclosures of inventions from researchers in an institution to the TTO, number of patents filed, number of patents granted, license revenue generated for the institution, and number of spin-off companies created (regardless of profitability and longevity).<sup>11</sup> Unfortunately, such metrics have come to dominate science policy at a broader level, since these are easily synthesized and understood by institutional and governmental policy-makers, even if they inadequately capture the broader societal benefits of publicly funded research institutions.

application, an undoubtedly important role. The TTO is especially important in the life sciences given the close relationship between research centers and the biotechnology industry. Indeed, many biotechnology companies were spawned by research institutions as university spin-off companies, and many prominent biotechnology clusters are centered around universities, such as Boston University, Stanford University, and Duke University.

The history of the TTO and the rise of the modern biotechnology industry are closely linked and often associated with the passage in the United States of the Bayh-Dole Act in 1980 that enabled universities to hold intellectual property rights in publicly funded research products and processes.<sup>6</sup> The Stevenson-Wydler Act was the equivalent for government departments.7 These acts were closely followed by a United States Supreme Court ruling that a genetically modified bacterium constitutes patentable subject matter. This decision in Diamond v. Chakrabarty was a landmark that opened the door for patents on the products of biotechnology such as gene sequences and life forms.8

Now, most research universities in the United States have a TTO or its equivalent, and these have formed a close network through organizations such as the U.S.based Association of University Technology Managers (AUTM).9 In its most recent survey on the state of technology transfer in the United States, well over a hundred universities plus colleges reported statistics to AUTM.<sup>10</sup> AUTM provides reported data to its members and compiles aggregate reports for public dissemination. Most countries in the industrialized world have since followed the U.S. model of enabling publicly funded research institutions, researchers, or some combination of the two to hold intellectual property rights in the products and processes of publicly funded research.

For example, the AUTM survey, since 2003, has included a Canadian supplement reporting on the activities of Canadian TTOs. The annual ATUM survey has, by default, become the dominant survey of technology commercialization from public research institutions, although other metrics are collected by national statistics agencies and the Organization for Economic Co-operation and Development. The AUTM metrics and their equiva-



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lents have been criticized as being overly focused on input/output measures such as number of disclosures of inventions from researchers in an institution to the TTO, number of patents filed, number of patents granted, license revenue generated for the institution, and number of spin-off companies created (regardless of profitability and longevity).<sup>11</sup> Unfortunately, such metrics have come to dominate science policy at a broader level, since these are easily synthesized and understood by institutional and governmental policymakers, even if they inadequately capture the broader societal benefits of publicly funded research institutions.

The other issue that is well-demonstrated by the AUTM metrics is the minimal return on investment for most research institutions from the activities of their TTOs, especially in smaller centers or less economically developed regions. The overwhelming success of some TTOs in generating licensing revenue is often masked by one lucky or big hit, e.g., Gatorade first developed by researchers at the University of Florida.

Within two years both universities had summed more than \$2 million in revenues.<sup>12</sup> It is naïve, therefore, to believe that the primary role of a TTO is to generate revenue for its host institution, or, in many instances, that a TTO can even generate enough revenue to be financially selfsustaining.

Another example of far-reaching success was the University of Stanford and University of California, Cohen-Boyer patent that set the starting line for genetic engineering and the advent of recombinant DNA. Within two years both universities had summed more than \$2 million in revenues.<sup>12</sup> It is naïve, therefore, to believe that the primary role of a TTO is to generate revenue for its host institution, or, in many instances, that a TTO can even generate enough revenue to be financially self-sustaining. In general, the relatively unpredictable and iterative progress from research to innovation to application is slow and longer than expected by policy-makers and especially politicians.

Our starting premise, therefore, is that, while we acknowledge the importance of technology transfer, the primary role of the TTO should be to facilitate the relationships between industry and other societal institutions and publicly funded research institutions and mobilize publicly funded research for the benefits of society, which includes but is broader than industry interests. The success and failure of TTOs should be judged on that basis, and not on a narrow sampling of primarily economic/ numeric indicators. In addition, many of the benefits derived from publicly funded research, including technology transfer, generally become apparent in the longerterm and not in the politically expedient near term. In general, the relatively unpredictable and iterative progress from research to innovation to application is slow and longer than expected by policymakers and especially politicians.

#### **Technology Transfer in Portugal**

Portugal has in the past few years made significant progress in technological development and know-how. In 2008 the country has moved, in Europe, from the group of "catching-up countries" to the "moderate innovators" group.<sup>13</sup> Portugal's exports have been steadily moving from lower technology products to mediumand high-technology goods.<sup>14</sup> Moreover, in 2008 corporate research and development (R&D) expenditures (0.61 percent

The growth in business sector expenses for R&D indicates the endeavor from the private sector in pursuing the scientific development and the technology capacity of Portugal. Currently, Portugal offers a competitive system of fiscal incentives for R&D in Europe, facilitating tax deductions of up to 82.5 percent of the investment in R&D.<sup>xv</sup>



Setting up a Technology Transfer Office for a Life Sciences Research Institute in a European Economy: Opportunities and Challenges Ana Margarida Prado, PhD, David Cristina, PhD, and Tania Bubela, PhD GDP) exceeded state R&D expenditures (0.57 percent GDP) for the first time.<sup>15</sup> The growth in business sector expenses for R&D indicates the endeavor from the private sector in pursuing the scientific development and the technology capacity of Portugal. Currently, Portugal offers a competitive system of fiscal incentives for R&D in Europe, facilitating tax deductions of up to 82.5 percent of the investment in R&D.<sup>15</sup>

This significant progress is driven by several initiatives that have tackled the country's shortcomings with regard to technological development.

One important area where these initiatives have been active is knowledge transfer between industry and the academic sector. As in most developed countries, science and technology policy in Portugal has moved toward facilitating exchanges between government, publicly funded research institutions, and industry, including the enhancement and modernization of intellectual property rights and of the national intellectual property system.

Historically, one of the engines behind Portugal's recent progress in technology transfer has been the National Institute for Industrial Property (INPI, Instituto Nacional da Propriedade Industrial). INPI is the national institution responsible for management, policy, and education on intellectual property. Since 1999, INPI has been actively implementing an original initiative aimed at establishing a network between itself, entrepreneurs, patent agents, and other stakeholders within the innovation system. INPI has focused on developing strategic partnerships with business associations, universities, technological centers, and incubators.

The tangible outcome of this initiative was the establishment of offices to support intellectual property rights known as GAPI (Gabinetes de Apoio a Propriedade Industrial). From 2001 to 2002, fifteen GAPI units were established serving diverse organizations and institutions such as business associations and universities.<sup>16</sup> Five more GAPIs were established between 2003-2005. It is important to understand that, prior to this initiative, most institutions in Portugal did not have any intellectual property (IP) management or knowledge transfer departments, so these GAPIs were an important springboard for Portuguese technology transfer. The GAPIs became the precursors to many of the

As a major upside, this initiative successfully brought together two formally disassociated communities in Portugal: intellectual property lawyers and managers and the research and development community. However, on the downside, many of the problems in Portuguese technology transfer can be traced to how the GAPI initiative was initially implemented.

TTOs currently active in Portugal.

GAPI funding came from both European programs and INPI. Besides providing professional and logistic support for each GAPI, these funds also promoted capacity building in the best practices for management of intellectual property rights and technology transfer as well as global networking through the participation of GAPI professionals in international workshops.

As a major upside, this initiative successfully brought together two formally disassociated communities in Portugal: intellectual property lawyers and managers and the research and development community. However, on the downside, many of the problems in Portuguese technology transfer can be traced to how the GAPI initiative was initially implemented. The GAPI units were autonomous from INPI and their organization and institutional policies were defined by their host institution, meaning there was no standardized format or guidelines for these offices.

As a consequence, Portugal, a very small country, now has 20 TTOs employing approximately 55 people. These TTOs have completely different models of operation and compete with each other. Clearly, for



Setting up a Technology Transfer Office for a Life Sciences Research Institute in a European Economy: Opportunities and Challenges Ana Margarida Prado, PhD, David Cristina, PhD, and Tania Bubela, PhD a country with limited resources, it would be highly beneficial to avoid organizational redundancies across different TTOs and centralize technology transfer, thus reducing institutional costs. However, due to the GAPI legacy of highly fragmented TTOs with very different operational models, a centralized TTO is extremely difficult to implement.

Some of these problems are currently being tackled by UTEN (University Technology Enterprise Network), a joint five-year effort between the University of Texas and Portugal that started in 2007. UTEN has, so far, managed to identify technologybased business opportunities, offer training to technology transfer officers, and create a fluid network between all Portuguese TTOs. Therefore, although the idea of a centralized TTO for Portugal may still be distant, there has been significant progress in aligning most Portuguese TTOs goals and practices.

So far we have focused on government and universities, however, in Portugal, industry also poses some interesting challenges. Since R&D has thus far played a small role in Portuguese industry, it is not surprising that the private sector has a certain lack of interest in engaging in interactions with academic institutions.

This, in turn, makes the TTO's job more challenging in that it has to educate both researchers and industry partners about the value of technology transfer. Furthermore, this lack of sophistication in the private sector can make attracting venture capital for startups very difficult since high-technology companies are viewed as risky endeavors by investors. Nevertheless, funding for high-technology startups is becoming more available, namely through private/public funds/programs.

If we take all these factors together, then we can safely say that, although much progress has been made in Portugal, there is still significant room for improvement.

# The Challenges and Opportunities in Setting up a TTO in Portugal

Keeping in mind the initial discussion on the role of a technology transfer office in a publicly funded life sciences research institution and the Portuguese policy goal of facilitating technology transfer for the benefit of Portuguese industry and broader society, we now discuss the specific case of establishing a technology transfer office at the Instituto Gulbenkian de Ciência (IGC). The policies and practices of such a TTO should, ideally, align with the mission of the IGC.<sup>17</sup> The mission of the IGC includes promoting science and serving the Portuguese research community, pursuing modern biomedical research in both content and technological basis, as well as producing internationally competitive science.<sup>18</sup> It has strong postgraduate education programs and is a leading life sciences research institute in Portugal. It is a highly academic institute with a history of scientific excellence.

Hence, due to its mother institution, the IGC carries a very strong social mission. This has led to an internal culture of Mode 1 research and of little interest in generating revenues through IP monetization. However, recently the IGC has started to show interest in high social-impact technology transfer initiatives as it is becoming clear that technologies that do not leave the lab have smaller social contributions.

This mission is based on the broader mission of Fundação Calouste Gulbenkian (FCG), a private foundation, which established and supports the IGC. The FCG has a very clear mission of improving Portuguese and global society. Consistent with this, it is involved in and fosters co-operative projects based on the United Nations millennium goals<sup>19</sup> (end of poverty, universal education, gender equality, child health, maternal health, combat HIV/AIDS, environmental sustainability, global partnerships) with Portuguese-speaking African countries and East Timor.

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Setting up a Technology Transfer Office for a Life Sciences Research Institute in a European Economy: Opportunities and Challenges Ana Margarida Prado, PhD, David Cristina, PhD, and Tania Bubela, PhD IGC carries a very strong social mission. This has led to an internal culture of Mode 1 research and of little interest in generating revenues through IP monetization. However, recently the IGC has started to show interest in high social-impact technology transfer initiatives as it is becoming clear that technologies that do not leave the lab have smaller social contributions.

So, for a TTO to be aligned with the IGC's goals it needs to take into account the institute's concern with excellence in scientific research and the social mission of the institute.

What kind of TTO, then, can be developed that incorporates both these elements? The policies will need to be carefully crafted to encourage high-quality applied scientific innovation in the life sciences. Thus, part of the mission of a TTO must address the possibility of facilitating or directly generating, through licensing revenues, additional resources for research.

Having a TTO within a research institution serves an important educational function for research faculty and students by (1) providing training on identification of research with translational potential; (2) providing training on IP protection, entrepreneurship, and business development; and (3) allowing access to networks that include entrepreneurs, investors, and industry. These initiatives, in turn, stimulate scientific innovation within the institute, by increasing the perceived impact of research findings.

However, such a traditional role for a TTO should not be the only goal, especially within an institution with a strong public-good mission. Any new policy must also recognize that technology transfer to industry via intellectual property rights and licensing is only one of the mechanisms to mobilize institutional research for the public good. A number of TTOs at institutions such as University of California, Berkeley, and the University of British Columbia have established global access policies to facilitate, for example, the transfer of technology to developing countries. In these circumstances, revenue generation should not be the primary concern, but rather take second place to the dissemination of useful products and processes. In this sense, it is very important for the TTO to value the overall social impact of a certain project over its immediate returns for the institute.

The final issue is the pragmatic one of implementation. The answer to this question is intimately related to the size of the institution, in other words, to its critical mass and power to engage the discovery and dissemination of new technologies. The constraints imposed result from the costs of seeking patent protection and the ongoing issue of generating successful commercial outcomes. Thus, the management of limited resources must be a priority.

One means for a TTO at a smaller institution such as the IGC to bypass the resource issue is to establish a collaboration with an already fully functional TTO from another organization. In such an event, creativity in partnering will be important so that it can answer the expectations of both parties. This type of engagement makes sense if both parties are willing to start a long-term relationship since the outcomes of technology transfer have a lag time of several years from disclosure to being available to society.

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To start a collaboration of this sort, a careful choice of collaborator will be essential. It is important to consider whether the mission of a candidate TTO organization aligns with goals of the FCG/IGC. The desired scenario would be to find a partner such that the IGC would engage in work collaboration as if it were an additional



Setting up a Technology Transfer Office for a Life Sciences Research Institute in a European Economy: Opportunities and Challenges Ana Margarida Prado, PhD, David Cristina, PhD, and Tania Bubela, PhD department of that organization. To align with the FCG/IGC's public interest mandate, as much as possible, this partner TTO should favor technology transfer by encouraging nonexclusive licenses and dissemination of innovation in general and, in particular, to developing countries at a lower cost. Willingness to adopt innovative models of IP management, such as supporting initiatives for patent pooling, are also considerations in selecting a partner TTO.

Other important factors to consider are accountability and transparency of the TTO in reporting on and justifying its activities to key stakeholders, including the public. So far, however, finding an appropriate partner has proven difficult, since most large international TTOs are reluctant to make such an effort for an institute with a small output in IP.

An alternative to partnering with a larger, established TTO is to change the focus of the technology transfer away from more traditional models used in larger institutions. Traditional TTOs tend to manage large IP portfolios and generate revenues through licensing agreements. Since the IGC has limited resources for securing and marketing a large volume of patents, an attractive option is to only secure IP for a few select projects that fit well with the institute's mission. These projects would have to be entrepreneur-driven to minimize the load on the IGC's resources and would need to have the potential for high social impact to fit with the institute's social mission. In summary, spin-offs that may be for profit or nonprofit driven by researcher/entrepreneurs or by external entrepreneurs. The role of the TTO, in this case, would be to work as an in-house entrepreneur while offering support, training, and networking opportunities to the researchers.

So far, we have found that the researchers are very open to working in this type of framework, and we are currently developing, as our flagship project, a nonprofit consortium developing a therapy for late-stage malaria. We believe this model of an entrepreneurship-driven TTO, in supporting entrepreneurial initiatives with a strong focus in social impact, addresses a need that is present in institutes other than the IGC, and we have initiated talks with another institute in Portugal to offer our services.

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In conclusion, there are many challenges in setting up a TTO in a developing European country, including resource and cultural challenges. However, there is also the tremendous opportunity to build an institution from the ground up, learn from the experience of other organizations, and truly align the mission of the TTO with the social and scientific goals of its host institution and country.

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Margarida Prado, PhD, is a postdoctorate fellow at the Instituto Gulbenkian de Ciência in Portugal where she teams setting and managing a technology transfer platform for the institute.



David Cristina, PhD, is a researcher turned biotech entrepreneur currently managing technology transfer at the Instituto Gulbenkian de Ciência in Portugal. He is also currently promoting a biotech startup company in Portugal, raising funds for proofof-concept research.



Tania Bubela, PhD, is an assistant professor in the Department of Public Health Sciences at the School of Public Health and is an adjunct professor in the School of Business at the University of Alberta in Edmonton, Alberta, Canada.

#### Notes

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# Research Discoveries after *Kubin*

Nancy W. Vensko, JD Steven M. Ferguson, MBA, CLP

#### Abstract

This paper will discuss commercializing discoveries made at research organizations, particularly with a view to the *In re Kubin* case, decided April 3, 2009, by the Federal Circuit. Here, the existence of a general method of isolating DNA molecules was held to be relevant to the question whether the DNA molecules themselves would have been obvious under § 103 of the patent act. How are DNA inventions patented anyway? What does it take for academic research to reach patients? How might the decision of *In re Kubin* effect research commercialization and technology transfer?

#### Introduction

*In re Kubin*, decided by the U.S. Court of Appeals for the Federal Circuit on April 3, 2009, substitutes the old rule on awarding patents for DNA research with a new one.<sup>1</sup> Specifically, the existence of a general

method of isolating DNA molecules is now relevant to the question of whether the DNA molecules themselves would have been obvious under 35 U.S.C. § 103. With the commercialization of biomedical discoveries made at academic or basic research centers being highly dependent upon patents to protect the substantial investment of risk capital for product development, will this new rule adversely affect those technologies based upon DNA —technologies at the forefront of today's molecular medicine?

#### **Patent Primer for DNA Inventions**

One of the judges of the three-judge panel that decided *Kubin* sensibly requested the advocates during oral argument to state their positions in a way that he could understand because he humbly admitted that he lacked a scientific background. Introductions on patent law, technology



transfer, and biological science are provided to assist those, who, like the judge, lack a certain background. These tutorials are helpful as a basis for understanding the full impact of *Kubin*.

Let us begin with a patent primer and first examine some basics that apply to all inventions coming from many biomedical research programs. To start: A patent protects an invention or discovery by giving its owner the right to exclude others from its use. Generally, the term of a new patent is 20 years from the date on which the application for the patent was filed in the United States. The Constitution of the United States sets forth the reasons for patenting in Article I, Section 8, by giving Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

Under this power Congress enacted the first patent law in 1790, with the most recent patent law being reenacted in 1952. The patent laws are now codified in Title 35 of the United States Code. The operative words from the Constitution, of course, are *limited* and *right* or temporary monopoly. The Constitution authorizes these awards of a temporary monopoly to inventors for their discoveries to promote the progress of the useful arts, of which the development of new drugs and medicines is certainly one.

DiMasi et al. estimated the average cost of new drug development, including unsuccessful products and financial opportunity costs.<sup>2</sup> This publication determined that the average research and development (R&D) cost per new drug, from concept to Food and Drug Administration (FDA) approval, is 802 million in year 2000 dollars.

Take, for example, the case of thyroidstimulating hormone (TSH).<sup>3</sup> Many valuable proteins occur in nature only in minute quantities or are difficult to purify from natural sources. The availability of substantially pure TSH now makes the diagnosis and treatment of human thyroid cancer a reality. Previously, the only available method to diagnose and treat human thyroid cancer involved administering TSH to stimulate the uptake of radioactive iodine into the cancer. Such stimulation was used as a diagnostic test to localize the tumor by scanning and was subsequently used to treat the cancer by giving large doses of radioactive iodine to kill the cancer. All of the diagnostic tests and therapies depended upon high levels of human TSH.

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However, there was not enough natural product available from human pituitaries collected at autopsies. Furthermore, even if available, the human pituitaries had been found to be contaminated with viruses. As a result, the regulatory authorities had forbidden the use of the natural product for any human diagnostic or therapeutic studies.

The diagnosis and treatment of thyroid cancer now involves cloning the gene for TSH and using it to make *recombinant* TSH. Recombinant TSH means making TSH by cloning the gene. TSH is now available in large quantities and is uncontaminated with viruses or other byproducts of collecting human pituitaries from autopsies. The recombinant TSH is used to achieve maximal uptake of radioactive iodine into the tumor for both diagnosis and treatment.

Although the exact cost of bringing this specific treatment from concept all the way to FDA approval has not been disclosed, a figure anywhere near the DiMasi et al. estimated average would represent a significant investment and substantial



risk of capital. By virtue of the temporary monopoly, patents let companies at least recoup the high cost of R&D, thus giving companies an incentive to invest in new drugs and laboratory tests.

What in the way of DNA-related inventions can be patented? You cannot patent an idea, but rather a practical application of that idea. In the language of the statute, anyone who "invents or discovers" a "process, machine, manufacture, or composition of matter" or "improvement thereof" may obtain a patent. These statutory classes of subject matter taken together include, in the words of the legislative history of the 1952 Patent Act, "anything under the sun that is made by man," plus processes for making the products. Accordingly, subject matter of DNA inventions would typically be eligible for patent protection if it is made by man, i.e., if it is manmade, as opposed to being simply a product of nature.

Products of nature cannot be patented because they are not "made by man." Nevertheless, we can patent natural substances, provided that they are "isolated and purified," because they do not occur in that form in nature. U.S. Patent No. 4,703,008, a representative patent, is directed to a purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin (EPO).

EPO is a drug that increases red blood cells. It is prescribed to patients with cancer undergoing chemotherapy, because the chemotherapy tends to cause the red blood cells of the patients to decrease thus making the patients who are already suffering from cancer anemic and weak. The EPO restores the red blood cells to normal.

The United States Patent and Trademark Office (USPTO) takes the position that an isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because that DNA molecule does not occur in that purified or isolated form in nature.<sup>4</sup> EPO is one such gene. Accordingly, you cannot patent a gene per se that is present in a human body, only an "isolated and purified" gene in a test tube.

The steps for obtaining a patent for a DNA invention require describing the invention in a patent application, including teaching how to make and use the invention (formal requirements). But to meet the substantive conditions for patentability, an invention must also be novel and nonobvious. Novelty means the invention must be new (i.e., original), as well as not being precluded from patenting by what is defined in the patent law as a "statutory bar." For example, an invention cannot be patented if the invention is publicly disclosed (such as by publication of a manuscript) or commercialized (such as by offer for sale). The U.S. provides a grace period of one year before such statutory bars come into play.

Even if the subject matter sought to be patented is novel and involves one or more differences from the prior art, a patent may still be refused if the differences would be obvious. In other words, the subject matter sought to be patented must be sufficiently different from what has come before to a person having ordinary skill in the art to be nonobvious. For example, in the original obviousness case decided by the Supreme Court of the United States in 1850, the substitution of porcelain for wood to make a doorknob was deemed to be unpatentable.5 The prior art was a wood doorknob. Even though the porcelain doorknob invention was novel in view of this prior art doorknob, it was nevertheless unpatentable because it would have been obvious to substitute porcelain for wood in a doorknob.

#### Patenting and Licensing DNA Inventions from Basic Research Programs

In general terms, DNA inventions (perhaps more appropriately termed as genomic inventions) arising from basic research



programs can be thought to include a wide variety of technologies and materials: cDNAs, expressed sequence tags (ESTs), haplotypes, antisense molecules, small interfering RNAs (siRNAs), full-length genes, etc.<sup>6</sup> The commercial use of these sequences can involve nucleic acid-based diagnostics, potential gene therapy applications, the development of new DNA and RNA, as well as the expression products themselves—the basis for the founding of the biotechnology industry.

Patenting and technology commercialization programs (such as licensing) at basic research organizations provide a means for getting new DNA inventions to the market for public use and benefit. With this public and commercial use of DNA inventions often comes new recognition of the value of basic research programs to the university or other organization that originated it. These inventions also serve as a helpful means to attract new R&D resources and partnerships to the laboratory. Through licensing or other technology transfer means, there is thus a return on investment whether that is measured in terms of financial, educational, or societal parameters or some combination thereof. Finally, there is an economic development aspect to the commercialization of DNA inventions via new job and company formation for the sale and delivery of innovative products.

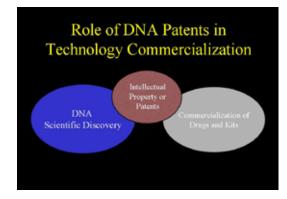
A substantial portion of the DNA inventions occurring at basic research programs arises from research that is federally funded. The Bayh-Dole Act of 1980<sup>7</sup> allows such grantees and contractors to retain ownership in subject inventions made using federal funds, seek patent protection on these inventions, and license these inventions with the goal of promoting their utilization, commercialization, and public availability. In 1986, Federal laboratories were given a statutory mandate under the Federal Technology Transfer Act<sup>8</sup> and Executive Order 12591 to ensure that new technologies developed in federal laboratories were transferred to the private sector and commercialized.

Commercialization of DNA inventions from nonprofit basic research institutions typically follows a multistep process as academic and federal laboratories typically do not provide, nor have the means to provide, commercialization of the technology themselves. A contractual agreement (typically a license) is created to give permission to use DNA patents, materials, or assets to bring a product concept to market. Financial consideration or other benefits are received by the research institution in exchange through what is often an agreement with a small company that will bring in a large corporate partner later in development.

#### Patent and Licensing Practices for DNA Inventions

Thus for research institutions, commercial applications or reasonable expectations of commercial applications are the key driver in determining how to effectively handle patenting and licensing of DNA inventions. However, explicit commercial applications are not always clear at the early development stages for such inventions. At the early stages of this process, patent protection for DNA inventions is generally sought when significant further R&D by the private sector is required to bring the invention to market, such as in the examples of TSH and EPO previously described and shown in a general nature in Figure 1.

Figure 1: Role of DNA Patents in Technology Commercialization





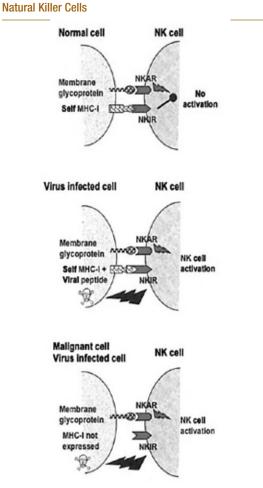
In contrast, when significant research and development are not required for DNA inventions, patent protection is likely not needed—such as is often the case for research materials and research tool applications. For example, for a DNA invention where publication alone is sufficient for dissemination and commercialization, patent protection may be an unnecessary expense and not valued by licensees. When patent protection is obtained, it is possible for basic research institutions to discern those applications that absolutely require exclusive licensing to attract investment and risk capital from those that may not.

# The Invention: DNA Encoding the Protein NAIL

Given the importance of patents and licensing to achieve commercialization of DNA inventions, what is the impact of *Kubin* on basic research institutions? The invention claimed in the 1999 patent application, naming Kubin and Goodwin as inventors, was related to DNA encoding the protein NAIL (*n*atural killer-cell *a*ctivation *i*nducing *l*igand). NAIL is useful for regulation of the immune response. Figure 2 illustrates the protein sequence (discussed below) of NAIL.<sup>9</sup> The sequence for NAIL goes from

1 to 365 and reads as depicted in Figure 2. Turning to biology, Figure 3 illustrates the mechanism of target cell recognition by natural killer (NK) cells. <sup>10</sup> The activation or lack of activation of cell-killing pathways depends upon the balance between activating receptors (NKAR, which interacts with cellular glycoproteins) and inhibitory receptors (NKIR, which interacts with self-major histocompatibility complex MHC-1 molecules). If the inhibitory receptor is not triggered (due to either lack of interaction of the inhibitory receptor with MHC-1 self molecules or lack of expression of MHC-1 molecules on the cell membrane), stimulatory activity prevails and the target cell is killed.

Figure 3: Mechanism of Target Cell Recognition by



Adapted/reproduced from Virginia M. Litwin (2007). Originally published in *Medical Immunology*: Refer to Note 10.

#### Figure 2: The Kubin Invention: DNA Encoding the Protein NAIL

1	MLGQVVTLIL	LLLLKVYQGK	GCQGSADHVV	SISGVPLQLQ	PNSIQTKVDS
51	IAWKKLLPSQ	NGFHHILKWE	NGSLPSNTSN	DRFSFIVKNL	SLLIKAAQQQ
101	DSGLYCLEVT	SISGKVQTAT	FQVFVFDKVE	KPRLQGQGKI	LDRGRCQVAL
151	SCLVSRDGNV	SYAWYRGSKL	IQTAGNLTYL	DEEVDINGTH	TYTCNVSNPV
201	SWESHTLNLT	QDCQNAHQEF	RFWPFLVIIV	ILSALFLGTL	ACFCVWRRKR
251	KEKQSETSPK	EFLTIYEDVK	DLKTRRNHEQ	EQTFPGGGST	IYSMIQSQSS
301	APTSQEPAYT	LYSLIQPSRK	SGSRKRNHSP	SFNSTIYEVI	GKSQPKAQNP
351	ARLSRKELEN	FDVYS (SEC	Q ID NO:2)		



The first panel of Figure 3 illustrates no activation. Here, in the normal cell, the inhibitory receptor is triggered (due to both interaction of the NKIR inhibitory receptor with self MHC-1 molecules and expression of MHC-1 molecules on the cell membrane), thus the cell-killing pathway is not activated.

The second panel of Figure 3 illustrates NK cell activation by a virus-infected cell. Here, in the virus-infected cell, the inhibitory receptor is not triggered (due to lack of interaction of the NKIR inhibitory receptor with self MHC-1 molecules), thus stimulatory activity prevails and the target cell is killed, depicted by the skull and crossbones symbol.

The third panel of Figure 3 illustrates NK cell activation by a malignant cell. Here, in the malignant cell, the inhibitory receptor is not triggered (due to lack of expression of MHC-1 molecules on the cell mem-

brane), thus stimulatory activity prevails and the target cell is killed, depicted, again, by the skull and crossbones symbol.

Putting it all together, the *Kubin* invention is related to a NKAR activating receptor, called NAIL, which interacts with a membrane glycoprotein, called CD48.

Concluding with the science of DNA, Figure 4 illustrates the central dogma of molecular biology. <sup>11</sup> According to the dogma, and as depicted in the living cell illustrated in Figure 4, DNA is made into RNA, and RNA is made into protein. DNA is short for deoxyribonucleic acid, RNA is short for ribonucleic acid, and protein, of course, is the basic building block of all living cells. The terms *gene* and *DNA* are used interchangeably, because a gene is a piece of DNA. Accordingly, one gene makes one protein. Referring to the amino acid chain in Figure 4, a protein, by definition, is a chain of amino acids.



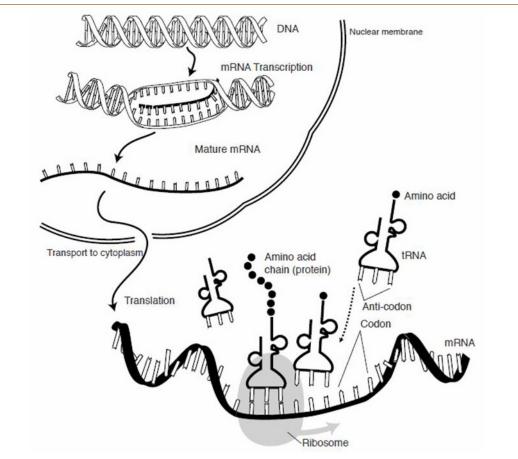




Table 1: The 20 Amino Acids and Their Three-Letter andOne-Letter Abbreviations

Aspartic acid	Asp	D
Glutamic acid	Glu	E
Arginine	Arg	R
Lysine	Lys	К
Histidine	His	Н
Asparagine	Asn	N
Glutamine	GIn	Q
Serine	Ser	S
Threonine	Thr	Т
Tyrosine	Tyr	Y
Alanine	Ala	A
Glycine	Gly	G
Valine	Val	V
Leucine	Leu	L
Isoleucine	lle	1
Proline	Pro	Р
Phenylalanine	Phe	F
Methionine	Met	М
Tryptophan	Trp	W
Cysteine	Cys	С

There are a total of 20 separate naturally occurring amino acids. Table 1 lists the amino acids and provides their three-letter and one-letter abbreviations. Each type of protein has a unique sequence of amino acids, and there are thousands of different proteins, each with its own particular amino acid sequence.

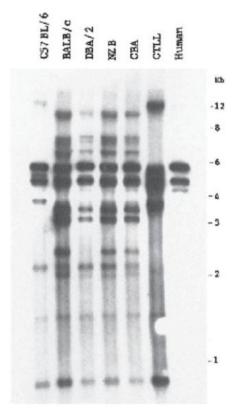
Returning now to Figure 2, it illustrates the amino acid sequence of NAIL. The sequence is 365 amino acids long. The first amino acid in this sequence reads M, which stands for methionine, with the three-letter abbreviation being Met and the one letter abbreviation being M. Next in the sequence comes L, which stands for leucine, with the three-letter abbreviation being Leu, and the one-letter abbreviation being L. Then comes G in the sequence, which stands for glycine, with the threeletter abbreviation being Gly, and the one-letter abbreviation being G. Using these first three amino acids as illustrations, you can now understand the order, or sequence, of amino acids in NAIL.

#### The Prior Art: Maniatis Laboratory Manual and a Protein Band on a Gel

The first of three pieces of prior art in the *Kubin* case was *Molecular Cloning: A Laboratory Manual* by Sambrook, Fritsch, and Maniatis (2d ed. 1989).<sup>12</sup> This is the Maniatis laboratory manual, so-called for the last named author. It is considered by many to be a cookbook for cloning genes.

The second piece of prior art was Mathew et al., *J. Immunol.* 151 (1993): 5328–5337 (Mathew article), as illustrated by the representative drawing reproduced in Figure 5.<sup>13</sup> The prior discovery in the Mathew article was related to a NKAR activating receptor in the mouse, called 2B4. The mouse 2B4 gene was cloned and sequenced. The genomic DNA blot analysis shown in Figure 5 identified a human homologue, or counterpart, of the mouse 2B4 gene (lane "human").<sup>14</sup> The human homologue turned out to be NAIL.

Figure 5: The Kubin Prior Art: Mathew article (1993)

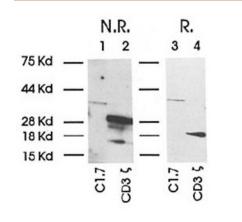


© 1993 The American Association of Immunologists Inc. Originally published in *The Journal of Immunology*. Refer to Note 13.



The third piece of prior art was U.S. Patent No. 5,688,690, to Valiante and Trinchieri (Valiante patent), as illustrated by the representative drawing reproduced in Figure 6, although the drawing actually appeared in the authors' publication (published within the one-year grace period) and was merely described in the Valiante patent.<sup>15</sup> This other prior discovery in the Valiante patent was related to a NKAR activating receptor in the human, called P38.

Figure 6: The *Kubin* Prior Art: Valiante and Trinchieri paper (1993)



© Valiante and Trinchieri, 1993. Originally published in *The Journal of Experimental Medicine*. Refer to Note 15.

The immunoblot analysis shown in Figure 6 of human NK cells probed with a monoclonal antibody (mAb C1.7), which was generated against human NK cells and mediated cell killing, identified a NKAR having a molecular weight of 38 kD (lanes 1 and 3).<sup>16</sup> It is true that the NKAR protein was separated from nature as a band on a gel. The NKAR protein weighing 38 kD, called P38, turned out to be NAIL. But the NAIL gene was never cloned or sequenced. To repeat, and in contrast, the *Kubin* invention is related to the cloning and sequencing of the gene for NAIL.

#### Binding Legal Precedent for DNA Inventions: *In re Deuel*

To determine whether the invention is patentable over the prior art, a court needs to conduct a factual and legal analysis. Additionally, under the theory of consistency in the law, known as *stare decisis*, the court must also follow binding legal precedent. In other words, a case must be decided the same way when the legally relevant facts are the same or substantially similar. Here, the binding legal precedent was *In re Deuel*, decided previously by the Federal Circuit in 1995.<sup>17</sup>

#### Figure 7: The Deuel Invention: DNA Encoding the Protein HBGF

Met Gln Ala Gln Gln Tyr Gln Gln Gln Arg Arg Lys Phe Ala Ala 15 Ala Phe Leu Ala Phe Ile Phe Ile Leu Ala Ala Val Asp Thr Ala 30 Glu Ala Gly Lys Lys Glu Lys Pro Glu Lys Lys Val Lys Lys Ser 45 Asp Cys Gly Glu Trp Gln Trp Ser Val Cys Val Pro Thr Ser Gly 60 75 Asp Cys Gly Leu Gly Thr Arg Glu Gly Thr Arg Thr Gly Ala Glu Cys Lys Gln Thr Met Lys Thr Gln Arg Cys Lys Ile Pro Cys Asn 90 Trp Lys Lys Gln Phe Gly Ala Glu Cys Lys Tyr Gln Phe Gln Ala 105 Trp Gly Glu Cys Asp Leu Asn Thr Ala Leu Lys Thr Arg Thr Gly 120 Ser Leu Lys Arg Ala Leu His Asn Ala Glu Cys Gln Lys Thr Val 135 Thr Ile Ser Lys Pro Cys Gly Lys Leu Thr Lys Pro Lys Pro Gln 150 Ala Glu Ser Lys Lys Lys Lys Glu Gly Lys Lys Gln Glu Lys 165 Met Leu Asp 168



In *In re Deuel*, the invention was related to DNA encoding the protein HBGF (heparin binding growth factor). HBGF is useful for stimulating cell division and, thus, wound healing. Figure 7 illustrates the amino acid sequence of HBGF.<sup>18</sup> The sequence for HBGF goes from 1 to 168 and reads as depicted in Figure 7.

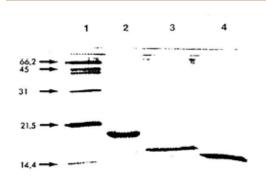
The first of two pieces of prior art in the *Deuel* case was *Molecular Cloning: A Laboratory Manual* by Maniatis, Fritsch, and Sambrook (1982).<sup>19</sup> This was the Maniatis laboratory manual previously noted, but in its first edition.

The second piece of prior art was European Patent Application No. 0 326 075, naming Bohlen and Gautschi-Sova as inventors (the Bohlen application), as illustrated by the representative drawing reproduced in Figure 8. This prior discovery in the Bohlen application was related to a HBGF in the cow, because the SDS-PAGE analysis shown in Figure 8 identified a bovine, or cow, HBGF having a molecular weight of 18 kD (lane 2).

A human homologue of the bovine HBGF protein was also identified. A total of 19 amino acids were determined (amino acid 33 to 51 in Figure 7) for HBGF, which were found to be identical for human and bovine HBGFs. It is true that both the bovine and human HBGF protein had been separated from nature as a band on a gel. But neither the bovine nor human HBGF gene had been cloned or sequenced. To reiterate, and in contrast, the *Deuel* invention was related to the cloning and sequencing of the gene for HBGF.

In re Deuel stands for the old rule that had guided the patenting of DNA for many years, specifically, that the existence of a general method of isolating DNA molecules is essentially irrelevant to the question of whether the specific molecules themselves would have been obvious and, thus, unpatentable. The Federal Circuit in Deuel reasoned that the applicant did not claim a method, but instead compositions. Accordingly, the issue was the obviousness of the claimed compositions, not the obviousness of the method by which those compositions were made. Therefore, a cookbook for cloning genes and a protein band found on a gel did not make the DNA sequence encoding the protein unpatentable (i.e., obvious).

#### Figure 8: The *Deuel* Prior Art: Bohlen Application



#### In re Kubin: The Decision

Despite the legally relevant facts being essentially the same, the Federal Circuit did not decide *In re Kubin* the same way as In re Deuel. Kubin took the position that, in KSR International Co. v. Teleflex Inc., 20 the United States Supreme Court had discredited the old rule of Deuel. While the Supreme Court did indeed seem to discredit one ruling of Deuel that "obvious to try" does not itself alone constitute obviousness, the Supreme Court did not discredit the other old rule of Deuel that the patentability of the sequence of the DNA molecule itself is unrelated to the method by which the gene is cloned. Nevertheless, the Federal Circuit panel in Kubin effectively overruled Deuel.

The Federal Circuit panel in *Kubin* concluded that the existence of a general method of isolating a DNA molecule is relevant to the question of whether the DNA molecule itself would have been obvious. So the obviousness of the method by which the gene is cloned could make the gene itself obvious. Continuing, the panel reasoned that it would have been "obvious to try" using the Maniatis laboratory manual. Additionally, there would have



Therefore, a cookbook for cloning genes and a protein band found on a gel in the opinion of the Federal Circuit panel did indeed make the DNA sequence encoding the NAIL protein unpatentable (i.e., obvious). Unless the United States Supreme Court or the Federal Circuit itself (in an en banc decision of the entire court) reverses this ruling by the *Kubin* panel, "the existence of a general method of isolating a DNA molecule is relevant to the question of whether the DNA molecule itself would have been obvious" will now be the new rule.

been a "reasonable expectation of success" in cloning the gene. This is because of an increased level of skill in the art (i.e., nucleic acid research) since *Deuel* was decided in 1995.

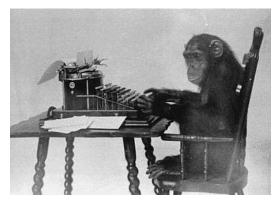
Therefore, a cookbook for cloning genes and a protein band found on a gel in the opinion of the Federal Circuit panel did indeed make the DNA sequence encoding the NAIL protein unpatentable (i.e., obvious). Unless the United States Supreme Court or the Federal Circuit itself (in an en banc decision of the entire court) reverses this ruling by the Kubin panel, "the existence of a general method of isolating a DNA molecule is relevant to the guestion of whether the DNA molecule itself would have been obvious" will now be the new rule. In view of this panel decision, the question for many is whether the skill in the art in the laboratory has indeed progressed so far and what might be the implications for development and commercialization of inventions coming from basic research.

# Commentary and Discussion for the Future

Try to imagine the amino acid sequence of NAIL, knowing that it is 365 amino acids long and that there are 20 amino acid choices at each position. The number of possibilities can be calculated mathematically. You have a 365 amino acid protein, and 20 choices for each amino acid, so there will be 20 to the power of 364 possibilities. Do not count the first amino acid because it is always Met. That is 20 times itself 364 times. This is a really big number, perhaps so big as to exceed the total number of particles in the universe!

In comparison to mouse NAIL, human NAIL turned out to show 54 percent amino acid identity, but which amino acids were identical was impossible to know until after the gene for NAIL was cloned. If you have an infinite number of monkeys sitting at an infinite number of typewriters for an infinite number of years typing at random then one would eventually type the entire works of Shakespeare (Figure 9). By analogy, given an infinite number of trials, you would eventually come up with the amino acid sequence of NAIL. Yet, creating an invention in the face of a nearly infinite number of possibilities is the first class of situations that the Kubin court agreed would not give rise to obviousness.

Figure 9: DNA Obviousness after Kubin?



Public domain photograph from Wikipedia.

If you have an infinite number of monkeys sitting at an infinite number of typewriters for an infinite number of years typing at random then one would eventually type the entire works of Shakespeare.

Emerson wrote: Build a better mousetrap, and the world will beat a path to your door. You cannot, however, patent an idea, e.g., the idea of building a better mousetrap. But you can patent a practical application of that idea, for instance,



the actual prototype snap-trap mousetrap itself. Sure, "obviously" many scientists would have wanted to sequence the gene (a good idea), and the protocols for doing so apparently existed (Maniatis laboratory manual), but *Kubin* was first to actually sequence the gene. <sup>21</sup> And a form of invention, the result of exploring a general technology giving only generic guidelines and generalized instructions, is the second class of situations that the *Kubin* court agreed would *not* support obviousness.

How do you reconcile the *Kubin* invention as falling into both of these two classes of situations that would *not* give rise to obviousness and as being ruled obvious? You scotch any precedent for the new rule. Is this new rule desirable when many economists believe that patents stimulate investment by fixing the "copying" problem so that a company can recover the cost of development, which for a new drug based upon a gene or other discovery to go from concept to FDA approval is cited to be on average \$802 million?

Most all genes are cloned by the Maniatis laboratory manual. Most all chemical compounds are prepared by conventional chemistry processes.<sup>22</sup> Most everything in mechanical engineering (ME) and electrical engineering (EE) is a combination of wellknown components. Under the reasoning of *Kubin*, gene sequence inventions, chemical compound inventions, and ME/EE inventions could arguably be unpatentable. Again, is this reasoning based on *Kubin* (taken to an extreme) desirable, even if it would contravene the patenting of most inventions?

With reference to the recent H1N1 flu virus, there is a need for a vaccine. Yet published reports indicate that "[v]accines against novel influenza A (H1N1) virus infection are being produced using methods similar to those used for seasonal influenza vaccines."<sup>23</sup> Extending the reasoning of *Kubin* to vaccines being produced using methods similar to those used in the art for making earlier vaccines, this vaccine could arguably be unpatentable in the United States. Once again, is this tentative result desirable given the need to attract investment in the development of technologies such as these arising from basic research?

The issue for research institutions is not only currently filed DNA sequence inventions being arguably unpatentable, but also certain DNA sequence patents being arguably invalid now.

Name of Court Decision	Date of Court Decision	Date of Maniatis Prior Art	Filing Date of Patent Application
In re Kubin	3 Apr 2009	1989	Eff F/D = 23 Mar 1999
In re Deuel	28 Mar 1995	1982	21 Jun 1990

 Table 2: Comparison of Relevant Kubin and Deuel Dates

Referring to Table 2, DNA sequence patents filed after the filing date of the patent application of *Deuel*, June 21, 1990, are susceptible to invalidation. This is because, under the reasoning of *Kubin*, DNA is arguably obvious since *Deuel*.

# Tips for Technology Transfer Officers at Basic Research Institutions

Assuming that *In re Kubin* remains good law, a university technology transfer office (TTO) that has a new DNA sequence invention could describe how to make and use the invention without citing the Maniatis laboratory manual for the procedure on cloning the gene. The TTO would still submit the sequence data, and then go ahead and cite the Maniatis laboratory manual for the protocol on how to make the DNA *given* this sequence. But then you must be prepared to argue that cloning the gene could not have followed the Maniatis laboratory manual and optionally provide objective indicia of nonobviousness.

Objective indicia of nonobviousness mean considerations demonstrating that the subject matter sought to be patented is sufficiently different from what has come before so that it may be said to be



inventive to that "hypothetical" person having ordinary skill in the art. Some such indicators include recognition by others, commercial success, and long-felt need. Another good argument for patentability is that the prior art teaches away from the claimed invention.

For NAIL, you could have argued that the Mathew article was published 1993, and the original Valiante and Trinchieri paper was published 1993, too. By contrast, the effective filing date of the Kubin patent application was 1999. That is six years after each of these references became public. If it was so obvious, why did it take six years to clone the NAIL gene? Additionally, you could have run the experiments to show that cloning the NAIL gene could not have followed the prior art, that using NK cells as a starting material failed, that using specially prepared NK cells activated by CD48 (or other nonobvious technique) was required to clone the NAIL gene. Finally, you could have argued unexpectedly superior properties of the NAIL gene.

The TTO might want to take a different approach by arguing that the Kubin lawyers lost based on a technicality. The argument goes that the prior art Valiante patent was unusually close to the Kubin invention, because the Valiante patent described the encoded protein band on a gel, prophetically applied the Maniatis laboratory manual to the problem of cloning the gene in Example 12, and made publicly available the very tool (mAb C1.7) for carrying out the method of cloning the gene. If the judges ruled narrowly in the Kubin case, then details that do not hew closely to the Kubin facts should save the research institution's DNA inventions from obviousness and unpatentability.

Although *Kubin* may have an adverse effect on the patenting of long-patentable genes, method-of-use patents should still be viable. Basic research institutions could offset *Kubin* by better identification of the function and use of the encoded proteins and focusing the patenting process on those properties and activities. Readers of *Kubin* may counter that the Federal Circuit seemed to find a biological feature that distinguished over the prior art (binding CD48) inherent to NAIL, thus not only was the product still obvious but also methods involving "inherent" biological features might also be unpatentable.

The rebuttal is that a method-of-use claim (e.g., administering NAIL to bind CD48), as opposed to a patent on a product, would be patentable, because a new and nonobvious use of even a known compound may be patentable over the prior art. Yes, method-of-use patents may be narrower than patents on the corresponding products. But the judiciary has apparently constrained the reach of Constitutionally authorized rewards for DNA sequence inventors.

#### Implications for Biotechnology Development

Under the central dogma of molecular biology, DNA sequence information has been everything. Under Kubin, DNA sequence inventions may arguably be unpatentable now. Perhaps the demise of the patenting of DNA inventions can be considered not a sea change but rather a reflection that molecular biology has evolved and advanced during past decades so that biotechnology itself has become more predictable. Various arguments (pro or con) from a scientific perspective can be made if indeed such "predictability" is now present or not, but it will be important to see if the U.S. Patent and Trademark Office and the courts extend such predictability to other requirements for patenting DNA inventions such as the "written description" and "enablement" of these inventions in a patent application.

Even with changing standards for patent protection, obtaining patents for DNA inventions remains a necessity for basic research institutions to attract privatesector firms to invest in these inventions to make new preventive, diagnostic, and



therapeutic products. Thus by careful and prudent management of DNA inventions in their portfolio along the lines described above, these institutions should still be able to reach their goal of having new health-care treatments and services reach the public.



Nancy W. Vensko, JD, is a partner with Fitch, Even, Tabin & Flannery in Chicago. She is also a member of Sinsheimer Juhnke Lebens & McIvor, in San Luis Obispo, California.



Steven M. Ferguson, MBA, CLP, is deputy director, licensing and entrepreneurship, in the Office of Technology Transfer at the National Institutes of Health in Rockville, Maryland.

#### Notes

<sup>1</sup>In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009).

<sup>2</sup>Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The price of innovation: New estimates of drug development costs," Journal of Health Economics 22 (2003): 151-185.

<sup>3</sup>U.S. Patent No. 6,284,491.

<sup>4</sup>Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

<sup>5</sup>Hotchkiss v. Greenwood, 52 U.S. 248 (1851). <sup>6</sup>Best Practices for the Licensing of Genomic Inven-

tions, 70 Fed. Reg. 18413 (Apr. 11, 2005). <sup>7</sup>Pub. L. No. 96-517, now codified in 35 U.S.C. §§ 200-212. Regulations for implementing the Bayh-Dole Act are found at 37 C.F.R. §§ 401.1-401.17.

<sup>8</sup>Pub. L. No. 99-502

<sup>9</sup>U.S. Patent Application No. 09/667,859.

<sup>10</sup>Virginia M. Litwin, "Lymphocyte Ontogeny and Membrane Markers," in Medical Immunology, ed. Gabriel Virella (New York, N.Y.: Informa Healthcare USA, Inc., 6th ed. 2007), 113-134.

<sup>11</sup>National Human Genome Research Institute, "Talking Glossary of Genetics," April 29, 2009, http://www. genome.gov/glossary/.

<sup>12</sup>Joseph Sambrook, Edward F. Fritsch, and Thomas Maniatis, Molecular Cloning: A Laboratory Manual (Cold Spring Harbor, N.Y.: Cold Spring Harbor Laboratory, 2d ed. 1989).

<sup>13</sup>Porunelloor A. Mathew, Beth A. Garni-Wagner, Kevin Land, Akira Takashima, Earl Stoneman, Michael Bennett, and Vinay Kumar, "Cloning and characterization of the 2B4 gene encoding a molecule associated with non-MHC-restricted killing mediated by activated natural killer cells and T cells," J Immunol. 151 (1993): 5328-5337.

<sup>14</sup>This is not the intact gene, because NAIL was apparently a so-called split gene and thus appeared as more than one band (two bands) on the gel.

<sup>15</sup>Nicholas M. Valiante and Giorgio Trinchieri, "Identi-fication of a novel signal transduction surface molecule

on human cytotoxic lymphocytes," J Exp Med. 178 (1993): 1397-1406.

<sup>16</sup>Because NAIL was separated as a protein band on a gel, the protein was in the prior art.

<sup>17</sup>In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995).

<sup>18</sup>U.S. Patent Application No. 07/542,232.

<sup>19</sup>Thomas Maniatis, Edward F. Fritsch, and Joseph Sambrook, Molecular Cloning: A Laboratory Manual (Cold Spring Harbor, N.Y.: Cold Spring Harbor Laboratory, 1982).

<sup>20</sup>KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007).

<sup>21</sup>PatentlyBIOtech, "The Blunders of In Re Kubin," April 8, 2009, http://patentlybiotech.wordpress com/2009/04/08/the-blunders-of-in-re-kubin/.

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What Are the Implications of Overlapping Areas for Technology Transfer? Perspectives from Science and Technology Studies

Hugo Pinto

#### Abstract

Technology transfer is a central aspect for innovation. Today universities assume a third stream of activities that add new dimensions to the traditional roles of education and research where technology transfer offices (TTO) are crucial actors. Departing from science and technology studies, this article explores the dynamics of these organisms presenting the ideas of Ludwik Fleck and the actor-network theory. The discussion underlines the practical relevance of marginal individuals in technology transfer facilitating the translation processes between different collectives of thought such as business and academy.

#### Introduction: Science and Business Proximities and Distances

The realities of business and science have been too often far apart. Nevertheless, nowadays there is a major emphasis on university-industry relations. A university cannot be related only to its two traditional roles: the training of human capital through education and the generation of new knowledge through (basic) research. Today, a third role of the university is recognized: to be interconnected with the community, which includes promoting regional development. But this new mission lacks an efficient and stable relationship with the actors of their environment, particularly with companies.

This interest is highlighted by the emergence of initiatives such as knowledge and technology transfer offices. These interface entities try to create linkages between the academy and business, supporting research projects in consortium, spinoffs and startup creation, and industrial property rights registration and licensing. These initiatives earn new support frameworks, from the regional scale to nationwide initiatives or even at the international level. Knowledge and technology transfer offices seem to have an important role in consolidating relations between researchers and entrepreneurs to ensure an alignment of interests, the speeches and timings between these two worlds, to promote an effective transfer.

Though still not deeply explored in the theories of science and technology studies (STS), the dynamics of these offices have



What Are the Implications of Overlapping Areas for Technology Transfer? Perspectives from Science and Technology Studies Hugo Pinto taken up some of the representative theories in this field of knowledge. The current literature review is a starting point to focus on the issues related with knowledge and technology transfer and interface entities under the scope of STS. Firstly, it aims to stabilize the concepts of knowledge and technology transfer. Secondly, the precursor ideas of Fleck and the actor-network theory will be presented briefly, trying to capture some insights to technology transfer practice and fields for future inquires within this thematic.

# Knowledge and the New Roles of University

Knowledge can be understood as the capacity acquired by individuals by their experiences, education, and training—the practical and theoretical understanding about a particular phenomenon. Scientific knowledge is one of the types of knowledge that prevails over the other types due to its outstanding impacts in the development of human society. Knowledge can be understood as the stock component of science, while research is the flow in the creation of new knowledge.

The importance of learning processes to knowledge production is discussed by Lundvall and Johnson<sup>1</sup> who differentiate four types of learning channels, understood as the dynamics of knowledge: know-what, know-why, know-how, and know-who. The first two types can be obtained in a relatively passive way, reading books, going to classes, or accessing databases, but the last two channels have their roots in more practical aspects. Traditional science, technology, and innovation policies give priority to know-why, valuing a linear vision of innovation, but learning requires a strong attention to all channels, suggesting the need of a learning mode based in doing, using, and interacting.

The traditional role of universities linked with the production of knowledge is now enriched with the needs and competencies to satisfy social needs. The segmentation of educational profiles, associated to the massification of higher education access, redefined the university role. The traditional education in an inelastic framework is now distributed by a multiplicity of functions linked with the participation of the university in the production of knowledge and technological innovation.

Knowledge can be understood as the capacity acquired by individuals by their experiences, education, and training—the practical and theoretical understanding about a particular phenomenon.

This discussion is related with the seminal book *The New Production of Knowledge*<sup>2</sup> that introduces the notion of the emergence of a new interactive research system more socially distributed. The main argument presented is that the production of knowledge, in the past almost completely allocated in scientific institutions and structured in disciplines, is now much more heterogeneous. The new mode of production of knowledge—defined as Mode 2 in opposition to the predecessor Mode (1)—is not going to substitute completely the first one, but it will be a complement.

The knowledge in Mode 2 is generated in a more applied context, what reduces the costs of knowledge transfer. Mode 2 is essentially transdisciplinary, trying to mobilize an enlarged set of theoretical perspectives and empirical methodologies to solve specific problems. In Mode 2 the actors involved are numerous and have a more intense interaction.

A fourth important characteristic refers to the increasing reflexivity of the process of knowledge creation, a more dialogic process capable of incorporating different points of view. The forms of quality control are another characteristic; the peer-review systems are now added with economic, social, and cultural criteria—becoming even more difficult to identify what is good science.

Another relevant perspective is Etzkow-

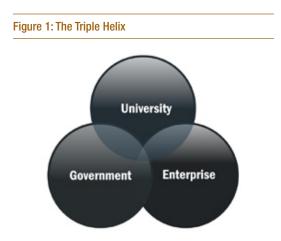


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itz and Leydesdorff's triple helix,<sup>3</sup> showing three spheres that intercross and actors that interact in multiple relations, the role of each group in the dynamics of the innovation system but stressing the common space that needs the arise of new actors capable of an effective intermediation (see Figure 1). This new context for innovative activities requires a diversity of intermediaries. University gains a more relevant role in innovation, once many research projects are developed in their infrastructures and are actively enrolled in the support to the creation of new intensive knowledge, e.g., providing incubation services. Industry has to interact with the university integrating new knowledge in economic activities. Government, focused in the territorial competitiveness, must provide financial support to basic research, be a venture capitalist in applied science, and an incentive to a cooperative environment.

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An ideal triple helix needs to develop innovation policies that confirm the different institutional roles but also reinforce the interdependences between the actors. The overlapping institutional spheres influence the roles of each other. The dynamics of the society changed from institutional spheres with well-defined frontiers to a flexible overlapping with strong interconnection with different groups of actors. Etzkowitz<sup>4</sup> underlines three relevant dimensions of the model: (i) an internal transformation of each helix, e.g., with bilateral linkages between companies or the new roles of the universities; (ii) the influence of each helix on the others, e.g., the government creating a new industrial policy; and (iii) the creation of a new layer of trilateral organizations and networks that emerge to develop a more cooperative environment for innovation.



The corollary of the triple helix model is that the new university has to be the entrepreneurial university characterized by a third mission, an effective participation in the creation of the territorial dynamism, promoting the development and researching of both fundamental and applied problems. Etzkowitz et al. state:

The entrepreneurial university requires an enhanced capability for intelligence, monitoring, and negotiation with other institutional spheres, especially industry and government. Beyond the ability of the top leadership of the university to engage with their counterparts in other institutional spheres, a midlevel organizational linkage capability gives the university the ability to identify confluence of interest between external organizations and their academic counterparts. Interface specialists make introductions, organize discussions, negotiate contracts, and otherwise act in an intermediary role to facilitate interactions with their counterparts and other potential partners in government and industry. Interface specialists emanating from various organizations and institutional spheres forge a common identity, independent of their employers. This is expressed organizationally in the creation of organizations representing the emerging interface professions.<sup>5</sup> The third stream of activities is extremely important in the creation of universityindustry collaboration generating techno-



What Are the Implications of Overlapping Areas for Technology Transfer? Perspectives from Science and Technology Studies Hugo Pinto logical spillovers, contributing to minimize market failures. The technology transfer process and its specific organisms that assume particular relevance in this context are in focus in the next section.

#### **Knowledge and Technology Trans**fer: **Process and Intermediaries**

The role of knowledge and technology transfer is clearly central to the innovation process. The relevance of technology transfer (TT) as a central topic for innovation policies increased since 1980 in the United States with the Bayh-Dole Act.<sup>6</sup> Simultaneously in the European Union (EU), the ESPRIT program, focusing in information technologies, underlined the importance of cooperation to research. The first Framework Program for Research and Technological Development (1984-87) also increased the attention paid to these issues being an important reference in the European context. Another important mark was the Green Paper on Innovation (1995), which highlighted the upcoming of the knowledge economy placing the university as a key agent in the generation of new knowledge and in the creation of facilities to approximate the two realities of academia and business.

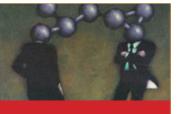
The corollary of the triple helix model is that the new university has to be the entrepreneurial university characterized by a third mission, an effective participation in the creation of the territorial dynamism, promoting the development and researching of both fundamental and applied problems.

Technology transfer activities are a significant source of income for a limited number of universities but are originating the generalized interest for the creation of technology transfer offices that also wish to access these alternative funds. For the EU, the importance of technology transfer is reinforced by the gap in technology performance relative to the U.S. and Japan, reported consecutively by innovative performance evaluations.<sup>7</sup> This gap is considered a European paradox, because apparently European countries have a good scientific output that is not effectively transferred to society, not permitting the appearance of innovation that induces economic growth.<sup>8</sup> The paradox is also related to the absorptive capacity of the technology receptor, the ability to recognize the value of new information and to assimilate and exploit it.

In a technology transfer process from the university to the enterprises, often classified as vertical, the companies more willing to benefit from technology transfer are the ones that have a significant level of previous contacts and proximity with the academic community. Technology transfer is different from other relevant notions such as dissemination of technologies or innovation diffusion; it is a voluntary and active process in the appropriation of new knowledge, with an important formal character, embodied in protocols, agreements, and payments, which originate contracts, patents, licenses, or the creation of technology-based firms.

Siegel et al.<sup>9</sup> suggest that a linear and somewhat simplified technology transfer process can be understood in five stages: scientific discovery, incentive of the technology transfer office to disclosure invention, evaluation of market value, decision to protect intellectual property, and market technology. This narrow view of technology transfer adds to a broader sense that includes all the flood of know-how, expertise, or technology from a whole organization to another, describing a wide range of interactions between different actors in the system of innovation.

Debackere and Veugelers add that "(...) behind these multitude of formal relationships lies a myriad of informal contacts, gate-keeping processes and industryscience networks on personal base. These informal contacts and human capital flows are ways of exchanging knowledge between enterprises and public research,



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which are more difficult to quantify, but nevertheless extremely important and often a catalyst for instigating further formal contacts."<sup>10</sup>

There is abundant empirical evidence that technology transfer occurs through multiple channels, such as personnel mobility, informal contacts, consulting relations, and joint research projects, assuming a smaller impact than patenting and spin-offs in this process. Only a minority of university-industry interactions is directed to realized commercial products.

This broader concept, more adapted to the knowledge-based economy and the multidimensional aspects of the innovative processes, creates the notion of knowledge transfer. Bozeman<sup>11</sup> stresses the importance of the distinction of the two notions suggesting that if one classifies knowledge transfer as scientific knowledge used by scientists to develop science and the other defines technology transfer as scientific knowledge used by scientists and others to new applications, then the latter should be the aim of interest.

There is abundant empirical evidence that technology transfer occurs through multiple channels, such as personnel mobility, informal contacts, consulting relations, and joint research projects, assuming a smaller impact than patenting and spin-offs in this process. Only a minority of university-industry interactions is directed to realized commercial products. R&D is aimed at getting up-to-date knowledge, obtaining access to students and faculty, and finding solutions to particular problems.

Bercovitz and Feldmann<sup>12</sup> have identified five crucial formal and informal mechanisms of university technology transfer:

 Sponsored research: an agreement by which the university receives funding to conduct a research project; it is important to understand that there is a supply of research relevant to industry, if there are economic incentives to finance university R&D or if antitrust provisions limit company involvement in research consortia.

- Licenses: legal rights to use a specific piece of university intellectual property—restrictions of funding sources on licensing or restrictions of university on licensing.
- Hiring of students: recruitment of students from the university, especially those working on sponsored projects there is a sufficient supply of students and screening mechanisms at work.
- Spin-off firms: a new entity that is formed around the faculty research or a university license—faculty members are allowed to work outside the university or are special provisions to facilitate spin-offs.
- Serendipity: simple luck or chance richness/relevancy of the related economic activities in the territory.

The transfer of knowledge happens in an interface area, where the technology transfer office (TTO) tries to eliminate the communication gap through an approach to the market of technology and institutional knowledge and the focus on business demand. In this overlapped membrane various types of bodies and structures have emerged, acting as intermediaries: technology centers, approval and testing laboratories, technology parks, science parks, services to support research and innovation, technology platforms, industrial property rights offices, incubation facilities. TTOs are entities in a frontier space where the interests of three distinct actors overlap-enterprises, academy, and government-and often assume more than one of these roles.

These interface organisms result from the efforts of the specific actors in solving common problems caused by an ineffective interaction of the spheres. These offices have the specific role to transfer intellectual capital and know-how among organizations to use in the creation and development of new products and services



What Are the Implications of Overlapping Areas for Technology Transfer? Perspectives from Science and Technology Studies Hugo Pinto commercially viable, connecting teaching, research, and extension resources; administration, internal marketing, and commu-

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nication; external marketing; and administration of the interaction process.

Howells<sup>13</sup> suggests the systemic value of intermediaries, not only on improving the connectedness within a system, but particularly in the creation of bridging ties and as system animator. In recent years many universities established a TTO as a consequence of the interest in technology transfer and its potential benefits. A dedicated TTO needs to assure the appropriate incentive mechanisms, working together with the researchers to overcome the moral hazard problems and assure the generation of projects. If there is a shared space between science and the business world, it is necessary that fruitful dialogues and common goals arise, even when the language of the actors involved seems to be very different.

Guston<sup>14</sup> shows how TTOs can be seen as boundary organizations, which characterize the vision advocated by the principal-agent theory (see Figure 2). A boundary organization can be seen as a way of stabilization, because it internalizes the contingent nature of the reality of science in its everyday practice, creating frontier objects for the collaboration between principals and agents. TTOs are boundary organizations that provide an area where the creation and use of bordering objects



is legitimate, causing the participation of principals and agents, as specialized mediators between two socially different worlds with different natures in terms of responsibilities and results.

Politicians, unable to foster innovation without the involvement of researchers, create incentives for them to get involved in applied research projects, close to market and business projects, supported and monitored by new actors who mediate, such as the TTOs, trying to solve gaps in translation.

#### Theories of Social Studies of Science and the TTO

The path followed in current review, led, so far, to three important conclusions:

- Technology transfer is a complex process but vital to society by bringing new knowledge and technology to the creation of value.
- Technology transfer involves several different actors, from universities or industry, with specific references and language with its own visions of each other, which creates barriers in dialogue.
- The importance of technology transfer brings out a common area where intermediary entities must be created to strengthen the interaction and the creation of shared goals between the groups.

In this section, the importance of two theoretical approaches linked to STS is stressed in the analysis of TT. These work fields gave comprehensive understanding of TT processes and TTOs activities, but remain largely unexplored.

#### FLECK'S COLLECTIVES OF THOUGHT

Ludwik Fleck was a forerunner of the constructivist approach who remained virtually forgotten until the 1970s, when his work was translated to English, through the incentive of Robert Merton. Since this almost serendipity rediscovery, the monograph *Genesis and Development of a Sci*-



What Are the Implications of Overlapping Areas for Technology Transfer? Perspectives from Science and Technology Studies Hugo Pinto entific Fact, written in 1935, has been object of great scholar interest. Merton found in Fleck clues of his personal interest on the influence of social structure on the production of scientific knowledge. Fleck's comparative epistemology offers a unique set of tools to look at the production and circulation of knowledge in contemporary societies, allowing the construction of a geography of intellectual fields, describing not only people and spaces but also the interchanging taking place.

Fleck presents an approach to science and philosophical concepts rooted in his own experience as a medical bacteriologist. This author shows how a disease can be seen as construction and considers it impossible for doctors to describe an infection, an event of great complexity, by a simple causality, since this depends on an interaction between two complex systems, the parasite and the host. This type of causality analysis would have meaning only if there was a common thought style. The thought style not only determines how an object is observed but also stresses certain elements neglected by others. Each thought style characterizes a specific collective. The thought style of a collective is the result of practical and theoretical education on a given individual, transitions from teacher to student, and is a traditional value that is the subject of study by a specific historical development and sociological specific laws.

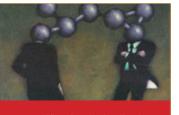
It must be stressed that it is not an optional feature of the individual but instead an imposition made during the socialization process. Individuals who have the same references belong to the same collective of thought and are limited in communication with other groups. However, the author assumed that there are styles of thought that are close, and for this reason, communication is facilitated for these groups, e.g., between physicists and biologists. Thus, there are varieties of styles and varieties of groups, which are more or less close. A certain thought style determines the perception and creation of tools and techniques, as well as the interpretation of results. The determination of the phenomena, incorporating them into a common classification, depends on the beliefs and practices of each epoch.

The thought styles can coexist and are restrictions on the understanding of each scientific discovery. Fleck noted that technical terms in a collective of thought, not only express their meaning but also assume a symbolic load (thought-charm), almost "sacred" to the practitioners and unattainable for the non-initiated, that transmit a specific power. The acceptance in a group is made after a period of learning in which the power and authority have an important role. During this process, the ability to recognize certain phenomena is accompanied by a reduction in the ability to recognize other phenomena and to use certain technical capabilities. Communication between groups depends on the circulation of facts and concepts. The facts produced by a particular group are assimilated by other organizations and translated

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#### to their thought style.

An imperfect translation occurs, modifying the facts, ignoring and highlighting aspects such as they fit or refute the own style of the receptor. The relationship between different groups is carried out by marginal individuals who belong to more than one collective or move around the intersection of several groups, favoring the creation of new thought styles and leading to the creation of proto-ideas—the genesis of inventions. There are the esoteric (experts that produce knowledge) and exoteric (educated amateurs) circles, which hold some tension and where members of the thought collective tend to repel nonmem-



What Are the Implications of Overlapping Areas for Technology Transfer? Perspectives from Science and Technology Studies Hugo Pinto bers. However, the advances in science are mainly made by the contact between the two circles. Ludwik Fleck stressed the importance of theory combined with practice, showing the fallacies that can be created when the latter element is missing in science.

#### ACTOR-NETWORK THEORY AND TRANSLATION

In the core of the conceptual framework of the actor-network theory, developed by Bruno Latour and Michel Callon, is the relevance given to players as human or nonhuman entities that make things and are treated as epistemologically equivalent. The group defines the network of relationships between entities. The actor and the network are mutually constitutive. Actors, people, or technologies are not fixed and do achieve significance through the relations with other actors. It is the network that allows players to translate their objectives and add other players to increase their power. At the heart of this framework is the concept of translation, which shows how the actors constantly engage in a process of translation of their languages, their problems, their identities, and their interests in the others.

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The translation is the mechanism that creates the actor-network: the problematization, the interessement, the enrolment, and the mobilization. This is a central process to the construction and deconstruction of reality. With this respect Callon states that, "To translate is to displace (...) but [it] is also to express in one's own language what others say and want, why they act in the way they do and how they associate with each other: is to establish oneself as a spokesman. At the end of the process, if it is successful only voices in unison will be heard."<sup>15</sup> Translating is to transfer, transferring interests, purposes, devices, applications. The transfer makes it possible to consider a set of practices that produce change.

At the beginning of the process of translation universes are separated without means of communication with one other, but at the end a unified discourse is structured with different sorts of displacements and transformations since the initial phases of the process. Latour proposes that the players are followed in the translation processes that are implemented through various activities, strategic competitors, evidence of force, mobilization and recruitment, development of devices for commitment, and mandatory references to consolidate alliances and partnerships between actors and teasing spokespersons of the association.

The concept of network points to the stabilization between different types of stakeholders (individuals, groups, or objects). Interactions between actors are building blocks of networks, and translation processes happen in a diversity of levels, assuming a key role to social order, generating institutions, governments, organizations, and agents that exist over time.

The network is the result of relatively stable balance of power in the translation processes. Translation between humans is analogous to negotiation of common interests between human and nonhumans actors, the process happens through the design of scripts. Technology transfer is a process of translation—by aligning the goals of the researcher, TTO, university, firm manager, designer, manufacturer, marketer, and end user—the initial technology will change. Technologies are neither passive nor neutral and exhibit distinctively valued social relations.

ANT is a good theoretical background to analyze technology transfer by focusing on the evolving process of translation, which will permit the spread of innovation. An in-



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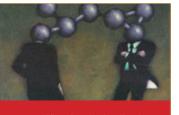
novation (idea, practice, object, or technology) is communicated through social systems, and it is a matter of time before the innovation becomes widely accessible. The speed at which the innovation is diffused depends on the perceived advantages, compatibility, comprehensibility, and also on the efficiency of the communication channels. ANT distances itself from the view that innovation and technologies are stable entities that are passed from person to person and then put into use. The technologies only make sense when used by a human actor, and this actor will always have certain interests and roles. When technologies are transferred within and between actor-networks, they make sense in different ways depending on the way they are translated by the actors and the way they used to sustain or challenge the network.

#### University-Enterprises Linkages: Insights and Unsolved Issues

TTOs are intermediary organisms operating in an area where they intersect the interests of researchers, businesses, and policy-makers. They are a type of body crucial to promote knowledge and technology transfer. TTOs behave as mediators, where it is difficult to understand who are the principals and who are the third agents. It is doubtless that at least we have common ground if we refer that there are three stakeholders (but are they principals?), the university, which wants to maximize the economic value of its research; the firms, which want to add value to their products through a differentiation induced by the R&D; and the government, which aims to stimulate territorial development through the transformation of

#### Table 1: Theories and Implications for TT

Theory Suggested Referen		Central Ideas	Practical Insights to TT	
Fleck	Ludwik Fleck, <i>Genesis</i> and Development of a <i>Scientific Fact</i> (Chica- go: Chicago University Press, 1979[1935])	Scientific knowledge results from a process of construction, a collective process of reproduc- tion, socialization, and learning. Facts have a genesis and a development. Scientific facts are produced dependent on styles of thought of particular collectives. Facts are translated to other collectives that adapt them to their specific styles. Translations are never perfect. Translation is done by marginal individuals, who belong to different collectives at the same time and increase cross-fertilization and migration of concepts between different areas and the generation of proto-ideas (the starting point for inventions).	Scientific and corporate actors constitute differ- ent collectives with different styles of thought. Translation is required to engage a success- ful technology transfer process that creates bridges from science to market. The TTOs must have marginal individuals in their staff to be able to assume on their territory the role of mediators. It is essential they not only have a relevant degree but also the ability to communicate and understand both scientific and corporate realities.	
ANT	Bruno Latour, <i>Reas- sembling the Social</i> (Oxford: Oxford Univer- sity Press, 2005)	Using the ANT approach, attention is given to the diversity of actors, the network construc- tion, obligatory passage points, and the transla- tion process. The concept of translation (the problematiza- tion, the interessement, the enrolment, and the mobilization) shows how the actors con- stantly engage in a process to translate their languages, their problems, their identities, and their interests into the others.	Each TT mechanism constitutes itself as a translation process where different actors cre- ate a network to reach common goals. Translation is pushed by a particular actor, the translation enabler (TE). Frequently the TE was the entrepreneur who developed the spin-off of the researcher who protected his knowledge, but today the TTO staff is assuming repeatedly this role. Boundary objects have specific roles and influ- ence the TT processes. The formal channels of TT are too often trans- formed in metrics (indicators) that are used to assess TT effectiveness but leave the process as a black box. This often leads policy-makers to consider means as ends—e.g., the number of patents. Analyzing how each mechanism develops facilitates the understanding of (in) success in each case.	



What Are the Implications of Overlapping Areas for Technology Transfer? Perspectives from Science and Technology Studies Hugo Pinto research and invention in profitable innovations. Despite these three stakeholders, TTOs' objectives remain specific and not a replication of the stakeholders' interests: to promote university-industry linkages and knowledge and technology transfer.

The study of the activity of TTOs is a field of great interest for analysis in the STS. The studies of Fleck, showing the differences between collectives of thought, stressed the importance of marginal individuals, able to communicate with various elements of different collectives, boosting the generation of proto-ideas. The elements of each TTO must have these characteristics and take on the role of intermediaries. ANT showed how science is done with an increasingly wide range of actors, humans, and nonhumans, and how the translation process is essential to the creation of shared visions and objectives, changing the social reality. In its surrounding the TTOs must assume the role of enhancers of the translation processes aimed to research collaborative projects to increase the linkages between universities and enterprises and promote the development in their territory. TTOs are facilitators, organizations adequate for the bordering areas if its members are attuned to two groups, with their individual objectives and a logic that can share. A relevant lesson to TTOs' executive boards is that they must be very careful and focus on the characteristics of staff. It is essential not only to have a degree in law, economics, or in a relevant scientific field but also the ability to communicate and understand both realities of science and business.



A former technology transfer officer at the University of the Algarve (Portugal) and European projects manager in the Business Innovation Center Algarve-Huelva, Hugo Pinto is currently developing a doctoral thesis, "Institutional Dimensions of Knowledge Transfer in European Union," at the Centre for Social Studies, University of Coimbra, with financial support from the Portuguese Science and Technology Foundation (ref. SFRH/BD/35887/2007). He can be reached at hpinto@ualg.pt.

#### **Notes**

<sup>1</sup>Bengt-Ake Lundvall and Björn Johnson, "The learning economy," *Journal of Industry Studies*, 1 (1994): 23–42.

<sup>2</sup>Michael Gibbons, Camille Limoges, Helga Nowotny, Simon Schwartzman, Peter Scott, and Martin Trow, *The New Production of Knowledge: The Dynamics of Science and Research in Contemporary Societies* (Londres: Sage, 1994).

<sup>3</sup>Henry Etzkowitz and Loet Leydesdorff, Universities and the Global Knowledge Economy—A Triple Helix of University-Industry-Government Relations (London: Continuum, 1997).

<sup>4</sup>Henry Etzkowitz, "The Triple Helix of University-Industry-Government Implications for Policy and Evaluation," Working Paper Sister, 11 (2002), http:// www.sister.nu/pdf/wp\_11.pdf.

<sup>5</sup>Henry Etzkowitz, Andrew Webster, Christiane Gebhardt, Branca Regina, and Cantisano Terra, "The future of the university and the university of the future: Evolution of ivory tower to entrepreneurial paradigm," *Research Policy*, 29 (2000): 313–30.

<sup>6</sup>The results of the Bayh-Dole Act are controversial like suggested by Einar Rasmunssen, Øystein Moen, and Magnus Gulbrandsen, "Initiatives to promote commercialization of university knowledge," *Technovation*, 26 (2006): 519–533. Some authors assure that the act wasn't particularly relevant in the modification of the university R&D activities (cf. Matthew Rafferty, "The Bayh-Dole Act and university research and development," *Research Policy*, 37 (2008): 29–40).

<sup>7</sup>Such as the European Innovation Scoreboard 2006—Comparative Analysis of Innovation Performance, http://www.proinno-europe.eu/node/doc/ EIS2006\_final.pdf.

<sup>8</sup>This paradox was, however, contradicted by recent research results (cf. Giovanni Dosi, Patrick Llerena, and Mauro Sylos Labini, "The relationships between science, technologies, and their industrial exploitation: An illustration through the myths and realities of the so-called 'European Paradox,'" *Research Policy*, 35 (2006): 1450–1464) showing that the weaknesses in the European system are both in the scientific knowledge production as well as in the industrial innovation system.

<sup>9</sup>Donald Siegel, David Waldman, and Albert Link, "Assessing the impact of organizational practices on the relative productivity of university technology transfer offices: An exploratory study," *Research Policy*, 32 (2003): 27–48.

<sup>10</sup>Koenraad Debackere and Reinhilde Veugelers, "The role of academic transfer organizations in improving industry science links," *Research Policy*, 34 (2005): 321–342.

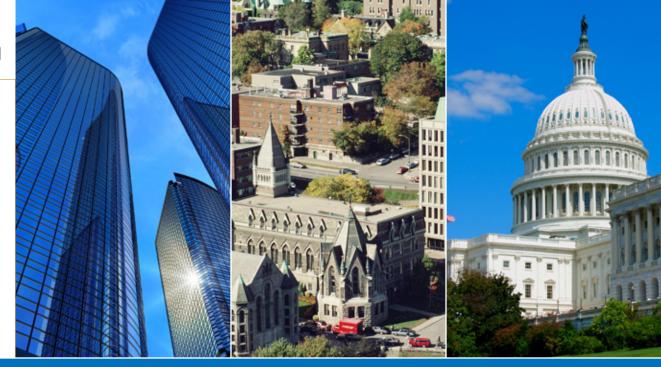
<sup>11</sup>Barry Bozeman, "Technology transfer and public policy: A review of research and theory," *Research Policy*, 29 (2000): 627–655.

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<sup>13</sup>Jeremy Howells, "Intermediation and the role of intermediaries in innovation," *Research Policy*, 35 (2006): 715–728.

<sup>14</sup>David H. Guston, "Stabilizing the boundary between U.S. politics and science: The role of the office of technology transfer as a boundary organization," *Social Studies of Science*, 29 (1999): 87–111. <sup>15</sup>Michel Callon, "Some Elements of a sociology of

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### Universities, Industry, and Government in Collaboration: A Review of the Literature on Research Centers

Jennifer M. Miller

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#### Abstract

Research has become more complex, involving large teams of researchers, often at multiple institutions. The university research center (URC) has emerged as an important feature of this research environment. URCs represent an especially large and growing influence over university research with ties to industry and commercialization potential.

The review begins with a summary of conceptual issues, including definition, description, categorization, and contextualization of URCs. In the second section, the review examines the central activity underlying the URC concept, collaboration. The third section reviews the literature on URC evaluation, including methodological recommendations and examples.

Finally, the concluding section develops

a systemic model of the URC and its stakeholders and recommends approaches to evaluation guided by the challenges facing the center approach to government-funded university research. The model includes the contributions government, industry, and university stakeholders make to URCs and the benefits they seek in return. This model is especially relevant to the challenge of sustainability for URCs. It also reflects the progression in research on URCs from the center level to increased consideration of issues affecting constituent parts of centers, such as faculty or firms, and situates each part within a system.

#### Introduction

The university research center (URC) has emerged as an important feature of the increasingly complex research environment. Research centers provide a venue to tackle multifaceted research questions, technological challenges, and societal problems that are beyond any one traditional department and often involve multiple institutions and partners. The National Science



Universities, Industry, and Government in Collaboration: A Review of the Literature on Research Centers Jennifer M. Miller Foundation (NSF) Engineering Research Centers (ERCs) that inspired the rapid growth of this model have been hailed as the most significant institutional innovation in science policy of the past thirty years.<sup>1</sup> Some even feel URCs may eventually replace disciplinary departments in certain areas of university research.<sup>2</sup> URCs represent an especially large and growing influence over university research with ties to industry and commercialization potential.

A variety of social science disciplines and administrative perspectives inform this review and synthesis of the existing body of knowledge about government-funded URCs in the United States. Various constituencies have been concerned with URCs from their own points of view: government program managers, industry sponsors, and university administrators. While considering these diverse perspectives, this review pays particular attention to topics of interest to university personnel involved in technology transfer.

Some even feel URCs may eventually replace disciplinary departments in certain areas of university research.<sup>2</sup>

The review begins with a summary of conceptual issues, including definition, description, categorization, and contextualization of URCs. This section also catalogs resources about URCs for those interested in surveying or benchmarking activities. The URCs are placed in context with an overview of challenges they face, from challenges inherent in their mission and structure to others that relate to their evolution as an institution and those tied to contemporary societal issues.

In the second section, the review examines the central activity underlying the URC concept, collaboration. This section summarizes what has been learned generally about collaboration in these centers and focuses more specifically on universityindustry collaboration, including the various benefits valued by industry partners. The third section reviews literature on evaluation of research centers, including methodological recommendations and examples of published evaluations. The examples demonstrate the application of valuation methods to research centers and document economic development, technology transfer, and other outcomes that have been attained from URCs.

The concluding section develops a systemic model of the URC and its stakeholders. This model offers insights on how to effectively structure URCs. Recommended approaches to evaluation are discussed in the context of challenges facing the center approach to government-funded university research.

#### Understanding the University Research Center

#### **DEFINITION AND DESCRIPTION**

In this review, URCs have been defined as entities at a university having research as their primary mission, extending beyond the boundaries of a single disciplinary department, and receiving some government funding. Most such centers also receive some funding from industry, and specific levels of industry support are sometimes required.

Early work on URCs in the higher education literature referred to them as organized research units (ORUs).<sup>3</sup> Friedman and Friedman provided the following definition of an ORU:

An Organized Research Unit (ORU) is an academic agency within the university whose purpose is intended to be complementary to the activities performed by departments. To be considered an ORU, an academic agency must:

- Receive budgetary support from internal and/or external sources independent of departmental allocation.
- 2. Occupy temporary or permanently assigned space with access to



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university-operated physical facilities and support services.

- 3. Be directed by an administrator drawn from faculty or equivalent ranks.
- 4. Participate in the university's broad-gauged educational functions, but *not be degree granting*.
- Be more than a facilitator of research such as a computer center or nuclear reactor, a diagnostic testing, and/or evaluation unit servicing internal or external clients or an institutional research and/or coordination office.<sup>4</sup>

The spirit of this definition has guided subsequent work. However, other approaches have also been used to define URCs.

Some have defined URCs more broadly based on less tangible criteria. For Stahler and Tash, URCs were uniquely defined within the university only by having research as their primary mission.<sup>5</sup> URCs could vary in terms of external support, size of staff, faculty/staff ratio, integration with departments and the university, inter- or multidisciplinarity, and proportions of basic and applied research. Based on a census of fifty-five URCs affiliated with the University of New Mexico, URCs were distinguished from the rest of the university by interdisciplinarity, by spanning boundaries beyond the university, and by a relatively time-limited nature.6

Youtie, Libaers, and Bozeman demonstrated the application of cross-case qualitative analysis to apply definitions to minimal and fully articulated URCs: "In short, the minimum conditions for a research center include (1) the recognition among the research specialists themselves as being affiliated with a center, (2) the provision of resources to be shared among researchers, (3) conditioned only by their agreement to certain rules for access to research."<sup>7</sup> To define fully articulated research centers, they added requirements for hierarchy, administrative procedures, agreements for ongoing resource sharing, external recognition, a defined timeline of existence, formal plans and objectives, and official ways for nonmembers to access or join the center.

They also noted that the following characteristics often applied to research centers, but did not consider them definitive: multiple funding sources, staff appointed directly to the center, connections to other organizations, multiple institutional roles, multiple types of research outcomes, student involvement, multidisciplinarity, multiple stakeholders, accountability, and a process for setting a research agenda.

Comparison of the definitions described above, as well as the variety of operational definitions used in empirical work, revealed the broad array of concerns used to define the URC conceptually. The definition used in this review was intentionally broad, since the literature does not consistently apply the individual elements of more detailed definitions. Key areas of diversity in URC definitions have been whether URCs were time-limited and whether the term implied multi- or interdisciplinarity. Overall, these center definitions stood in sharp contrast with investigator-level funding mechanisms that have continued to provide most government support for university researchers.8

The definition used in this review was intentionally broad, since the literature does not consistently apply the individual elements of more detailed definitions. Key areas of diversity in URC definitions have been whether URCs were time-limited and whether the term implied multi- or interdisciplinarity. Overall, these center definitions stood in sharp contrast with investigator-level funding mechanisms that have continued to provide most government support for university researchers.<sup>8</sup>

Other literature about URCs has defined them by reference to specific government programs, especially the NSF-sponsored University-Industry Cooperative Research



Universities, Industry, and Government in Collaboration: A Review of the Literature on Research Centers Jennifer M. Miller Centers (UICRCs), Engineering Research Centers (ERCs), and Science and Technology Centers (STCs).<sup>9</sup> NSF annual reports from the time period of these programs' creation discussed their rationale and intent, with an emphasis on cooperation and increasing the international competitiveness of U.S. industry.<sup>10</sup> The dramatic expansion of the URC model in the 1980s coincided with legislation central to technology transfer, such as the Bayh-Dole Act and the Federal Technology Transfer Act. URCs and technology transfer legislation can be considered complementary aspects of national science and technology policy.

These NSF centers served as models for URCs sponsored by other government agencies. Agency-sponsored programs that have been discussed in the academic literature include current initiatives by the Environmental Protection Agency to study particulate matter and by the Department of Health and Human Services to study tobacco use.<sup>11</sup>

A distinct but related concept is the federally funded research and development center (FFRDC), which can be sponsored by the NSF or another government agency and administered by a university, a nonprofit organization, or a firm.<sup>12</sup> In contrast with the collaborative URCs, FFRDCs are under more direct agency control. However, unlike the national laboratories, the FFRDCs are not under the direct control of government personnel.

#### CATEGORIZATION

The earliest taxonomy of centers divided URCs into standard, adaptable, and shadow centers.<sup>13</sup> Standard centers had stable funding tied to an ongoing mission. Adaptable centers adjusted their research agendas to compete for available funding. Shadow centers were contained within a single department and sometimes even under the control of one faculty member. While standard centers were the most influential, some centers working in partnership with industry would probably have been classified as adaptable centers. Shadow centers seemed to be of concern mainly because they added complexity to university governance and would not fall within many definitions of URCs.

Some categorization systems applicable to broader research policy constructs have also been applied to URCs. Centers can be based on projects or problems, corresponding to firm pull or science push models.14 It has also been possible to categorize URCs in a typology developed for R&D laboratories.<sup>15</sup> Recognizing that the traditional framework used to categorize these laboratories as government, industry, or university was no longer adequate in a time of extensive cross-sector collaboration, Bozeman and Crow developed a nine-category typology based on levels of government and market involvement. Funding was used to measure government influence and appropriability of research products was used to measure market influence.

Mallon and Bunton surveyed center directors affiliated with medical schools and identified a minority of centers as *power centers*.<sup>17</sup> These centers exerted strong influence on their universities. Academic leaders consulted directors of power centers, and the directors could go to the academic leaders for immediate resource allocation and general access to decision makers.

Two recent efforts have attempted to identify particularly influential types of URCs. Bozeman and Boardman focused on multipurpose, multidiscipline university research centers (MMURCs).<sup>16</sup> They noted that MMURCs have assumed a role similar to national labs, addressing problems through multiple disciplines and large-scale R&D. These centers focused on complex policy-related research and were accountable to numerous internal and external stakeholders.

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Universities, Industry, and Government in Collaboration: A Review of the Literature on Research Centers Jennifer M. Miller *centers*.<sup>17</sup> These centers exerted strong influence on their universities. Academic leaders consulted directors of power centers, and the directors could go to the academic leaders for immediate resource allocation and general access to decision makers. However, Friedman and Friedman noted that centers at medical schools were less likely to be freestanding and more likely to be time-limited than were other URCs.<sup>18</sup> Identifying influential URCs and managing their influence has remained an important consideration.

Even more recently, mission and motivation have emerged as important dimensions in the classification of URCs. One such attempt at categorizing URCs emphasized formal and informal transfer mechanisms.<sup>19</sup> By considering motivations, structures, and types of outputs, they identified three types of centers. Boundary pushers had a fixed structure with formal transfer processes and emphasized general research. Expertise builders engaged in a mix of basic and applied research and produced formal and informal outputs. These centers had fixed transfer processes but were also active in developing new transfer mechanisms. Problem solvers were motivated to solve specific problems for industries or regions. They focused on applied research, emphasized flexibility in structure and transfer processes, and produced more informal outputs.

A similar effort by Flynn et al. categorized URCs based on the primary motivation for their creation.<sup>20</sup> This typology included technical-support processing centers that focused on proposal development, thematic-driver centers dedicated to a specific research area, and organizingculture centers that endeavored "to create and maintain an organized and sustainable collective research culture."<sup>21</sup> Technical support and organizing culture centers were university-driven, consistent with the idea of entrepreneurial universities,<sup>22</sup> while thematic centers were more likely motivated by external funders. Flynn et al. praised the organizing culture model for its potential to result in general growth in research programs across multiple related themes.<sup>23</sup> However, an earlier study had found that URCs were created primarily due to an entrepreneurial faculty member seeking external funding, the desire to conduct interdisciplinary research, and to increase autonomy from departments.<sup>24</sup> The Flynn et al. typology may be more normative than descriptive.

URCs have been of interest to social scientists both to study the centers themselves and as a setting to study other activities, such as collaboration or technology commercialization.

Future work on categorization of URCs should focus explicitly on the research and administrative perspectives of those likely to use the classifications. Current classification systems seemed to focus primarily on the concerns of higher education administrators. A classification based on characteristics of interest to various types of industry partners would be useful. Santoro and Chakrabarti empirically categorized URCs as network or problem oriented based on information from partner firms.<sup>25</sup> However, their work created only two categories that corresponded to existing classifications of host universities by tier. A more granular taxonomy with a theoretical rationale rooted in the URC concept might be more useful.

#### IDENTIFICATION OF UNIVERSITY RESEARCH CENTERS

URCs have been of interest to social scientists both to study the centers themselves and as a setting to study other activities, such as collaboration or technology commercialization. Social scientists have used several resources to identify URCs as samples or settings for study. First, the *Research Centers Directory* lists research centers in the United States.<sup>26</sup> As a sampling frame, it defines research center very broadly.



Universities, Industry, and Government in Collaboration: A Review of the Literature on Research Centers Jennifer M. Miller Partnerships: A Compendium of State and Federal Cooperative Technology Programs is another valuable resource to identify and gather information about centers receiving government funding.<sup>27</sup> The NSF Web site, www.nsf.gov, lists the centers its programs currently support. These resources could be useful for technology transfer professionals looking to connect with peers managing similar relationships with URCs.

#### CONTEXT AND CHALLENGES

The URCs that serve as the focus of this review come mainly from the NSF-led initiative, beginning in the 1980s, to create government-funded research centers at universities. The first challenge these NSF centers were asked to confront was to improve U.S. competitiveness in world industrial markets. The implementation of research centers introduced conflicts with academic governance structures and culture.

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Other challenges have been sustainability and developing effective center management practices. The following section discusses challenges that face university research centers in competitiveness, conflict with academic institutional structures, management practices, and sustainable finance and leadership.

One of the most fundamental challenges for URCs has been tied to one of the driving forces for their creation: an attempt to promote the competitiveness of U.S. industry in global markets.<sup>28</sup> Some authors have expressed skepticism about whether these substantial investments in this form of collaborative research would make U.S. industry more competitive.<sup>29</sup>

Devine, James, and Adams expressed specific concern about URCs as an institution suited to achieving this goal: "Because of their organizational structure, such centers essentially are precluded from the development of commercializable products or processes as their primary goals. Rather, the prime objectives include expansion of general knowledge, graduate student education, and redirection of university research toward interdisciplinary, industry relevant problems."<sup>30</sup>

Hetzner et al. observed that industrial partners were primarily large firms that may have been participating for corporate citizenship rather than competitiveness reasons.<sup>31</sup> They proposed that projectbased support for university-industry partnerships might be more suited to advancing competitiveness and innovation. Less attention appears to have been paid to the challenge of competitiveness during the relatively prosperous 1990s. However, current economic conditions and economic stimulus funding for science and technology may return this challenge to the forefront.

In 1972, Ikenberry and Friedman observed that URCs are *at* the university but not *of* the university.<sup>32</sup> Regarding conflicts with academic governance and culture, Friedman and Friedman identified four identity crises facing URCs.<sup>33</sup> These centers were not central to defining the university, lacked a standard intellectual core, had inconsistent naming and structural conventions, and were often marginalized within the university community by

Reflecting this perception of URCs as tangential to a university's mission, Mallon used the analogy of a city and its suburbs to describe the university's discipline-based core and its peripheral organizations, such as research centers.<sup>34</sup> He focused on the influence of these suburbs on institutional decision-making.



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a narrow and applied research focus. Reflecting this perception of URCs as tangential to a university's mission, Mallon used the analogy of a city and its suburbs to describe the university's disciplinebased core and its peripheral organizations, such as research centers.<sup>34</sup> He focused on the influence of these suburbs on institutional decision-making. This model revealed that disjointed governance resulted in flexibility and responsiveness while allowing departments and the academic core to maintain consistency. While universities have always included some peripheral functions, Mallon noted that suburbs have grown to include corporate alliances, public-private research, forprofit divisions, spin-offs, and technology transfer.

There has been disagreement about whether sustainability was in fact an important property of centers. For example, early work by Ikenberry and Friedman noted centers' impermanence, and Teich questioned whether self-perpetuation should be a goal.<sup>39</sup> More recently, Rogers et al. considered their relatively time-limited nature an important characteristic of URCs.<sup>40</sup>

He predicted the following trends in university governance as a result of disjointed decision making: a reduced role for formal faculty governing bodies, less faculty unity as alternative employment arrangements become more common and less marginalized,<sup>35</sup> influence over institutional decisions by faculty who bring in game-changing external funding, and greater influence for peripheral functions such as URCs with ties to external markets.

Mallon observed that centers have previously been thought to have little influence on university governance, but that their influence may have increased as they became increasingly involved in recruiting faculty, generating revenue, and staffing with postdoctoral researchers and research scientists. This influence was most evident in power centers.<sup>36</sup>

In terms of center management, Bozeman and Boardman noted the following inherent challenges facing government and industry sponsors conducting research in a university environment: the academic calendar and educational mission, the emphasis discipline-based reward systems place on open publication by peerreviewed journals, faculty researchers' impatience with accountability procedures, and faculty researchers' commitments to individual research agendas.<sup>37</sup> They also described ongoing management challenges for center leadership when resources became spread across too many partnerships or ineffective partnerships needed to be terminated. The greatest management accomplishment for center directors was bringing together multiple organizations and disciplines.

As the center model became more established, the question of sustainability for individual centers became more salient. Many center funding programs were structured so that government support ended after a predetermined amount of time. For example, the ERC program allowed for a maximum of eleven years of funding. The intention was for centers to secure other funding, including continued support from industry. It has not been clear that industry and state government partners would continue support for these centers if they were no longer able to leverage significant federal money.<sup>38</sup> There has been disagreement about whether sustainability was in fact an important property of centers. For example, early work by Ikenberry and Friedman noted centers' impermanence, and Teich questioned whether self-perpetuation should be a goal.<sup>39</sup> More recently, Rogers et al. considered their relatively time-limited nature an important characteristic of URCs.<sup>40</sup>

#### Collaboration

Collaboration has been the main reason to do research within the structure of a URC rather than in some other institutional



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form.<sup>41</sup> URCs have provided a setting to study a broad range of collaboration activities and outcomes, with several studies particularly focused on university-industry collaboration and technology transfer outcomes.

Boardman and Corley compared noncenter faculty with center faculty in terms of percent of time spent collaborating with colleagues of various types, including the immediate work group, others at the home university, industry partners, researchers at other U.S. universities, and researchers outside the United States.42 They found that center faculty spent more time collaborating and faculty affiliated with centers with industry ties spent more time collaborating with industry. They also found that centers decreased collaborations with researchers at other universities and increased involvement in government lab and international collaborations.

There has been conflicting evidence about interdisciplinarity within URCs. An early but influential study found a lack of interdisciplinary collaboration.<sup>43</sup> In Friedman and Friedman's 1982 survey, "[o]nly about one-third of ORU directors reported faculty interactions with more than one department. The notion of faculty and staff from different departments working together on a single project is also not borne out by the data. Only 28 percent of the ORU directors sampled thought that was a good description of their research mode of operation."<sup>44</sup>

More recent work, however, has confirmed that URCs are achieving collaboration across disciplines. Mallon and Bunton found that 42 percent of medical center URCs described their research as interdisciplinary, and 39 percent described it as multidisciplinary. The membership of an interdisciplinary URC has also been considered as a social network.

Aboelela et al. conducted a social network analysis of an interdisciplinary center researching antimicrobial resistance. From inception through its first year of operation, the URC network grew and became more centralized, consistent with a more hierarchical form.<sup>45</sup> The average size of members' effective networks increased from two to nearly seven people. However, the density of connections among the disciplinary groups decreased somewhat. The results generally reflected the first half of the year as successfully building a network and encouraging team members to get acquainted. In the second half, subgroups emerged through collaboration on grant proposals.

With a sample of scientists and engineers at NSF and Department of Energy URCs, Bozeman and Corley developed a framework for understanding researchers' individual-level strategies for collaboration.<sup>46</sup> Their focus was on mentoring strategies in which faculty collaborated with graduate students, junior faculty, and researchers from under-represented demographic groups; an activity they hypothesized was especially valuable in developing scientific and technical human capital. They found that URC faculty with a mentoring approach to collaboration had a more favorable view toward universityindustry collaboration and applied research.

Attention has recently turned to spatial issues related to URC collaboration. Taking a very large-scale perspective on spatial issues in collaborative research, Clark noted that the United States has not used a *conscious geography* to consider the spatial distribution of production and innovation in relationship to its NSF URC programs.<sup>47</sup> That is, the geographic distribution of resources and productive and innovative capacity has not been an integral and systemic design factor in U.S. centers programs.

She described two models: a coordinated model in which regions were sites receiving public investment and a competitive model in which states and regions invested their own revenues to compete for economic development opportunities driven by university R&D. These were



Universities, Industry, and Government in Collaboration: A Review of the Literature on Research Centers Jennifer M. Miller contrasted with a collaborative model in Canada, where centers were horizontally networked across the country and vertically networked with regional industrial clusters and multiple levels of government. She suggested potential advantages of collaborative over coordinated and competitive models.

Toker and Gray found strong support for the importance of spatial factors as an influence on collaboration in URCs.<sup>50</sup> Their study showed that spatial arrangements that gave scientists visibility and easy physical access to colleagues resulted in more consultations and that these consultations were associated with increased innovation activity.

Other studies have considered spatial issues within the URC itself. Goodman introduced the planning process for a new cancer research facility on the University of California, San Diego campus.<sup>48</sup> He noted that the objectives of the center included facilitating interaction among physicians and cancer researchers; bringing together basic, clinical, and behavioral science efforts; and fostering research collaboration.

Goodman and Weissberger updated the case with lessons learned throughout the implementation process, including their approach to combining the separate cultures of the medical center and the medical school.<sup>49</sup> Toker and Gray found strong support for the importance of spatial factors as an influence on collaboration in URCs.<sup>50</sup> Their study showed that spatial arrangements that gave scientists visibility and easy physical access to colleagues resulted in more consultations and that these consultations were associated with increased innovation activity.

These accounts of URC design did not address any issues related to universityindustry collaboration. Technology transfer professionals might consider how they could contribute to the facilities' planning process and whether they would benefit from being embedded in URCs and, therefore, in proximity to URC researchers.

A recent paper has attempted to model collaboration in URCs more generally. Alexopoulos et al. drew on the knowledgebased theory of the firm—where organizations derived advantage by allowing nonmarket logic to govern their economic activities—to develop a model of URCs as collaborative communities.<sup>51</sup> In their model, mission and goals influenced leadership and management practices, driving knowledge-related behavior and creating collaboration capability, resulting in innovation and value. A strength of this model was its inclusion of micro, meso, and macro levels of organizational behavior.

These studies confirmed the importance of collaboration to the function of and rationale for URCs. They highlighted the need to consider multiple types of collaboration, beyond the early concern for interdisciplinarity. They also connect collaboration within URCs to innovation outcomes and to the development of science and technology human capital.

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#### UNIVERSITY-INDUSTRY COLLABORATION

Because the impetus to create URCs came from industrial competitiveness concerns, collaboration with industry and technology commercialization have been prominent themes in the study of URCs. Etzkowitz and Kemelgor went so far as to imply that university-industry interaction in URCs could take the place of a formal technology transfer program.<sup>52</sup>

However, it seems equally plausible that



Universities, Industry, and Government in Collaboration: A Review of the Literature on Research Centers Jennifer M. Miller the interaction in centers may catalyze increased need for technology transfer programs. Empirical work on URCs has moved from an early focus on the center level to a more recent focus on individual center constituents, such as firms or faculty members. However, other recent work has taken a broad view of centers' economic impacts beyond the university.

Several studies have considered how URC affiliation affects faculty. Empirical evidence has lent support to the proposition that faculty affiliated with URCs were more likely to engage in several types of interactions with industry. In their study of the effects of industry contracts and grants, Bozeman and Gaughan found that URC-affiliated faculty had higher ratings on a scale of industrial involvement.53 Both industry and federal contracts and grants were also found to independently predict industry interaction. This finding built on their earlier work, which had established that center scientists with ERC or STC grants or prior industry experience were 1.9 times as likely to receive an industry grant.54

Boardman found that tenured and tenure-track faculty affiliated with biotechnology URCs sponsored by NSF's centers programs were more likely than their counterparts in other URCs to be communicate with industry.<sup>55</sup> The effect was not found for researchers in biotechnology URCs not sponsored by NSF and did not extend to tangible interactions like patents and publications. A study of faculty affiliated with URCs found that tenure-track faculty valued basic research more than commercially relevant research, relative to their tenured colleagues.<sup>56</sup>

This may have been because the tenure process itself placed a higher value on basic research. A potential implication of the study was that further research should be done to support reassessment of faculty promotion and reward systems, a topic of interest to technology transfer professionals because reassessment might place greater weight on technology transfer outcomes. A number of studies considered firms' interactions with URCs. Santoro and Chakrabarti found that firms affiliated with URCs could be separated into clusters: collegial (22 percent), aggressive (46 percent), and targeted (32 percent).<sup>57</sup> The predominantly large, high-tech firms described as collegial were less concerned about the flexibility of universities' intellectual property policies than were the other two types of firms.

Aggressive firms' involvement with URCs included noncore technology to a greater extent than did that of targeted firms. The collegial model of firm involvement was consistent with earlier findings from evaluation of the IUCRC program.<sup>58</sup> The predominance of the aggressive and targeted approaches in the more recent study may indicate a change in firm motivations over time.

Some evidence indicated that URC participation affected firms by slightly increasing their patenting activity and R&D investment.<sup>59</sup> They found some support for their argument that firms joined URCs because they valued university technology transfer and that faculty consulting, joint research, and hiring graduate students were the main channels of influence.

A survey of firms affiliated with ERCs found that firms' affiliations with these centers resulted in benefits primarily in the area of knowledge transfer.<sup>60</sup> These results also confirmed that firms placed a high value on hiring center students and graduates. Some firms that affiliated with IUCRCs may have avoided R&D costs they would otherwise have occurred, but the extent to which this motivated their participation was unclear.<sup>61</sup>

Technology transfer professionals may find applications of this work in building relationships with faculty, understanding the diverse benefits valued by partner firms and how center collaborations deliver those benefits, and being alert for changes in firm priorities.



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#### **Evaluation**

Because of the resources involved, URCs typically have faced a great deal of scrutiny and accountability pressure. There has been a corresponding attention to URC evaluation topics in the literature. This section first reviews publications that specifically address evaluation methodology for URCs, then considers evaluations that apply these methods to give a sense of how they work in practice and the results that have been documented.

#### **METHODOLOGY**

A substantial body of methodological recommendations for the evaluation of public R&D, including URCs, has been provided by Ruegg and Feller based on their review of the Advanced Technology Programs evaluation program.<sup>62</sup> A key underlying concept that guided their evaluation methodology was the logic model, a diagram of program elements showing "linkages among mission, activities, resources (inputs), outputs, outcomes, and impacts" in preparation to identifying performance measures. Anderson, et al. used concept mapping to develop a logic model for evaluation planning for a Centers for Disease Control-funded program conducting applied research on disease control and prevention.63

Technology transfer professionals may find applications of this work in building relationships with faculty, understanding the diverse benefits valued by partner firms and how center collaborations deliver those benefits, and being alert for changes in firm priorities.

Gray reviewed evaluations of government supported industry-university cooperative research in ERC, STC, federal IU-CRC, and state IUCRC programs, including published and unpublished evaluations.<sup>64</sup> He described evaluation practices in terms of a framework with ex-ante, interim, and outcome evaluation approaches used at the program, center, and project levels of analysis. He found that these centers have been extensively evaluated, mostly at the interim and outcome stages.

Modified peer review—including both scientific reviewers and those from economic, managerial, and technical perspectives—was the most prevalent technique. Industry-focused peer evaluation and local economic development ex ante review were two novel center-level approaches. Project-level review, or comparative evaluation of the multiple individual research activities undertaken by a given center, seemed to be the most problematic, as some center research was considered to be low quality.

Project-level review, or comparative evaluation of the multiple individual research activities undertaken by a given center, seemed to be the most problematic, as some center research was considered to be low quality.

Gray described the technique of improvement-oriented evaluation employed at IUCRCs.<sup>65</sup> This effort started as a traditional judgment-oriented evaluation but explicitly added program improvement to provide evaluations that documented outcomes, promoted continuous improvement based on data and regular feedback, and communicated best practices. These evaluations were distinctive in their use of on-site evaluators to conduct evaluations, communicate feedback, and help center directors improve performance.

#### **EXAMPLES**

This section presents examples of published evaluations of URCs, focusing on a variety of economic development, technology transfer, and other outcomes.

Technology transfer has been measured in terms of intermediate and final outcomes. Cohen et al. collected descriptive and outcome data from university-industry research centers.<sup>66</sup> The authors reported output and intermediate outcomes in several categories: inventions, patent



Universities, Industry, and Government in Collaboration: A Review of the Literature on Research Centers Jennifer M. Miller applications, patents granted, licenses, copyrights, trade secrets, prototypes, new products, new processes, improvements to existing products and processes, increased efficiencies in existing R&D projects, and new R&D projects.

Notably, 63.3 percent of their respondents said technology transfer was an important objective, but only 6.3 percent of center effort was allocated to technology transfer. Similarly, Mallon and Bunton found more than 90 percent of medical school URCs devoted little or no effort to patenting and technology transfer and indicated that such activities were given low priority.<sup>67</sup> Examining intermediate outcomes, or technology transfer interactions, trust, geographic proximity, and the flexibility of university policies for intellectual property were found to be positively associated with technology transfer activity.68 The existence of barriers to engagement in technology transfer and possible differences between medical school and other URCs are questions for future research.

Two studies have focused on technology commercialization outcomes at the University of New Mexico. Rogers et al. inventoried URCs and developed a framework to evaluate their outcomes, including technology transfer.69 They defined eight dimensions of effectiveness: technology transfer, placement and training of graduate students and staff, budget, publications, staff size, duration, role of director, and multidisciplinarity. However, the use of inputs, such as budget and staff size, as measures of effectiveness seemed problematic and may have contributed to the study's conclusion that larger centers were more effective.

In a subsequent paper, Steffensen, Rogers, and Speakman presented case studies of six spin-offs.<sup>70</sup> These cases explored facilitating mechanisms, planned and spontaneous spin-off processes, and the potential for spin-off companies to promote economic development. They listed distinct qualities of spinoffs as outcomes of URCs: creation of jobs and wealth, role models for future entrepreneurs, transfer of technology, jobs for graduates, and ownership of part of the new company by the university.

One important outcome for URCs has been the decision by industry partners to renew memberships. Gray, Lindblad, and Rudolph found that professional networking, research relevance, and quality of administrative services, including those related to intellectual property rights, were significant predictors of firms' intention to renew.<sup>71</sup>

About 80 percent of firms surveyed indicated that they would probably or definitely renew their memberships. In this study, no predictive value was found for structural characteristics of centers, such as size. Rivers examined factors at the individual and suborganizational level that influenced firm renewal decisions, finding that social networks affected this decision, as did perceptions of center characteristics, such research relevance and the extent to which membership fees leveraged other funding.<sup>72</sup> The membership fee was found to mediate the effect of the center's intellectual property agreement on membership decisions.

Rivers examined factors at the individual and suborganizational level that influenced firm renewal decisions, finding that social networks affected this decision, as did perceptions of center characteristics, such research relevance and the extent to which membership fees leveraged other funding.<sup>72</sup>

Some approaches to URC evaluation have looked broadly at economic development impacts. One such study found that the Packaging Research Center (PRC), an ERC with highly successful industrial partnerships in microelectronics, had a total impact on the Georgia's economy of \$351 million over a ten-year period.<sup>73</sup> \$192 million of this was the center's direct impact, and \$159 million was indirect and



Universities, Industry, and Government in Collaboration: A Review of the Literature on Research Centers Jennifer M. Miller induced impact. From the perspective of state government, the study claimed a 1,079 percent return on investment for Georgia's \$32.5 million investment.

The following elements were used to quantify the economic impact: external income, including NSF support; sponsored research; membership fees; in-kind support; income from intellectual property and faculty consulting income; spending by out-of-state attendees at center workshops; increased employment; and value of PRC graduates hired by and pro-bono assistance to in-state firms.

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Indirect effects were due to purchases by PRC-related organizations and induced effects were purchases made by employees from PRC-related earnings. This study employed the RIMS II methodology to quantify indirect and induced impacts by selecting those direct impacts believed to have secondary effects, selecting appropriate multipliers, and using those multipliers to estimate indirect and induced effects.<sup>74</sup>

Roessner later expanded on this methodology by also including impacts at the national level.<sup>75</sup> The study examined three ERCs and found impacts ranging from \$22 million total impact on the U.S. economy over nine years and more than \$121 million in regional impact on five partner states to \$173 million total impact on the U.S. economy over ten years and \$87 million in regional impact on California to \$46 million total impact on the U.S. economy over seven years and \$256 million regional impact on Michigan.

The lower impacts for the first two centers were attributed to missing data rather than to actual differences in impacts. The conceptual framework for national benefits was based on Ruegg and Feller.<sup>76</sup> This model calculated returns to innovation from consumer surplus, equating social benefits to the sum of firm profits and cost savings. The report also discussed data collection issues, especially those relevant to time-limited URCs. This study also expanded the methodology to include measures of intangible outputs, such as graduate employment, and included an appendix of data sources and methods.

Bradshaw et al. demonstrated that economic development impacts could also be identified from problem-focused or science-push URCs.77 Their case study of the Toxic Substances Research and Teaching Program (TSRTP) at the University of California, a program which included a multidisciplinary URC, emphasized benefits in the areas of knowledge, employment, and applications of technology leading to product innovation. Their approach emphasized the importance of the career trajectories of funded students and faculty in realizing economic development benefits. They identified more than \$445 million in additional grants to program students and faculty, 200 jobs created, and 25 or more spin-off companies attributed to the TSRTP and related leveraged funding.

These broad economic development evaluation approaches are impressive in their breadth and the high level of benefits they attribute to URCs. However, lack of a counterfactual and concerns about the appropriate application of multipliers to calculate economic impact limit confidence in the specific economic benefits claimed.

#### Conclusion

The review concludes with a synthesis of the literature, presentation of a systemic model of URCs in context, and recommended directions for future URC evaluation.

Research centers have been compared to a collection of interdependent strategic alliances.<sup>78</sup> URCs can be modeled as a system of the contributions government,



Universities, Industry, and Government in Collaboration: A Review of the Literature on Research Centers Jennifer M. Miller industry, and university stakeholders make to URCs and the benefits they seek in return. This model considers the URC as an alliance with both formal and informal aspects. Based on the importance of trust to the success of these collaborative ventures and the forward-looking focus of industry partners in decisions to affiliate, this model posits that a URC can be successfully established if sufficiently credible formal or informal contracts support agreements that the parties will make the expected contributions and that the desired benefits will be obtained and distributed to the interested participants.<sup>79</sup>

The URC will be sustainable if the strategic alliances can maintain a "norm of reciprocity" in pursuit of a long-term goal.<sup>80</sup> This model is especially useful for addressing the challenge of sustainability for research centers. It also reflects the progression in the research on URCs from the center level to increased consideration of issues affecting constituent parts of centers, such as faculty or firms, and situates each part within a system.

The systemic model considers contributions by and benefits to each category of URC stakeholders. Government typically contributes to URCs as a source of funding. This funding is provided in exchange for benefits including technology for public good applications, such as defense and public health, as well as benefits in the areas of international competitiveness and economic development that are typically mediated through industry.

An important consideration here that currently receives scant attention in the literature is the geographic correspondence between the government entity providing the funding and industry-mediated market outcomes. The systemic model can address this by incorporating nonappropriable outcomes that may have benefits outside the sphere of the sponsoring governments and industries. Technology transfer professionals should consider appropriability of outcomes as a factor that helps determine how their universities contribute to regional or national economic development.

Industrial support of URCs typically comes in the form of sponsored research, membership fees, or in-kind contributions.<sup>81</sup> Industrial participants consider access to ideas and hiring graduates as the main benefits of participation.82 Access to intellectual property through the university's technology transfer office may also be a benefit of participation, as can an enhanced reputation through affiliation with a top school.83 Commercialization of intellectual property is one way firms contribute to global competitiveness and economic development, although this contribution can also come through knowledge transfer.

Based on the importance of trust to the success of these collaborative ventures and the forwardlooking focus of industry partners in decisions to affiliate, this model posits that a URC can be successfully established if sufficiently credible formal or informal contracts support agreements that the parties will make the expected contributions and that the desired benefits will be obtained and distributed to the interested participants.<sup>79</sup>

Considering universities at the macroorganizational level, the contributions they make to URCs are primarily in terms of facilities, human resources, and funding. Since URCs are rarely self-sufficient financially, universities may also contribute seed, bridge, or other funding.<sup>84</sup> Universities may benefit financially from indirect cost allocations in government funding and from licensing revenue. While URCs may not be the profit centers they have often been considered, these types of funding diversify the university's support base.

Other benefits to universities are mediated through faculty and students. As faculty benefit from research opportunities, access to equipment, and personal prestige from center affiliation and stu-



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dents gain educational and job placement opportunities, a university gains institutional prestige.85

This model points to an understanding of research centers as a three-legged stool, with support coming from government, industry, and the university. For a URC to maintain its mission in the areas of education, economic development, and industrially relevant research, it needs a sustainable way to receive ongoing support from each entity. The relative importance placed on any single benefit or input is likely to vary among centers and individual constituents, but each element bears consideration when evaluating the center's sustainability as a system.

The withdrawal of support from any entity is likely to result in a transformation of the center's mission to direct its work toward the interests of its remaining active stakeholders. The withdrawal of government support, in particular, would be expected to result in greater industry influence on academic work through sponsored research and less concern about the geographic or political distribution of industrial benefits from center research. A potential policy implication is that government support of URCs should be sufficiently flexible to sustain the center over an appropriate time frame. Evaluation should consider an array of benefits and the appropriate and sustainable balance between contributions and benefits for all stakeholders.

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Jennifer M. Miller is a doctoral student in the Department of Public Policy at the University of North Carolina at Chapel Hill. She is the winner of the AUTM Foundation's 2010 Graduate Student

Literature Review Prize. She can be reached at jennifermiller@unc.edu.

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