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## HISTORY OF MEDICINE

# Patents, Profits, and the American People — The Bayh–Dole Act of 1980

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In June, the U.S. Supreme Court issued a unanimous opinion in *Association for Molecular Pathology v. Myriad Genetics* that invalidated the claim of ownership of the *BRCA1* and *BRCA2* genes. On one level, the legal contretemps leading up to this decision grew out of the University and Small Business Patent Procedures Act of 1980, commonly known as the Bayh–Dole Act.<sup>1</sup> Sponsored by Senators Birch Bayh (D-IN) and Robert Dole (R-KS), the law reversed decades of government policy by allowing scientists, universities, and small businesses to patent and profit from discoveries they made through federally funded research — like Myriad's research on breast-cancer genetics, which built on previous publicly funded work and was partially supported by the National Institutes of Health.

The Bayh–Dole Act is beloved by the biotechnology and investment communities. In 2002, the *Economist* called it “possibly the most inspired piece of legislation to be enacted in America over the past half-century” because it “helped to reverse America's precipitous slide into industrial irrelevance.”<sup>2</sup> The law certainly contributed substantially to the increase in patents awarded to

universities over the past three decades — from 380 in 1980 to 3088 in 2009. More difficult to confirm is industry's estimate that between 1996 and 2007, university-based research-licensing agreements contributed \$47 billion to \$187 billion to the gross domestic product.<sup>3</sup> Indeed, the law's many critics question how much it has actually benefited the economy (as opposed to individuals and shareholders) and the extent of its social costs.

Nevertheless, many academic researchers assume that Bayh–Dole is an inviolate aspect of doing business. But a review of its origins and consequences supports the idea that policies governing the fast-changing worlds of medicine and biotechnology merit frequent reappraisal and reform.

Bayh–Dole's inspiration was not a perceived need to transform the conduct of research but the economic doldrums of the 1970s. Oil embargoes and the resulting energy crisis, combined with the eroding U.S. automobile, steel, and household-appliance industries, deflated the stock market. Pundits predicted that Japan and Germany would soon rule the world's economy. Adding to this malaise was the fallout of Water-

gate, the custodial presidency of Gerald Ford, and the Iran hostage crisis.

In 1978, a group of constituents representing Purdue University lobbied Bayh to seek ways of reaping profits from government allocations for university-based research, arguing that although the United States spent billions of dollars annually funding more than half of all academic research and owned 28,000 patents, it had little to show for the investment. There is debate over how many of these patents had been developed into marketable products. Industry representatives insist that less than 5% of all government-funded inventions resulted in licenses for commercial use. But technology-transfer critics argue that the number of patent licenses may be a misleading measure of invention utilization. The Defense Department sponsored the majority of the inventions considered in such estimates, and though contractors could have retained title to the patents, most of these inventions had limited value for the civilian market. In contrast, 325 federal government patents were sponsored by the Department of Health, Education, and Welfare, and 75 (23%) of

those were licensed as of 1976. Furthermore, critics contend, the low industry figure “overlooks both unlicensed development of patented inventions and development or commercial utilization of unpatented inventions.”<sup>4</sup>

Still, many small companies hesitated to market government-patented discoveries under non-exclusive licenses. Since it typically takes millions of dollars to transform a discovery into a profitable product, industry advocates argued, few firms would pursue something that could be reproduced by a competitor once the first company had succeeded. This argument convinced Bayh that he’d found a proposal that might reduce bureaucratic regulatory waste, aid individual discoverers, universities, and start-up businesses, and buttress the economy.<sup>5</sup>

Around the same time, Dole, long an advocate of health care innovations, expressed concern about several lifesaving drugs and medical devices funded by the National Institutes of Health that were being held back because of licensing issues. Dole and Bayh decided to collaborate on a comprehensive technology-transfer bill.

Other senators also wanted to reform patent law and improve the economy. Adlai Stevenson III (D-IL) preferred centralizing patent control in the government by establishing federally operated technology-development centers around the country. Russell Long (D-LA) opposed individuals’ or businesses’ generating wealth from discoveries paid for by taxes, which should remain freely available to all. Both threatened to oppose Bayh–Dole in favor of bills enacting their approaches.

After much political wrangling, the Senate Judiciary Committee unanimously backed Bayh–Dole.

On April 23, 1980, the Senate approved it on a 91-to-4 vote. Bayh then struck a deal with Representative Robert Kastenmeier (D-WI) to add the Bayh–Dole provisions to the House’s Omnibus Patent Bill. But before the reconciled version was readied for final Senate consideration, Congress adjourned for the 1980 elections.

Those elections were a political maelstrom. Ronald Reagan defeated Jimmy Carter. The Republicans gained 12 Senate seats, including Bayh’s, winning control of the Senate for the first time in 32 years. Bayh–Dole was granted one more chance only because the outgoing Congress, having failed to pass a budget, had to return in December.

During a lame-duck session there’s little time for debate, and any senator can place a hold on a bill, stopping it in its tracks. Russell Long agreed to relinquish his threat of a hold as a “farewell present” to Bayh. Stevenson relinquished his hold after extracting a promise that no hold would be placed on his patent bill.

Bayh–Dole almost died again when Senate Majority Leader Robert Byrd (D-WV) announced that the bill had to be called up or lose its place in the voting queue.<sup>5</sup> Bayh was in his office far from the Senate floor and couldn’t make it there in time, but Dole was located by a Bayh aide and introduced the bill, which passed by unanimous consent and was sent to the White House.

President Jimmy Carter considered a pocket veto — ignoring the bill until the lame-duck session adjourned. His administration had advocated a more comprehensive approach balancing the competing stakeholders’ interests and a unified approach to patents across all federal agencies. But Carter’s aides, along with small-

business leaders, convinced him to sign it into law on December 12. Carter left it to the Reagan administration and future Congresses to implement, amend, and expand the law. Nevertheless, his signature opened the floodgates to a river of money that has become more turbulent over time.

When the Bayh–Dole Act was written, its aim was primarily to stimulate economic growth by more efficiently mining the untapped scientific riches of hospitals, laboratories, and universities. Much has changed since then.

Moreover, some of the most vexing quandaries weren’t fully addressed in the original legislation. In *Myriad*, the Supreme Court has taken on one such question: Who should benefit from discoveries pertaining to nature or the human body? But others remain — for example, what conflicts of interest must be identified and contained in order to protect patients? How can scientific discovery proceed if all innovations and research tools are patented and the discoverers control access to them?

It’s time for Congress to recalibrate Bayh–Dole. Profits and patents can be powerful incentives for scientists, businesspeople, and universities, but new and ongoing risks — including high prices that limit access to lifesaving technologies, reduced sharing of scientific data, marked shifts of focus from basic to applied research, and conflicts of interests for doctors and academic medical centers — should be mitigated or averted through revisions of the law. All Americans should be able to share in the bounties of federally funded biomedical research.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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## “Good” Patients and “Difficult” Patients — Rethinking Our Definitions

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Four weeks after his quadruple bypass and valve repair, 3 weeks after the bladder infection, pharyngeal trauma, heart failure, nightly agitated confusion, and pacemaker and feeding-tube insertions, and 2 weeks after his return home, I was helping my 75-year-old father off the toilet when his blood pressure dropped out from under him. As did his legs.

I held him up. I shouted for my mother. As any doctor would, I kept a hand on my father's pulse, which was regular: no pauses, no accelerations or decelerations.

My mother was 71 years old and, fortunately, quite fit. She had been making dinner and said she dropped the salad bowl when I yelled for her. She took the stairs two at a time. Something about my tone, she said.

Together, we lowered my father to the bathroom floor. I told her to keep him talking and to call me if he stopped, and then I dialed 911.

In the emergency department, after some fluids, my father felt better. My mother held his hand. We compared this new hospital with the last one where we'd spent so many weeks but which had been diverting ambulances elsewhere that evening. The doctor came in and reported no ECG changes and no significant labo-

ratory abnormalities, except that the INR was above the target range. The doctor guessed the trouble was a bit of dehydration. He would watch for a while, just to be safe.

My mother waited with my father. The rest of us filed in and out, not wanting to crowd the tiny room. Then my father's blood pressure dropped again. I told the nurse and stayed out of the way. She silenced the alarm, upped the fluids, and rechecked the blood pressure. It was better. But less than half an hour later, we listened as the machine scanned for a reading, dropping from triple to double digits before it found its mark. The numbers flashed, but the silenced alarm remained quiet. I pressed the call button, and when the nurse arrived I asked her to call for the doctor. When no one came, I went to the nursing station and made my case to the assembled doctors and nurses. They were polite, but their unspoken message was that they were working hard, my father wasn't their only patient, and they had appropriately prioritized their tasks. I wondered how many times I had made similar assumptions and offered similar assurances to patients or families.

After weeks of illness and caregiving, it can be a relief to be

a daughter and leave the doctoring to others. But I had been holding a thought just beyond consciousness, and not just because I hoped to remain in my assigned role as patient's offspring. At least as important, I didn't want to be the sort of family member that medical teams complain about. Now that I'd apparently taken on that persona, there was no longer any point in suppressing the thought. Although the differential diagnosis for hypotension is long, my father's heart was working well, I had adhered to the carefully calculated regimen that we'd received for his tube feeds and free water intake, and he did not have new medications or signs of infection. Those facts and his overly thin blood put internal bleeding like a neon sign at the top of the differential.

I rested my hand on my father's arm to get his attention and said, “Dad, how much would you mind if I did a rectal?”

We doctors do many things that are otherwise unacceptable. We are trained not only in how to do such things but in how to do them almost without noticing, almost without caring, at least in the ways we might care in different circumstances or settings. A rectal exam on one's father, of course, is exactly the