SCIENCE AND SOCIETY

A US perspective on technology transfer: the changing role of the university

Lita L. Nelsen

Technology transfer — the patenting and licensing of university research results — is now a standard part of university activities in the United States. The effect on the economy, and particularly on new start-up companies, is large. As this activity is emulated around the world, several questions arise. What lessons can be learned? How will it change the university — for good or bad? How can the change be thoughtfully controlled?

Technology transfer means many different things in interactions between universities and industry. It can signify the publication of research, the delivery of seminars, consultancy, or — perhaps most importantly — the transfer of the skills and knowledge that a student who is graduating from a research university, and is newly educated in the state of the art, brings to his or her future employers. Formally, however, the term denotes the management of intellectual property from research that is sponsored by a company but carried out at a university (sometimes confusingly referred to as 'collaborative research'), and the licensing of university intellectual property to both established and start-up companies. Although university technology transfer has benefited many industrial sectors, from software to new materials, the biggest effect seems to have been in the biotechnology industry, as most US biotechnology companies trace their origins to university laboratories and to licences for university-owned technologies.

In the United States in 1980, the passage of the Bayh–Dole Act transformed the process of technology transfer from universities and began a revolution in how to view the 'proper' role of the university in its interactions with business and in economic development. It had both national and worldwide effects.

The Act allowed universities to own the patents on inventions made using Federal funding. As most US university research is funded by the Federal Government, these universities were now in control of most of the patents generated from their research. Under the Act, universities were allowed to license the inventions to companies and to receive royalties, and were required to share an (unspecified) fraction of the royalties with the inventors. Effectively, a financial incentive was included in the law to encourage both universities and investigators to participate in the process of technology transfer. The patents would also provide protection from foreign firms copying the technology.

Making deals with industry

The primary objective of the Bayh–Dole Act, as shown in the legislative history, was to encourage industry to invest in new technology and spur US economic competitiveness. Out of this investment have come new products for the public, new jobs, and whole new businesses. University technology, in particular, is high risk as it usually involves state-of-the-art findings for which neither technical feasibility nor market acceptance is proven. The universities grant licences to their patents to those companies that are willing to invest in these high-risk, early-stage technologies — and the protection provided by these patents offers an incentive to the companies to take that risk.

Frequently, an exclusive licence is necessary to persuade companies to enter into such an agreement. This requirement is exemplified by the development of a drug from a basic research finding: without a patent on the drug to protect it from competition, a pharmaceutical company will not invest the hundreds of millions of dollars in development and clinical testing that are needed to bring a new drug to market. As fewer than two in a hundred new research compounds succeed in going from the laboratory into a final approved pharmaceutical product, a company must be able to protect itself from competition — through patents — to recoup its investment in development.

Exclusive licences are also required for venture capitalists to invest in start-up companies based around unproven, early-stage university technology. Although start-up companies were a relatively rare occurrence in university licensing in the first decade after the Bayh–Dole Act, in the fiscal year 2001–2002, licences to start-up companies constituted 12% of all license and option agreements that were reported by US and Canadian universities and other non-profit research institutions (see the 2002 Association of University Technology Managers (AUTM) Licensing Survey Summary in the online links box).

Learning how to do technology transfer

In the first decade after the Bayh–Dole Act there was a slow growth in the number and capability of technology transfer offices in US universities. Growth was limited by a dearth of people skilled in the practice of technology

Box 1 | Patenting and publication rules for scientists

In most countries in the world, a patent must be filed in one country (often the home country) before 'public disclosure' of the invention. Public disclosure includes either written or oral disclosure in sufficient detail that the invention could — at least hypothetically — be duplicated by another person who is 'skilled in the art'. Filing of the patent in other countries can then be delayed for up to a year.

The US system is different, and allows for the filing of a patent up to a year after the invention is published in writing. This year is known as the 'grace period'. However, if the US is the first country in which the patent is filed, and this filing occurs after any written or oral public disclosure, patents will be barred in most other countries. So, most US universities will hope to get the patent filed before public disclosure, so that worldwide patents can be obtained. This is particularly true in the pharmaceutical field, in which worldwide markets are sought to justify the initial costs of development and clinical testing of drugs.

Researchers often forget that published abstracts (including those that are published online) and poster presentations will qualify as 'public disclosure' if the invention is sufficiently well-described.

transfer (it is a profession that is still learned primarily on the job), and by the reluctance of university administrations to invest in filing patents and hiring staff when they had no assurance that licensees could be found and that investment would be returned by royalties. There was also the matter of educating the researchers, making them aware of the utility of patenting their technology, helping them recognize what constituted an 'invention' — particularly in the life sciences — and assuring them that patenting would not hinder their ability to publish, provided that the process was handled well (see BOXES 1 and 2).

A few universities nevertheless — either by chance or by extraordinary foresight — 'hit the lottery', with single inventions that brought in many millions of dollars per year (BOX 3). These blockbusters had both positive and negative effects on the attitude of university administrations towards technology transfer. On the positive side, the blockbusters attracted attention and showed that technology transfer could be financially profitable for a university, increasing the incentive for the administrations to invest in developing a technology transfer office. On the negative side, however, some universities greatly overestimated their own probable economic returns, and invested large amounts of money in their technology transfer operations with the expectation of rapid riches, without understanding the low probability of a blockbuster invention arising at their institution.

"…the passage of the Bayh–Dole Act transformed the process of technology transfer from universities and began a revolution in how to view the 'proper' role of the university in its interactions with business and in economic development."

The start-up phenomenon

Beginning in the 1990s, interest in technology transfer increased substantially in universities, and interest in start-up companies based on university technologies also accelerated (for examples, see the 2002 AUTM Licensing Survey Summary in the online links box). Several forces were instrumental in driving this increase in interest. First, an even greater emphasis was placed by large companies on short-term earnings — and short-term results. This, in turn, made it difficult to invest in very early (university-stage) technology, which would require substantial investment and many years to bring to market. Second, a trend developed on the part of large companies to 'outsource' many of their activities — including part of their research and development — to reduce staff and to allow changes in strategy without a considerable amount of internal disruption.

Third, an increase in the available venture capital was seen, which was led in part by the ability of pension-fund managers to invest in venture capital funds. Fourth, the success of a few university start-up companies that paid back their investors even beyond their expectations was well-publicized. These instances resulted in the gain of millions of dollars by their universities from the equity shares that the universities got in return for their intellectual property. Both venture capitalists and university administrators took notice. Fifth, a 'role model' (or copycat) phenomenon occurred, in which university faculty members became aware of their peers' successes as founders of companies, and became interested themselves.

Local, national and even international governments took note of the trend towards the formation of university start-up companies, and of economists' studies showing that small companies were the main source of job growth. Expectations rose that universities would be an essential source of new economic development for the 'knowledge age', through entrepreneurship based on the universities' technological discoveries and intellectual-property protection.

In the US, many state legislatures provided funds for their universities to expand their technology transfer activities, including establishing 'incubators' (subsidized laboratories and other facilities that housed new companies and provided advice and business services). The response of other countries to the successes of US technology transfer was also notable. Both Japan and Taiwan, for example, changed their legislation governing university intellectual property and the regulations that governed faculty members' interactions with industry, in acts that both countries referred to informally as their 'Bayh–Dole' acts. Germany made radical changes in policies governing the ownership of patents made by university investigators — moving away from personal ownership to ownership by the universities. The UK government moved to regularize intellectual-property-ownership policies in British universities (a process that is still in flux), and devoted hundreds of millions of pounds to various initiatives to improve their universities' interactions with industry and to encourage entrepreneurship based on university-derived technologies. Portugal, Denmark, Finland, France, the Netherlands and other European countries began, and continue, efforts to increase their university technology transfer activities. Developing countries such as South Africa, Brazil and India are investing in building technology transfer capability in their universities and research institutions, and the trend continues even into some of the lesser developed countries.

It is not clear which of these initiatives worldwide will have the financial ability and sustained commitment to invest over the decade or longer that is required to build sustainable university technology transfer organizations. Certainly, funding by US state legislatures has been erratic and many of the initiatives have, predictably, failed because of a lack of sustained commitment. It can only be hoped that many of the mistakes of US governments and university administrations can

be avoided. Foremost among those mistakes are unrealistic expectations — for example: that a sustainable technology transfer organization can be built with a small commitment of funds and personnel; or (worse) that a bolus of investment up-front and hiring of a high-priced business leader with visions of building a highly profitable enterprise on the basis of commercial models will result in financial success within a couple of years; or even that the effect on the local (or even national) economy will be significant within a few years; and (worst) that the financial returns to the university from technology transfer will be sufficient to support the university and remove the need for government support.That last idea was surprisingly prevalent (and is still prevalent in some spheres), despite 20 years' worth of data from US and Canadian universities with relatively mature technology transfer offices that show that the average university's income from royalties and start-up companies is about 3% of its research budget. The median is even lower, as the data are distorted by a few blockbuster patents.

Fortunately, both university administrations and government agencies worldwide are beginning to move their primary emphasis away from revenues and towards the other benefits of technology transfer, most notably: bringing products, particularly medical products, to the public; encouraging industry to use new technologies sooner, thereby modernizing the technological base of the economy — only through such incorporation of the latest technologies can the country's industry hope to compete in the world economy; local economic development through entrepreneurship; and finally, training of investigators and, notably, students to be aware of the potential applications of their research findings and to become involved in their translation into commercial reality. This last point can be expected to have an effect, not only on the university, but also on the industries in which the graduating students become employed. Revenue generation remains important in technology transfer, as few universities could afford to sustain a money-losing proposition for long and all universities treasure the discretionary income it can generate, particularly in hard economic times, but expectations are becoming more realistic.

"…is technology transfer to industry a purpose of the university, or a useful by-product of the educational and research enterprise?"

Box 2 | The complexity of technology transfer: lessons learned

One of the earliest important university inventions in the life sciences, the 'Cohen–Boyer patent', is an illustration of learning by both universities and faculty members. This invention was the core technology involved in gene splicing, and was developed by Herbert Boyer of Stanford University, California, USA, and Stanley Cohen of the University of California, San Francisco, USA. The researchers did not recognize the findings as a potentially patentable invention, and the results were published without any previous 'invention disclosure' having been filed with the university technology transfer offices. The potential commercial importance of the discovery, it is said, was brought to the attention of the Stanford Office of Technology Transfer by a journalist. Stanford and UCSF then decided to file a patent. US law allows a patent to be filed within one year after an invention is published; but almost all other countries prohibit the filing of a patent unless it is done before publication. So the Cohen–Boyer invention was patented in the US, but nowhere else. This patent earned more than $300 million in royalties; it is estimated that more than $100 million more would have been earned if the patent had been filed before publication and worldwide royalties were available.

The Cohen–Boyer licensing story shows the complexity of technology transfer and the role of professionalism. On the one hand, large amounts of revenue were lost because of the loss of foreign patent rights. On the other, the non-exclusive, low-cost broad licensing strategy that was devised by Stanford for this technology — complete with royalty-reduction incentives for early signers of licences — probably made the patent far more successful than it might have been with a less prudent strategy.

Defining the role of the university

Protection of intellectual property and technology transfer is now a standard part of university culture in almost all North American universities and in many others worldwide. Its success, however, has brought into focus the question of the role of the university in the economy. Simply put: is technology transfer to industry a purpose of the university, or a useful by-product of the educational and research enterprise?

The answer has many implications. For example, if technology transfer is seen merely as a useful by-product, it is easier to defend the 'traditional values' of academic research.Emphasis can be placed on longer-term 'discovery research' rather than solutions to short-term practical problems. Investigator-initiated research can be sustained, in which the investigator works on projects of personal intellectual interest, rather than sponsor-defined projects. Open research environments can be encouraged, as confidentiality is not required among members of the university's laboratories. Freedom of exchange of materials and data with academics in other institutions can also be advocated, so that researchers can build on each other's work. And, most importantly, prompt and free publication can be defended, whereby the investigator has the right, and even implied obligation, to publish their results without censorship by the company that is sponsoring the research.

On the other hand, if an avowed purpose (perhaps government mandated in some countries) of university research is 'to help industry', 'to make the nation's industry more competitive', 'to help build the economy through entrepreneurship', or even 'to generate income to support the university', then it is not clear in which situations the traditional academic values should prevail over more profitable or practical industrial standards. There is no natural law governing this predicament.

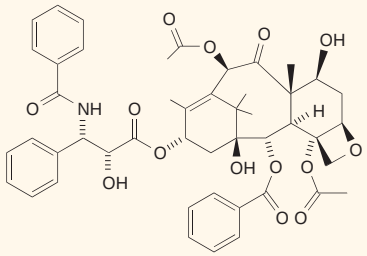
Similarly, if technology transfer (along with revenue generation) is a purpose rather than a by-product, it is more difficult for the university to answer such questions as: will we let the nascent start-up company use our laboratories — even though space is scarce for the university's own research; will we allow university personnel to work on development projects for the company; will we still insist on university ownership of its patents so that we can enforce diligent development and not let the licensee sequester the technology?

"…it is important that governments and universities themselves explicitly define where technology transfer stands in the priorities and purposes of their university."

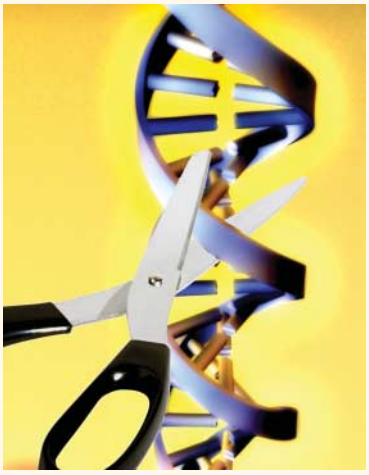
Box 3 | Hitting the lottery

A few university inventions — no more than a few dozen among more than twenty thousand that have been patented in the past 20 years — have resulted in more than $100 million to each of their universities. Examples are listed below.

- University of Florida's 'Gatorade' sports-drink patent, which was licensed along with the trademark.
- Michigan State University's patent on cisplatin (a chemotherapy drug).
- University of Wisconsin's patents on warfarin (an anticoagulant) and the use of vitamin D in milk.
- University of California, San Fransisco/Stanford University's Cohen–Boyer patent on the enzymatic splicing of genes and insertion into another organism ('recombinant engineering'; see also BOX 2).
- Columbia's 'Axel' patent on recombinant engineering in mammalian cells.
- Florida State University's patent on the synthesis of taxol (a chemotherapy drug).



Taxol



Finally, defining technology transfer and aid to industry as primary purposes of the university — so that they are equal with education, discovery and dissemination of knowledge — will risk distorting the direction of university research away from long-range, far-thinking projects towards shorter-term industrial problems. Basic research without obvious purpose — such as, for example, the 1950s research on inheritance of traits by fruit flies, which ultimately led to the genomics revolution — might be sacrificed. This would endanger the discovery of new technology breakthroughs for the next generation.

This said, it is important that governments and universities themselves explicitly define where technology transfer stands in the priorities and purposes of their university. If the university is to change its purpose towards a more industrial model, then so be it, but this should be a well-thought-out and -articulated decision, taking into account all the probable consequences — rather than something that 'just happens' by gradual erosion of the older standards.

Managing conflicts of interest

The US experience of the past two decades is informative in this area. In the late 1980s and early 1990s, technology transfer was growing in importance, and universities had not yet set explicit standards for technology transfer *vis-à-vis* traditional academic values, priorities in decision making, and conflicts-of-interest rules. Many articles were written warning that universities were — or, more likely, were about to be — 'selling out to industry'. But on the whole, this catastrophe didn't happen.

The leading US research universities addressed the concerns of potential distortion of the academic purpose away from open dissemination and into proprietary protection for commercial purposes primarily by discussing it openly. Through this dialogue a set of norms evolved, which had a very large effect on technology transfer practices and policies. The universities affirmed the priority of education, fundamental research, and dissemination of knowledge over technology transfer (although they still supported a robust technology transfer enterprise). At the present time, for example, no major university will accept a sponsored research agreement from industry that allows the sponsor to restrict publication of results (or to delay it for any but a short period of time to get patents filed). Essentially all of the major universities insist on university ownership of intellectual property arising from such research, and insist on full payment of indirect costs ('overheads') by the sponsor.

In licensing and start-up activities, universities have crafted conflicts-of-interest policies that set limits on the use of university facilities, define how students are protected from exploitation when undertaking research for industry, and delineate the separation of faculty members' obligations to the university from his or her activities with their start-up companies. The priority of getting the technology developed over 'making the most money' has been clearly articulated, and provisions assuring diligent efforts that ensure that the product reaches the market are a part of all licence agreements.

The dialogue among the universities continues to the present day, although more-sophisticated norms are developing as the universities learn from their technology transfer experiences. For example, universities are now discussing ways to ensure

"…there will continue to be a balancing act that is required to reap the benefits of university interactions with industry, while protecting the university's mission."

that medicines and vaccines that are produced under their licences are made available at accessible prices to developing countries. And they are developing norms for the licensing of technologies that are useful in research, to ensure that academic researchers can use these research tools unhindered by exclusive licences to others.

The effects of this dialogue and the explicit setting of priorities and policies have gone far in preventing the distortion of core values in US universities, in spite of thriving and growing technology transfer operations within them. David Baltimore, president of Caltech, in a recent review[1] of Derek Bok's 'Universities in the Marketplace: The Commercialization of Higher Education' (REF. 2), noted that, "at least at the major universities, their revenue-enhancing activities have not seriously distorted such [core] values. Universities have become more complicated, but the administration, faculty and students have been aware of the need for vigilance and have exercised it."

Technology transfer from universities will no doubt continue to grow in importance worldwide. And there will continue to be a balancing act that is required to reap the benefits of university interactions with industry, while protecting the university's mission. This mission will probably vary from country to country. It will be up to each government (and each university) to define this mission within the context of the country's needs, to articulate the mission and to craft policies that guide the university in its technology transfer activities. The major private US universities carefully define technology transfer as a by-product of discovery research — a perspective still also largely held in Europe. Yet, universities in the UK and in several Asian countries, and even some state universities in the United States, are being pushed by their governments to concentrate on technology transfer as a fundamental mission. It remains to be seen whether these different emphases will influence the nature of universities in the decades to come.

Lita L. Nelsen is at the Technology Licensing Office, Massachusetts Institute of Technology, 77 Massachusetts Avenue, Cambridge, Massachusetts 02139-4307, USA.
e-mail: lita@mit.edu

doi:10.1038/nrm1337

1. Baltimore, D. Higher education: On over-weighting the bottom line. *Science* **301**, 1050–1051 (2003).
2. Bok, D. *Universities in the Marketplace: The Commercialization of Higher Education* (Princeton Univ. Press, USA, 2003).

Competing interests statement
The author declares that she has no competing financial interests.

Online links

FURTHER INFORMATION
Association of University Technology Managers: http://www.autm.net
Access to this interactive links box is free online.