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UNDERSTANDING THE IMPORTANCE OF BAYH-DOLE

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Two recent news articles have taken opposite views of the impact that the Bayh-Dole Act has had on research institutions. But, say Ashley J Stevens and John Fraser, the facts speaks for themselves

December 2 2005 marked the 25th anniversary of the passage of the Bayh-Dole Act, which changed US law to permit universities and small businesses to claim title to inventions and patents resulting from federally funded research. In the past three years, two of the most prestigious and respected business magazines in the world, *Fortune* and *The Economist,* have arrived at diametrically opposite views on the impact of the Act. *Fortune* decries Bayh-Dole; *The Economist* embraces it. How could two such thoughtful magazines reach such different conclusions?

One reason could be that the *Fortune* writer's assertion that "court dockets are now clogged with university patent claims" and his conclusion that litigation costs represent a hidden "drug tax" for consumers and patients are based on an erroneous interpretation of data. "The Law of Unintended Consequences," written by Clinton Leaf and published in the September 19 issue of *Fortune*, states: "In 2002, North American academic institutions spent over $200 million in litigation (though some of that was returned in judgments) – more than five times the amount spent in 1991."

Leaf indicates that this information comes from the Association of University Technology Managers (AUTM) Licensing Survey, which AUTM has conducted annually since 1991. Were it true that US universities spent $200 million a year suing US industry, government and the American public would be justifiably outraged. However, Leaf failed to read the definitions in the Licensing Survey report.

The data that the author errantly assumed was related to litigation, called Legal Fees Expenditures in the survey, is in fact the amount that academic institutions spent to obtain patent protection. This protection creates IP from research results so institutions can license the results to industry for development. The definition of the survey's Legal Fees Expenditures explicitly excludes litigation costs. Further, Legal Fees Reimbursement, which the author also briefly references, shows that more than 40% of patent costs are reimbursed by licensees.

The correct interpretation of the data is that universities, which spent $38 billion on research in fiscal year 2003, made a net investment of around $120 million – just 0.3% of their research expenditures – to turn scientific results into IP that could be licensed to companies for commercialization.

Fortune's characterization of the Bayh-Dole Act is at odds with the views of numerous individuals and groups dedicated to advancing medical treatment, including the Biotechnology Industry Organization (BIO). During the Organization's 2005 annual meeting, BIO and AUTM jointly honoured former Senator Birch Bayh with an award recognizing the Bayh-Dole Act's contribution to the establishment of the biotechnology industry.

THE DRUG BOOM

In the presentation to Bayh, BIO identified 60 drugs derived from university research. One example is Hepatitis B vaccine. The original blood-based hepatitis vaccine was patented by Baruch Blumberg

at the Fox Chase Cancer Center, who received a Nobel Prize for his work. Blumberg's discovery led to a series of National Institute of Health grants which funded work at the University of Washington on the surface antigen protein from human hepatitis B virus, a highly contagious blood-borne virus. The University's work was transferred to industry, and a series of joint university-industry patents resulted in a method of making a hepatitis B vaccine using yeast. This vaccine is given routinely to newborns in the US, Europe and China. Prior to Bayh-Dole, the technology for this new manufacturing process would have sat on the shelves of the USPTO gathering dust along with 28,000 other inventions.

More than 300 biotech drug products and vaccines targeting more than 200 diseases – including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis – are now in clinical trials. In addition, more than 200,000 Americans are directly employed in the biosciences field. This number does not include the hundreds of thousands of jobs and billions of dollars of economic impact this industry has had on the US economy since Bayh-Dole was enacted.

According to "Innovation's Golden Goose," published in *The Economist*'s December 2002 *Technology Quarterly*: "Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

The Economist article also makes some very insightful observations about second-guessing of the Bayh-Dole Act:

> The Bayh-Dole act did two big things at a stroke. It transferred ownership of an invention or discovery from the government agency that had helped to pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers involved got a piece of the action.
>
> There has always been a fringe that felt it was immoral for the government to privatize the crown jewels of academic research. Why, they ask, should taxpayers be charged for goods based on inventions they have already paid for?
>
> That is easily answered. Invention, as [*Technology Quarterly*] has stressed before, is in many ways the easy bit. A dollar's worth of academic invention or discovery requires upwards of $10,000 of private capital to bring to market. Far from getting a free lunch, companies that license ideas from universities wind up paying over 99% of the innovation's final cost.

Countries around the world are expressing their agreement by adopting laws similar to the Bayh-Dole Act. Germany, Korea and Taiwan are the most recent countries allowing academic institutions, as opposed to individual professors, to own inventions resulting from research in their labs. In Japan, the government is privatizing the entire university system in part because they want Japanese universities to become economic catalysts, like their US counterparts. The British and Canadian governments have established pools of funds to accelerate the commercialization of university research. (In the US, universities fund commercialization themselves without government support.)

Bayh-Dole has also contributed significantly to economic development. Between 1980 and 2004, US universities, hospitals and research institutes combined spun out 4,543 companies based on licenses from those institutions. Two-thirds of these companies are still operating – a high survival rate. Yet the process of creating and funding a new company is extraordinarily difficult because academic technologies are early-stage, unproven and high-risk. In the fiscal year 2004 AUTM Licensing Survey, respondents reported that almost 50% of new spin-out companies received funding from individuals: the entrepreneur, the professors' friends and family, and individual angel investors. Venture capitalists financed fewer than 20% of spin-outs.

THE PUBLIC INTEREST

So why do universities engage in technology transfer? It is not, as the *Fortune* article implies, for the money. Few achieve the blockbuster deal that Emory did with Emtriva and Truvada. Most institutions see a modest surplus from their technology transfer activities at best. Typically 95% or more of the economic impact from technology commercialization is outside the institution, with the

corporations that develop and sell the technology. So again, why do it?

University of Michigan President Mary Sue Coleman succinctly captured why universities are committed to commercialization in a speech at the 2005 AUTM Annual Meeting: "I think many people are often confused about why we are interested in technology commercialization, in nurturing startup companies, and in facilitating more patents and licence agreements. It is not about the promise of future revenues that might be generated from this activity ... You heard me correctly. It is not about the money. Of course, revenue generation serves as an incentive. But first and foremost, technology transfer must serve our core mission: sharing ideas and innovations in the service of society's well-being."

Getting research results to the public is, quite simply, our mission.

Somewhere between a "Law of Unintended Consequences" and "Innovation's Golden Goose" lies the truth. But that's a broad range and one, as evidenced by the efforts of *Fortune* magazine, that can be fraught with misinterpretation.

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COMMENTS

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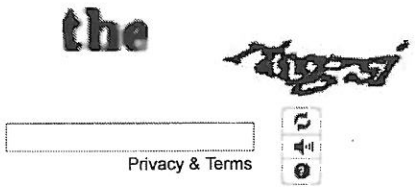

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