The Law of Unintended Consequences

Twenty-five years ago a law known as Bayh-Dole spawned the biotech industry. It made lots of university scientists fabulously rich. It was also supposed to usher in a new era of innovation. So why are medical miracles in such short supply? **BY CLIFTON LEAF**

ILLUSTRATION BY BRAD HOLLAND

Even in the mute efficiency of international wire transfers, $540 million makes a noise when it lands in your bank account. To Kent Alexander, that sound was a thud—and in this case "not one single thud, but a lot of different thuds." All afternoon on July 21, 2005, Alexander, who is Emory University's general counsel, president Jim Wagner, and other senior members of the school's administration were receiving e-mailed reports from the finance department: "121 million just hit!" And then, 50 minutes later, "183 million just hit!" Half an hour after that, an even richer stash arrived. *Thud.*

"It was an out-of-body experience," says Alexander, 46. "By any definition, it's a huge deal. As one of our trustees was saying, 'It doesn't get any bigger than this on Wall Street.'"

The deal in question had closed only days earlier, when a pair of biotech companies, Gilead Sciences of Foster City, Calif., and Royalty Pharma of New York City, outbid several other parties for Emory's roughly 20% stake in the powerful anti-retroviral drug Emtriva, which is used to treat HIV. The drug was developed more than 15 years ago by three of the university's scientists, working on federal research grants, but received FDA approval only in July 2003. Now, however, Emtriva (a modest seller in its own right) was being married to another antiviral in a single pill. The combination drug, called Truvada, was expected to have a worldwide market of nearly $1 billion in 2006. Emtriva was becoming a blockbuster. Citigroup set up the auction and hammered out the terms with bankers from Lazard. A white-shoe law firm, Covington & Burling, calculated the drug's projected royalty streams through the year 2021, when the patent life was scheduled to end.

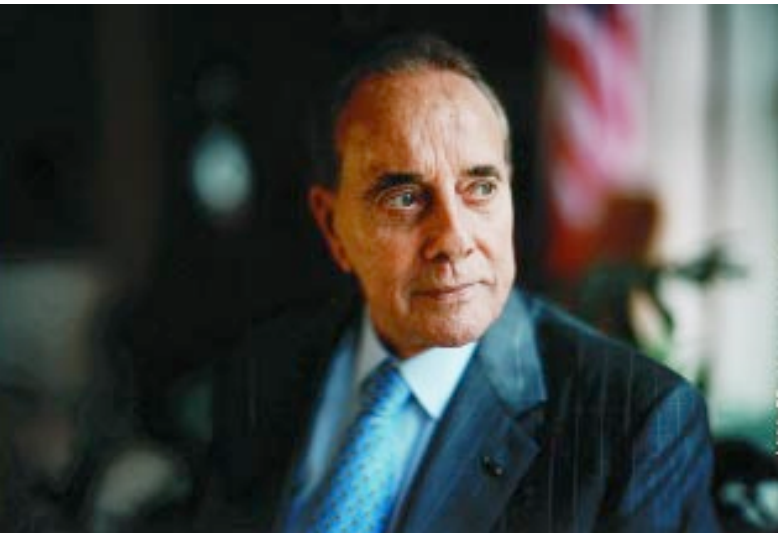
The hard work was over, and now it was time for a champagne toast and a brief "end-zone dance," as president Wagner described it. In a short while they could start thinking about how to reinvest their windfall—around $320 million after fees and the 40% cut that belonged to the three Emory inventors. The cash would enhance Emory's leadership in AIDS-vaccine research—and help Wagner's plan to turn the university into a top-tier "destination" school. "This is just such a win-win-win story," Wagner says jubilantly. "We have an invention here that addresses a real international scourge, and we are now taking these resources and reinvesting them in American research and education. It's a pretty happy story."

Well, not entirely.

The Emtriva case may sound like yet another innovation in an unending stream of medical miracles, from "smart drugs" to gene therapy. But believe it or not, it's an example of a profound system failure. For a century or more, the white-hot core of American innovation has been basic science. And the foundation of basic science has been the fluid exchange of ideas at the nation's research universities. It has always been a surprisingly simple equation: Let scientists do their thing and share their work—and industry picks up the spoils. Academics win awards, companies make products, Americans benefit from an ever-rising standard of living.

That equation still holds, with the conspicuous exception of medical research. In this one area, something alarming has been happening over the past 25 years: Universities have evolved from public trusts into something closer to venture capital firms. What used to be a scientific community of free and open debate now often seems like a litigious scrum of data-hoarding and suspicion. And what's more, Americans are paying for it through the nose.

Let's go back to Emtriva for a moment. Raymond



LAWMEN With strong belief in the power of the private sector (and a little luck), former Senator Birch Bayh (top) got his bill passed in the face of heated opposition. Co-sponsor Bob Dole's assessment of his role: "I just sort of went along for the ride."

PREVIOUS PAGE: SCULPTURE FROM FEBRUARY 1950 FORTUNE COVER BY WILLIAM ZORACH

BAYH: MARK WARFORD; DOLE: DAVID BURNETT—CONTACT PRESS IMAGES

Schinazi, a virus specialist at Emory, got the idea for the drug after hearing a lecture by a Canadian researcher, Bernard Belleau, at a 1989 AIDS conference in Montreal. Belleau had discovered a compound that helped shut down the virus's genetic machinery, and Schinazi soon realized that with some chemical wizardry, the substance could be transformed into something far more potent. Thanks to a bit of "serendipity," Schinazi says, he and two Emory colleagues were able to do just that: create a compound that may be orders of magnitude more active than Belleau's. In the end, the difference between the two substances came down to one atom of fluorine. It's a perfect example of how one inspiration can build on another.

This combination of open exchange and fervent competition between great researchers helps bring about scientific advances. And when the system works, the sum of each contribution is greater than the whole. But what happened next in the Emtriva saga was a race to the patent office. Emory got there first—by a week.

What used to be a scientific community of free and open debate is now **a litigious scrum** of data-hoarding and suspicion.

That filing in 1990 triggered a morass of lawsuits over Emtriva and a related compound. Belleau's biotech employer sued; so did pharmaceutical giant Glaxo Wellcome (now GlaxoSmithKline), which had licensed what it thought was Belleau's discovery. Emory found itself embroiled in litigation that a veteran patent attorney called the most complex he'd ever seen. (One federal case had 36 individual "lead attorneys.") Emory's squadron of lawyers not only had to fight through those cases but also skirmish through four long challenges at the U.S. Patent & Trademark Office (USPTO) and repeat those battles in Europe, Australia, Japan, South Korea, and Canada. All told, the disputants wrangled on for nearly a decade and a half and consumed millions of dollars in attorney's fees.

And that's just for one dispute. From 1992 to September 2003, pharmaceutical companies tied up the federal courts with 494 patent suits. That's more than the number filed in the computer hardware, aerospace, defense, and chemical industries combined. Those legal expenses are part of a giant, hidden "drug tax"—a tax that has to be paid by someone. And that someone, as you'll see below, is you. You don't get the tab all at once, of course. It shows up in higher drug costs, higher tuition bills, higher taxes—and tragically, fewer medical miracles.

So how did we get to this sorry place? It was one piece of federal legislation that you've probably never heard of—a 1980 tweak to the U.S. patent and trademark law known as the Bayh-Dole Act. That single law, named for its sponsors, Senators Birch Bayh and Bob Dole, in essence transferred the title of all discoveries made with the help of federal research grants to the universities and small businesses where they were made.

Prior to the law's enactment, inventors could always petition the government for the patent rights to their own work, though the rules were different at each federal agency; some 20 different statutes governed patent policy. The law simplified the "technology transfer" process and, more important, changed the legal presumption about who ought to own and develop new ideas—private enterprise as opposed to Uncle Sam. The new provisions encouraged academic institutions to seek out the clever ideas hiding in the backs of their research cupboards and to pursue licenses with business. And it told them to share some of the take with the actual inventors.

On the face of it, Bayh-Dole makes sense. Indeed, supporters say the law helped create the $43-billion-a-year biotech industry and has brought valuable drugs to market that otherwise would never have seen the light of day. What's more, say many scholars, the law has created megaclusters of entrepreneurial companies—each an engine for high-paying, high-skilled jobs—all across the land.

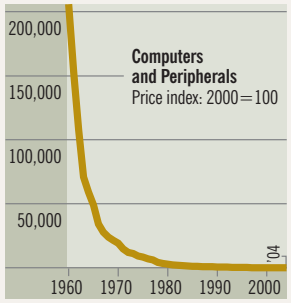
That all sounds wonderful. Except that Bayh-Dole's impact wasn't so much in the industry it helped create, but rather in its unintended consequence—a legal frenzy that's diverting scientists from doing science.

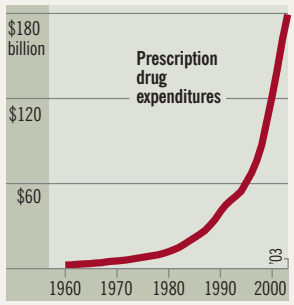
Birch Bayh is likable—eminently so. He has a kind face, easy laugh, and enough self-deprecating charm to get a proud liberal Democrat elected (and reelected twice) in Indiana—a state as Republican red as Birch Bayh is, well, likable. That was a wonderful gift to have in the U.S. Senate, and it no doubt partly accounted for the fact that his patent bill overcame tremendous suspicion (as being "anti small business"), opposition by President Carter, and the Reagan Revolution, which cost Bayh his Senate seat in 1980.

At the time, the gospel of the U.S. government, or at least of the longtime Democratic majority in Congress, was that if the government paid for it, the taxpayers owned it. That was the thinking that drove

Anti–Moore's Law

IT prices have been falling for years. And biomedicine? Not so much.





FORTUNE CHARTS / SOURCES: BUREAU OF ECONOMIC ANALYSIS (COMPUTERS); CENTERS FOR MEDICARE AND MEDICAID SERVICES (DRUGS)

JACKPOT
Emory's Raymond Schinazi in his Atlanta lab: He struck it rich when a couple of biotechs bought the license for his HIV drug.

some of the nation's proudest achievements—the splitting of the atom, the development of antibiotics, the moon shot, and the nuclear Navy.

Bayh sought to turn that policy on its head, essentially giving away all this taxpayer property for free—and, some worried, creating potentially thousands of new private monopolies in the process. It was a heretical view (for a liberal, no less), but Bayh was convinced that government ownership was squashing innovation and the nation's productivity. The stagflation of the 1970s was already clouding the new decade of the '80s; America's economic engine seemed to be choking; and the domestic automobile, steel, and electronics industries were fast losing their global dominance. There seemed to be a productivity malaise descending on the homeland—and some kind of catalyst for change was needed.

It was a report by the Comptroller General of the U.S. that offered, if not the remedy, one culprit for the national gloom: unlicensed patents. A 1979 audit of government-held patents showed that fewer than 5% of some 28,000 discoveries—all of them made with the help of taxpayer money—had been developed, because no company was willing to risk the capital to commercialize them without owning title. "Discoveries were lying there, gathering dust," says Bayh today, from his office at the Washington law firm Venable LLP. "So the taxpayers weren't being protected. We'd spent $30 billion in research for ideas that weren't helping anybody."

When the bill was finally passed, against all odds, on the last possible day of a lame-duck session of Congress, it didn't make a whiff of news beyond the Beltway. Even Bayh had no clue what effect the new amendments would have. "I don't think anybody could have reasonably anticipated the enormity of the chain reaction that followed," says Bayh today.

A dozen schools—notably MIT, Stanford, the University of California, Johns Hopkins, and the University of Wisconsin—already had campus offices to work out licensing arrangements with government agencies and industry. But within a few years Technology Licensing Offices (or TLOs) were sprouting up everywhere. In 1979, American universities received 264 patents. By 1991, when a new organization, the Association of University Technology Managers, began compiling data, North American institutions (including colleges, research institutes, and hospitals) had filed 1,584 new U.S. patent applications and negotiated 1,229 licenses with industry—netting $218 million in royalties. By 2003 such institutions had filed five times as many new patent applications; they'd done 4,516 licensing deals and raked in over $1.3 billion in income. And on top of all that, 374 brand-new companies had sprouted from the wells of university research. That meant jobs pouring back into the community.

A modern alchemy was at work: Ivory towers were being turned into gold, and society was benefiting from hundreds of novel treatments introduced for a host of diseases. After years of intense study and living grant to mouth, investigators at the University of California at San Francisco, for example, had come up with a treatment for infants with respiratory distress syndrome, an ailment that affects some 25,000 babies a year. A startup by University of Florida researchers got $15 million from some VCs in Menlo Park last year to develop a gene therapy for a type of emphysema called Alpha-1. Physicists at the University of Wisconsin in Madison figured out a way to turn static MRI views of blood vessels into videocamera-like images.

The anecdotal reports, fun "discovery stories" in alumni magazines, and numbers from the yearly AUTM surveys suggested that the academic productivity marvel had spread far and wide. But that's hardly the case. Roughly a third of the new discoveries and more than half of all university licensing income in 2003 derived from just ten schools—MIT, Stanford, the usual suspects. They are, for the most part, the institutions that were pursuing "technology transfer" long before Bayh-Dole.

Even so, every school labors under the fantasy that it's going to find the next Emtriva—or Gatorade, a huge success that came out of the University of Florida. The jackpot is too rich not to go for it.

In 2001, economists Richard Jensen from Notre Dame and Marie Thursby of the Georgia Institute of Technology published a survey of university licensing activity over a five-year period in the 1990s. They asked administrators and faculty researchers at 62 universities, "What's the most important outcome of technology transfer?" The top answer by far given by university officials was "revenue." Yes, it was nice to see important discoveries commercialized and the knowledge disseminated as widely as possible. But hey, we're in this for the money.

That certainly seemed to be the message in a recent court case involving Columbia University. Last year

GREG FOSTER

Whom to Thank?

Did Bayh-Dole boost scientific output—or did a surge in government funding do it?

162%

■ **Change in NIH appropriations, most of which becomes grant money for academic institutions, 2003 vs. 1993.**

157%

■ **Change in U.S. patents issued to academic institutions, 2003 vs. 1993.**

Columbia threatened to revoke the licenses of several leading biotech and pharmaceutical companies for the use of a critically important process in drug discovery and development called co-transformation. (The companies sued, and the cases ended up in a federal court in Massachusetts.) In the late 1970s three Columbia researchers, Richard Axel, Michael Wigler, and Saul Silverstein, all working with funding from the NIH, figured out a way to vastly improve the efficiency of a technique used in genetic engineering. They filed for patents in February 1980—prior to Bayh-Dole. But the NIH assigned the title to Columbia once the university promised to "use all reasonable effort to bring the [Axel patents] to the commercial market through licensing on a non-exclusive, royalty-free, or reasonable royalty basis." The federal agency even admonished Columbia not to engage in "repressive" licensing practices.

The Axel patents were amazingly huge moneymakers for Columbia (and yes, the three inventors got rich too), bringing in a total haul of about $600 million during their 20-year patent life. The university had licensed co-transformation to 11 drugmakers and collected royalties on 19 different drugs for various diseases. Amgen had used the Axel technology while making its bestselling anemia drug, Epogen; Bayer and Wyeth each made hemophilia drugs; Genentech used it in making its blockbuster breast-cancer drug, Herceptin.

But when the patent life ran out, Columbia announced that—surprise—it had secured a new patent, issued in 2002, that won't expire until 2019. (The patent application was filed in secret in 1995.) And the invention, as it turns out, comes out of the original taxpayer-funded work done by Axel, Wigler, and Silverstein long ago (and somehow not included in the three patents Columbia had already received). University lawyers had pulled off the trick by filing a secret "continuation" application (which keeps an original patent disclosure alive for possible new claims to be added) and then abandoning it—repeating this procedure again and again until the clock was about to run out. So the patent granted in 2002, noted federal district court Judge Mark Wolf, "relates back to its *great-great-great-great-great-great-grandparent* application" in 1980. The aim of this new "submarine" patent, says Boston attorney Donald Ware, who represented several of the plaintiffs, was to enable Columbia to surface with a claim "covering new advances the biotechnology industry had made during the intervening years." By delaying their filing as long as possible, they could get many more years of patent protection. And revenue, of course.

U.S. patent laws were amended in 1995 precisely to prevent this method of gaming the system. (Patents now expire 20 years after the original filing, or "priority date," rather than 17 years after the issue date, as they used to.) But Columbia managed to file two final applications on June 7, 1995—the day before the new law was to go into effect. When Judge Wolf indicated he was inclined to rule in favor of the plaintiffs, Columbia promised it would no longer attempt to charge the companies a licensing fee. (The case was then dismissed.)

No one at Columbia University would speak on the record about the Axel patents. The university's outside counsel, David Gindler, of the Los Angeles firm Irell & Manella, insists the school did nothing improper. "I don't think Columbia had a strategy to do anything other than get the full patent protection to which it's entitled," he says. "Universities should be able to get the same thing that companies get." Gindler elaborates: "It's perfectly proper for Columbia to do what any of the other biotech companies would do—to request companies take licenses to the patent and pay a reasonable royalty."

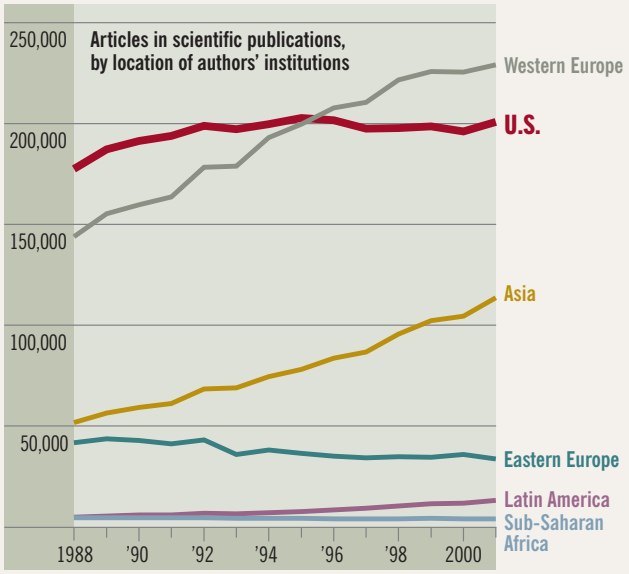
And later Gindler elaborates further: "Columbia acted no differently than the rest of the business community in the United States."

Columbia is hardly the only academic center to fancy itself a hard-charging corporation. Court dockets are now clogged with university patent claims. 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. Stanford Law School professor emeritus John Barton notes, in a 2000 study published in *Science*, that the indicator that correlates most perfectly with the rise in university patents is the number of intellectual-property lawyers. (Universities also spent $142 million on lobbying over the past six years.) Attorney Gindler defends the legal wrangling as part of a global good:

The biotech industry as a whole has **lost more than $45 billion** since birth.

Publish or Perish

The U.S. has surrendered the lead in the sharing of scientific discoveries.



FORTUNE CHART / SOURCE: NATIONAL SCIENCE FOUNDATION, SCIENCE AND ENGINEERING INDICATORS, 2004

Your Tax Dollars at Work

Bayh-Dole by the numbers

98%

■ Rise in NIH budget from 1998 to 2003—much of which goes to fund university research.

49%

■ Typical share of each federally funded research grant ("R01") that universities claim to cover "indirect costs"—that is, overhead.

21%

■ Increase in lab space, measured in square footage, at American universities, from 1998 to 2003.

32%

■ Average rise in tuition at public four-year universities from 1998 to 2003.

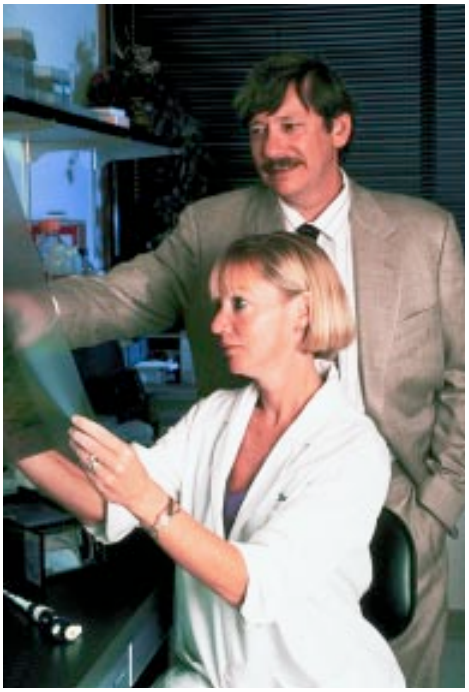
SOURCES: NATIONAL SCIENCE FOUNDATION; THE COLLEGE BOARD; NIH; NATIONAL CANCER ADVISORY BOARD, SUMMARY OF JUNE, 2002 MEETING

"The money that comes into universities like Columbia for licensing is plowed back into the mission of the university to conduct more research," he says. "It's not used to pay shareholders or to fill corporate coffers. It's used for a really noble purpose."

So what do universities do with all their cash? That depends. Apart from the general guidelines provided by Bayh-Dole, which indicate the proceeds must be used for "scientific research or education," there are no instructions. "These are unrestricted dollars that they can use, and so they're worth a lot more than other dollars," says University of Michigan law professor Rebecca Eisenberg, who has written extensively about the legislation. The one thing no school seems to use the money for is tuition—which apparently has little to do with "scientific research or education." Meanwhile, the cost of university tuition has soared at a rate more than twice as high as inflation from 1980 to 2005.

The enormous investment by tuition-paying students, parents, and taxpayers of all ages might be worth it if the university research was paying off huge dividends. But here's the hard, surprising truth: In one crucial area of science—productivity, which Bayh-Dole was intended to supercharge—it isn't.

Measuring productivity, in general, is a difficult thing. In science it is nigh impossible. How can you tell whether an idle experiment in a basement lab somewhere is going to pay off one day with a cure for Parkinson's disease or ALS? You can't. And yet scientists try to measure their own scientific "output" all the time, and the unit of measurement is the number of papers that run in top-tier journals. Publish a lot in, say, *Nature* or *Cell*, and chances are you'll get your grant or tenure. It's a crude measure, but one that's quietly accepted in academic circles.



GEORGE FREY/GETTY IMAGES

ANOTHER JACKPOT
Mark Skolnick and Donna Shattuck-Eidens in 1994, the year they found the first breast-cancer gene. His firm now controls all DNA testing for that gene.

Each year, the National Science Foundation calculates which countries are contributing to the global knowledge pool by tallying up the number of their researchers' published papers in key journals all over the world. The U.S. traditionally holds an edge, not least because the vast majority of influential academic journals are published in English (and often edited and "peer-reviewed" by American scientists).

Trouble is, even with that advantage, the U.S. contribution to global knowledge has been stagnating. While the number of journal articles produced by American researchers has risen slightly since 1988, the rest of the world has raced ahead (see chart).

Or you could forget such squishy "knowledge indicators" and go to the hard stuff: drugs. FDA scientists have an entire vocabulary for describing new compounds that come into its office. When something is considered truly novel and innovative, the FDA calls it a new molecular entity, or NME. Many of the other drugs regulators see are reformulations, old compounds with new indications for use, or "me too" drugs that are similar to several on the shelf. But even the label NME doesn't mean a drug necessarily fills a critical gap in health care.

When regulators see promising clinical data for a drug that really is needed by patients right now—as with the HIV drug Emtriva in 2003—it gives the drug a "priority review." The idea is to get it out to doctors as quickly as possible. So those who want to measure the performance of the world's drug manufacturers should look not only at the total number of FDA-approved compounds and biologics in a current year, but also at how many priority NMEs are making it through. By both measures, the productivity picture is much worse than it was in 1996 (although 2004 seems to have had a bumper crop). From 2000 through the end of 2003, the average number of priority NMEs each year was eight; in the previous four years, it was twice that.

For a number of common diseases, it seems that progress has stalled. Since the advent of genetically engineered human insulin in 1977, there has been relatively little new help for diabetics. Age-adjusted death rates for those with the disease have gotten *worse*, not better, during the past 25 years. Patients with Parkinson's, Alzheimer's, and multiple sclerosis have waited anxiously for anything promising to appear in the pipeline. And in cancer, one remarkable study led by the FDA's cancer czar, Richard Pazdur, seems to say it all: A full three-quarters of the 71 cancer drugs approved by the agency from 1990 through 2002 did not show any survival benefit over the old, standard care.

What about the explosion in the biotech industry over the past 25 years—aren't those firms churning out innovative products? Here again, the numbers suggest otherwise. Consider the Nasdaq biotech in-

THE ROLE MODEL
John Preston, a legend in tech transfer, perfected MIT's entrepreneurial system—which predates Bayh-Dole by decades.

dex, which is a fair proxy for the industry. The combined market cap of its 157 companies is around $319 billion. This huge stake held by public shareholders is the direct result of Bayh-Dole, which gave these brave new firms something of value—intellectual property—to take to the market. The legislation also made it possible for venture capitalists to bring companies public quickly and thus see a return on their initial investment.

What the law didn't do was give the companies something worthwhile to sell. Only 36 of the 157 companies on the index are profitable. And judging by the cold, hard measure of revenues, it's clear that few have produced drugs that doctors view worthy enough to prescribe. Forty percent of Nasdaq's biowonders had sales under $20 million in the past 12 months; 22% had less than $5 million. For every Genentech success story, there are dozens of teetering failures, with laser-fast burn rates and very little to show the buy-and-hold believers who purchased shares on the open market. Indeed, the industry as a whole has lost more than $45 billion since birth.

How could a law with so much intuitive promise to liberate research and boost productivity have the opposite effect? You can put part of the blame on the nation's patent policies—which began their own strange evolution at the same time as—you guessed it—Bayh-Dole. The Supreme Court's decision in 1980 to allow for the patenting of living organisms opened the spigots to individual claims of ownership over everything from genes and protein receptors to biochemical pathways and processes. Soon, research scientists were swooping into patent offices around the world with "invention" disclosures that weren't so much products or processes as they were simply knowledge—or research tools to further knowledge.

The problem is, once it became clear that individuals could own little parcels of biology or chemistry, the common domain of scientific exchange—that dynamic place where theories are introduced, then challenged, and ultimately improved—begins to shrink. What's more, as the number of claims grows, so do the overlapping claims and legal challenges. This isn't merely a hypothetical situation, a "worst-case scenario" painted by academic handwringers. It has already happened, as two professors at the University of Michigan Law School, Michael Heller and Rebecca Eisenberg, observed in a seminal 1998 article in *Science* magazine.

Now technology-transfer offices instruct faculty to go over the most embryonic of discoveries "in-house," to see if there is anything potentially marketable in the work before they talk to colleagues. Researchers are told, always, to file provisional patent applications before publishing a paper or speaking at a conference. (Such public disclosures, according to European patent laws, immediately nix any chance to patent the finding overseas, where much of the licensing market is.) Before sharing resources like cell lines, reagents, tissue specimens, gene expression data, or knockout mice (those bred without certain genes to simulate a disease process), researchers at different universities are now asked to sign a "material transfer agreement," or MTA, and that means first having to run the contract by one's department head or a university lawyer. Then there is the most vexing of all patent-law confections: the "reach-through licensing agreement," or RTLA. These contracts grant the owner of a patented biomedical tool the right to a royalty on any compound that's ultimately discovered through its use. Imagine a carpenter having to pay Black & Decker a percentage of every kitchen he rebuilds.

Heller and Eisenberg dubbed this new dismal state of affairs the "Tragedy of the Anticommons." And that's what it is—a tragedy that's still in the making.

In October 1990 a researcher named Mary-Claire King at the University of California at Berkeley told the world that there was a breast-cancer susceptibility gene—and that it was on chromosome 17. Several other groups, sifting through 30 million base pairs of nucleotides to find the precise location of the gene, helped narrow the search with each new discovery. Then, in the spring of 1994, a team led by Mark Skolnick at the University of Utah beat everyone to the punch—identifying a gene with 5,592 base pairs and codes for a protein that was nearly 1,900 amino acids long. Skolnick's team rushed to file a patent application and was issued title to the discovery three years later.

By all accounts the science was a collective effort. The NIH had funded scores of investigative teams around the country and given nearly 1,200 separate research grants to learn everything there was to learn about the genetics of breast cancer.

The patent, however, is licensed to one company—Skolnick's. Myriad Genetics, a company the researcher founded in 1991, now insists on doing all U.S. testing for the presence of unknown mutation in the two related genes, BRCA1 and BRCA2. Those who have a mutation in either gene have as high as an 86% chance of getting cancer, say experts. The cost for the complete two-gene analysis: $2,975.

Critics say that Myriad's ultrarestrictive licensing of the technology—one funded not only by federal dollars but also aided by the prior discoveries of hundreds of other scientists—is keeping the price of the test artificially high. Skolnick, 59, claims that the price is justified by his company's careful analysis of thousands of base pairs of DNA, each of which is prone to a mutation or deletion, and by its educational outreach programs.

Whatever the answer, it's clear who pays for it. You do. You pay in the form of vastly higher drug prices and health-care insurance. Americans spent $179 billion on prescription drugs in 2003. That's up from … wait for it … $12 billion in 1980. That's a 13%

JASON GROW

hike, year after year, for two decades. Of course, what you don't pay as a patient you pay as a taxpayer. The U.S. government picks up the tab for one in three Americans by way of Medicare, Medicaid, the military, and other programs. According to the provisions of Bayh-Dole, the government gets a royalty-free use, forever, of its funded inventions. It has never tried to collect. You might say the taxpayers pay for the hat—and have it handed to them.

What might progress have looked like without the law? No one can answer that for sure. But one possible scenario is what happened to that other high-technology, university-incubated industry: the computer business.

Intellectual property was and is important in information technology. But very few electronic hardware, software, or Internet-related inventions are licensed through university intermediaries. Even companies that swear blood oaths against each other don't tie themselves into knots licensing bits and pieces of their technologies in airtight, exclusive deals. Rather, they broadly license their entire patent portfolios. In a piece of hardware that may straddle technology covered in a hundred patent claims, the strategic value of a single patent is low, says David Mowery, a professor at the Haas School of Business at UC-Berkeley. "One reason you see these big cross-licensing deals is because the effort required to determine the value of every patent in Sun's pile as opposed to IBM's as opposed to HP's is so great relative to the likely value of any single patent. So they come in with their proud stack and they just say, 'We'll let you have access to ours if you let us have yours.' "

This necessary sharing of resources has created giant new businesses and business models. And the effusive crosstalk between rivals is one driver in the lowering of prices for technology components (see chart). Semiconductor prices have fallen by an astounding 28% a year since 1974, in near synchronicity with Moore's law, coined way back in 1965. Meanwhile, the American consumer has benefited from one paradigm shift in technology after another.

Universities believe, however, that biomedical discoveries—which account for more than half their invention disclosures and most of their licensing revenue—are simply a riskier proposition than computers. Not only are the failure rates sky high, there's also the FDA to worry about. No company would invest the huge capital to turn what was essentially a theory into a compound if it knew that rivals could come along later, after the hard work was done, and sell the same pill. Besides, exclusive deals let the schools offload their patent costs—often as much as $25,000 for the first filing—right away.

Those fears aside, the truth is that even if some skittish VCs stay home, the science will get done. In

You might say **the taxpayers pay for the hat—** and have it handed to them.

SIGNS OF VIGOR This nondescript building in Cambridge, Mass., has figured in waves of technological change. It was the site to which Bell made his first long-distance phone call; today it houses a biotech firm.

other words, Bayh-Dole has served mostly as a nervous mother for a science that never needed one. New biomedical discoveries are now coddled and kept out of the rain—and it's hurting progress.

The NIH recently said it thinks research tools should be freely licensed, for example, but there are no teeth in its policy. According to the provisions of Bayh-Dole, federal agencies do have the power to "march in" when necessary technology is not being disseminated into the public domain. In 25 years, however, the NIH has never used that power.

A better solution is simply to amend the law. The right to make a profit from a taxpayer-funded discovery should come with an *explicit* demand: The patent holder has to license the invention as broadly as possible—which would make exclusive deals the rare exception, not the rule. The fact is, the right people will always find a way to turn a good idea into something tangible. If you have any doubt, spend an afternoon in Cambridge, Mass.

New discoveries are now coddled and kept out of the rain—and it's **hurting scientific progress.**

"There are doughnuts in the conference room this morning," says John Preston. "A Saudi crown prince is coming for a visit." Preston, a senior lecturer at MIT's Entrepreneurship Center, former head of the university's technology licensing office, and a true pioneer in tech transfer, isn't the least bit excited about the prominent guest. It is hard to tell—but he may be excited about the doughnuts.

Here in his ground-floor office in the Muckley Building, next door to Kendall Square, Preston, 55, is drinking from a mug that's marked NERD PRIZE. It's a pet name for the Entrepreneurship Center's now somewhat famous "$50K Competition"—in which students and even faculty researchers vie for seed money based on the quality of their business plans. The contest, now in its 16th year, has showcased some notable winners—and losers. (The top prize in 1998 went to Internet search engine Direct Hit, which was later sold to Ask Jeeves for $447 million; the loser, Akamai, now has a market cap of $1.9 billion.)

The "$50K" is just one of scads of MIT projects to bring out the inner entrepreneur in campus denizens. At MIT, the discourse between university and industry isn't merely pervasive, it's a central feature of the culture. Every student has to do research; every faculty member gets a day off a week to consult for industry.

A 1997 BankBoston (now Bank of America) study tried to trace the effects of MIT's commitment to "useful knowledge," as the school's founder put it in 1861—tallying up all the companies founded by at least one MIT alum or faculty member, in addition to those spun off from an MIT lab. The study identified 4,000 companies, employing 1.1 million people, which together have $232 billion in annual worldwide sales. Among the bounty: blue-chip names like Hewlett-Packard (cofounder Bill Hewlett, class of 1936), Raytheon (Vannevar Bush, class of 1916), Intel (Robert Noyce, '53), Gillette, Tyco International, Digital Equipment Corp., and Campbell Soup. All these big companies formed way before Bayh-Dole.

Many of the companies (and jobs) remain in the Boston area, attracting more talent, venture funding, and commercial investment—which, in turn, creates new companies. The loop feeds on itself, and a "cluster," that El Dorado of economic development, is born.

MIT understood that dynamic before anybody else. Forty years before Bayh-Dole, in fact, it set up a university office to license home-grown discoveries. By the mid-1980s—in part, thanks to a national attitude shift after the law's enactment—MIT wasn't merely granting rights to its technology, says Preston, but also aggressively taking equity positions in startups and doing its best to nurture young companies with money, management help, and the advice of seasoned MIT entrepreneurs. Even Preston—a big fan of Bayh-Dole—admits that the science would have probably come anyway.

Later, tooling around in Preston's Saab 9-5, the evidence of past economic booms and boomlets is unearthed like an archeological dig. History seems to fold upon itself in the redbrick building at 700 Main Street (what used to be called 28 Osborn). This is the place to which Alexander Graham Bell made his first long-distance phone call in 1876. Later, in another flush time, the building was used to make railroad cars, then Federal-style furniture for the Brahmins across the River Charles. The faded white lettering from the factory still calls out from the façade. The building was then rented by Edwin Land in the 1930s to house a research facility for what would one day be a newfangled camera called Polaroid. And then, at the turn of the millennium, it became the home of Transkaryotic Therapies, a homegrown biotech that was acquired in July by British company Shire Pharmaceuticals.

American ingenuity, it seems, never needs much of a jump start. Just a good sign painter. F

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