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FEDERALLY FUNDED RESEARCH, THE BAYH-DOLE ACT, AND THE COVID VACCINE RACE

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John Aubrey Douglass
University of California Berkeley

ABSTRACT

This essay discusses the world of federally funded intellectual property (IP) before and after the Bayh-Dole Act and its impact on the world of science and commerce, before then exploring the complicated debates over ownership of the science behind the life-saving COVID-19 vaccines that will bring normalcy back to the world. Before 1980, federally funded science in the U.S. was largely focused on meeting the Cold War national defense needs of a nation in a science and technology race with the Soviet Union. The 1980 Bayh-Dole Act initiated in earnest the recognition that the advancement of national ecosystems of science was also vital for global economic competitiveness. The act allowed university generated IP with federal grants to be owned and licensed by universities for commercial purposes. Before, the federal government retained ownership of IP. The result was a transformation in how universities researchers viewed the research and IP they generated, leading to start-up companies and supporting a revolution in biotech and other emerging areas of science. Although many research-intensive universities already had technology transfer offices, these now proliferated. Universities generated policies on IP ownership, including a policy in which any profits resulting from patents and licenses are shared between the researcher, the department or school they belong to, and the university. Universities and other nonprofits were also required to reinvest Bayh–Dole patent revenues in science research and education, generating substantial resources to new research projects. But the success of the Bayh-Dole Act, and the discoveries it helped generate, also contributed to an increasingly complicated world of IP ownership. The act and similar legislation, as well as federal funding, contributed to the foundational science that led to the variety of COVID-19 vaccines. Its provisions also raise questions about the role, and ownership, of federally funded research that made the vaccine possible. The new Biden administration has put a priority on production and distribution of COVID vaccines, but it may later attempt to control the price and profits of pharmaceutical companies under the "march-in" rights reserved to the federal government. At the same time, the emergence of "vaccine nationalism," in which nations and drug makers prioritize control of IP and production of vaccines for their own population, is testing the ability of the world to effectively respond to the virus as it mutates. In the aftermath of the COVID pandemic, the strengths and weaknesses of the IP world set out by the Bayh-Dole Act will be debated and focused on two questions: who profited from the pandemic and at what global public expense?

Keywords: Bayh-Dole Act, University Research, Intellectual Property, COVID Vaccine, Pharmaceutical Industry

A bit over forty years ago, in the waning days of his presidency, Jimmy Carter signed the 1980 Bayh-Dole Act launching a transformation in the pursuit and purpose of science in the United States. Before 1980, federally funded science was largely focused on meeting the Cold War defense needs of a nation in a science and technology race with the Soviet Union. The 1980 act, named after the two sponsoring Senators, Birch Bayh of Indiana and Bob Dole of Kansas, initiated in earnest the recognition that the advancement of science was also vital for global economic competitiveness.

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* John Aubrey Douglass is Senior Research Fellow and Research Professor at the Center for Studies in Higher Education, UC Berkeley. He is the author of *Neo-Nationalism and Universities* (forthcoming Johns Hopkins University Press) with contributions by colleagues, and *The New Flagship University: Changing the Paradigm from Global Ranking to National Relevancy* (Palgrave Macmillan 2016). This article is based in part on the book project, *The Nexus of Science and Economic Policy*. The author would like to thank Karin Fischer, Bruce B. Darling, George Blumenthal, Jud King, and Jim Hyatt for their reviews of earlier drafts of this paper.

The act allowed university generated intellectual property (IP) generated with federal grants to be owned and licensed by universities for commercial purposes. Before, the federal government retained ownership of IP. The result was a transformation in how universities researchers viewed the research and IP they generated, leading to start-up companies and supporting a revolution in biotech and other emerging areas of science.

Although many research-intensive universities already had technology transfer offices, these now proliferated. Universities generated policies on IP ownership, including a policy in which any profits resulting from patents and licenses are shared between the researcher, the department or school they belong to, and the university. Universities and other nonprofits were also required to reinvest Bayh–Dole patent revenues in science research and education, generating new resources for university research activities.

But the success of the Bayh-Dole Act, and the discoveries it helped generate, also contributed to an increasingly complicated world of IP ownership, built on the concept of national science ecosystems and ownership of IP. The act and similar legislation support much of the foundational science that led to the variety of COVID-19 vaccines. The following briefly discusses the world of federally funded IP before and after the Bayh-Dole Act, and its impact on the world of science and commerce. I then explore the complicated debates over ownership of the science behind the life-saving COVID-19 vaccines, the rise of "vaccine nationalism"[1] and "vaccine diplomacy," and their implications for a global response to the pandemic.

BEFORE BAYH-DOLE

Bolstered by the success of the Manhattan project and Vannevar Bush's report *Science: The Endless Frontier*, a vast federally supported science community came of age in the post-World War II era, growing substantially after the successful launch of Sputnik. The huge leap in scientific prowess of the U.S. owes much to the Soviet Union's success in launching the world's first satellite, thereby proving superiority in that country's missile program and its future ability to launch intercontinental ballistic missiles with nuclear warheads. The result was not only the space race, but a huge increase in federal funding for basic research and the training of scientists in America's growing network of universities.

Multiple new agencies emerged to fund science research in America's universities, including the National Science Foundation (NSF), the National Institute of Health (NIH), the Defense Advanced Research Projects Agency (DARPA), and the National Aeronautics and Space Agency (NASA). And while much federal funding went to developmental research – like rocket technology – new dollars now went to emerging fields of science without any direct sense of its practical usage, allocated largely under a peer review system run by scientists, and not by politicians or business interests.

To ensure that Cold War enemies did not acquire American science and technology knowledge, in 1963 President John F. Kennedy issued an executive order ensuring that discoveries, patents, and licenses generated by federal grants to university researchers would be owned by the government in Washington. That Cold War mentality meant that a huge trove of possible commercial applications of university generated discoveries never saw the light of day. With rare but spectacular exceptions – like GPS and the initial framework for the internet – the federal government proved a poor manager of IP. Prior to the enactment of Bayh-Dole, the U.S. government had accumulated 28,000 patents, but fewer than 5 percent of those patents were commercially licensed.

SCIENCE AS ECONOMIC POLICY

The Bayh-Dole Act also came at a pivotal time of change in the federal economic policy. Faced with an imploding economy, the nation's first trade deficit in the twentieth century, and a waning industrial sector, the new presidential administration of Ronald Reagan vigorously pursued for the first time the integration of science policy as a component of economic policy. In this cause, Reagan officials largely followed the creed of both supply-side economics and corporate welfare.

While Reagan sought large and regressive scale cuts in federal funding for social services, only in two areas did he pursue increased spending: first, and most prominently Reagan provided a seemingly unlimited open check for defense; and second, a surge in funding for science and technology under the concept that it would promote long-term economic growth. Science and technology was increasingly perceived as America's economic advantage.

New monies flowed to the NSF, NASA, and other agencies. And his administration sought to spur private sector generated science and technology by providing new tax incentives for R&D investment, including private sector investment in university research, and supporting changes in intellectual property laws that broaden long-term ownership of IP.[2] The Reagan administration also pursued interventionist policies in semiconductor production in the face of rising competition from Japan, but ended funding for industry-specific projects in alternative energy championed by Carter – arguably a short-sighted and costly mistake.

Like China today, Japan represented a relatively new and significant economic competitor in automotive and electronic related industries and, increasingly, in semiconductors. The Reagan administration charged Japan with the dumping of computer chips on the American market and put $300 million of sanctions on Japanese goods. The federal government also funded the founding of SEMATECH, a government-academia-industry partnership was dedicated to "fundamental change in manufacturing technology and the domestic infrastructure to provide United States semiconductor companies the capability to be world-class suppliers." The technology sector, the only area of trade in which the U.S. had a sizable trade surplus, was to be promoted and protected.

In a campaign that began during the Carter administration, leaders at the NSF sought evidence of the economic impact of federally funded academic research, launching a series of studies to provide data. The goal was to bolster the argument that science funding generated broad social goods, including making the U.S. more economically competitive. It was an argument that found increasing support in the business sector and within the halls of Congress.

Under NSF Director Richard Atkinson, the agency's General Counsel, Chuck Herz, led a federal inter-agency group that helped develop the first iteration of what would later become the Bayh-Dole Act.[3] And the concept that science policy should be integrated into economic policy found immediate purchase in the Reagan administration, including incorporating science policy into the work of Reagan's White House Economic Policy Council.[4]

GAME CHANGER

The Bayh-Dole Act was a game changer. After 1980, universities could now own exclusively the patent rights to federally funded research conducted by their faculty, graduate students, and professional researchers. As stated in the legislation, the intent was not only to use "the patent system to promote the utilization of inventions arising from federally-supported research or development" but also "to promote collaboration between commercial concerns and nonprofit organizations, including universities."[5] The hope was that the benefits of taxpayer funded research would bolster broad public benefits in areas such as cell biology and plant sciences, materials, and new computer and communications technologies derived from advances in mathematics, computer science, and electrical engineering. In turn, it was thought that research discoveries and advances from basic and applied research would produce economic benefits to the nation through the creation of new business sectors and companies.

Universities could now manage the technologies they produce as an asset. While the federal government would no longer own or profit directly from government funded research, the concept was that it would lead to a growth in active licenses and innovation, boosting revenues from profits, wages, and salaries, and thus generating taxes and expanded economic productivity. The Stevenson-Wydler Act, passed that same year, also provided funding for the NSF to support Industry-University Cooperative Research Centers – an initiative long talked about in the higher education community that borrowed the language of federal cooperative agriculture research centers first established in the 1890s.

The Bayh-Dole Act also permitted non-profit organizations and small business firm contractors to retain ownership of inventions funded under federal contracts. The concept of technology transfer, long a part of U.S. universities, particularly in agriculture and engineering, was now aligned with the other sciences at the edge of a transformative period in biology and computing. One result was the private sector, which was increasingly investing in research and development, looked for partnerships with universities in promising science and technology fields. These partnerships brought new resources to science and engineering departments.[6] This came at a time that a number of the major private sector research endeavors, like the AT&T Bell laboratory, and labs supported by Shell and Dow Chemical, were winding down. The private sector increasingly looked to universities to help with foundational research.[7]

In addition, federal law provided tax credits for private sector funding for universities research. That existed before Bayh-Dole, but the act generated increasing interest in university-industry research collaborations, particularly in biotechnology. And, as noted previously, a provision of the act required universities to reinvest patent net income in science research and education, with the concept that some of the benefits of successful patents and licenses would spread to other areas of discovery.[8]

The federal shift in policy and increased funding for basic research would eventually prove profound in promoting research and creating new incentives for start-ups in emerging technologies and arguably providing the foundational research eventually led to the rapid development COVID-19 vaccines. It also provided a wider path for universities to turn their discoveries into products and services that could transform lives and enhance our quality of life.

CONFLICT OF INTERESTS?

It is important to note that the concept of leveraging university generated science to support private sector economic growth was not always welcomed by academics, in the U.S. and elsewhere. Reflecting a Humboltian model, academic researchers generally

adhered to the concept that science should be protected from the crass world of the private sector, and that they should be free to pursue knowledge without concern for monetary value. That concern goes back to a 1918 critique by Thorsten Veblen on the domination of university and college boards by businessman. After Sputnik, faculty and university leaders feared the dominance of federal funding of science that fed the military industrial complex.[9]

By the time of the 1980 Bayh-Dole Act, that concern largely faded and a new one emerged: private sector influence and direction of academic science. Some observers worried that the federal and private sector money meant that important areas of research would be neglected or underfunded – an argument that is hard to quantify. But also influencing the zeitgeist of America's vast network of public and many private universities: their long history of social and economic engagement, often enshrined in their original charters. The general concept that university generated science and talent should interact and promote regional economies was already in their DNA.

In the four-plus decades after Bayh-Dole, much has been written on universities "selling out" to private sector funding for research, particularly in the field of biotechnology. Over time, universities have generally learned how to manage their relationships with commercial enterprises as well as with government directed programs intended to support specific technologies or industries. Such investments have become one part of a larger research and training portfolio that retains significant autonomy.

Hence, blue sky research remains the bread and butter of most STEM related research in universities, with a serendipitous path toward commercialization or advances in, for example, therapeutics. But it is also true that many universities falsely hoped for a "home run" patent that would generate large sources of income. We now know that is a rare event – most patents and licenses fail to generate any income at all, and the legal costs of filing and defending IP is often very large, usually more than consuming the income generated from successful inventions and discoveries.

THE IMPACT OF BAYH-DOLE

The impact of the Bayh-Dole Act on research productivity and advancements in technology is often measured in university generated patents and licenses, and models that attempt to assess their economic impact. One study estimates that the Bayh-Dole Act played a role in the creation of almost 300 new vaccines and drug therapies, including breakthrough treatments for human papillomavirus, hepatitis B, HIV, and Crohn's disease. Another study estimates that the law bolstered economic output in the U.S. by more than $1.7 trillion, generated 5.9 million new jobs, and led to over 13,000 new start-up companies.[10]

Yet such estimates are generally viewed as methodologically flawed. The path and credit of decades of federally funded research leading to a major technological innovation is often hard to assess. More importantly, the Bayh-Dole Act helped shift the mindset of research-intensive universities to include a greater focus on areas of research that might quickly and eventually lead to technological advances. Universities began to develop a technology transfer infrastructure and build a culture that bolsters the arrival and vibrancy of the knowledge economy.

And, as many economists have detailed, arguably the largest benefit of the act and similar legislation was not so much the generation of university owned IP, but the acceleration of what is often called "brain circulation" – the movement of talented people between the academy and technologically oriented businesses – and the proliferation of start-ups often founded by academics.[11] University managed research parks and incubators proliferated, creating relatively new environments to encourage academic entrepreneurialism, along with university research foundations that provided seed funding for promising discoveries.

The American university research ecosystem – with features including joint university-industry partnerships, IP ownership, and the dependency on peer review in the allocation of federal research grants – is now the global model, with significant national and, in the case of Europe, pan-continental versions. By 2000, most if not all members of the Organisation of Economic Cooperation and Development (OECD) had legislation modeled on the Bayh-Dole Act, including the UK, Japan, France, Germany, Austria, Denmark, Norway, Portugal, Spain, and Finland.

Much of Europe was slower than the U.S. in recognizing the value of university owned IP, in promoting university-private sector collaborations, and in providing tax incentives for the private sector to invest in university research. That has all changed. Besides nation specific examples, simply look at the evolving scale of EU science initiatives that began in earnest in 2000 with the adoption of the Lisbon Strategy establishing the European Research Area and now manifest in the Horizon Europe program.

With a focus on the so-called knowledge economy, regional and local governments have also become significant players in attempting to better integrate their universities with their economic development strategies. Economic "hub" partnerships between government, the private sector, and universities are nearly everywhere.[12] In California, for example, arguably the biotech capital

of the world, voters recently approved $5.5 billion in bonds to fund university led stem-cell research in the state, with the concept it will not only lead to advances in health, but boost the biomedicine industry. This is actually the second time California voters have approved a bond act to fund stem cell research, the first, in 2005, created the California Institute for Regenerative Medicine.[13]

THE COVID-VACCINE RACE

Can we draw a line of causation between the new innovation environment created by the Bayh-Dole Act and the development of a COVID-19 vaccine? Many argue you can. But more relevant questions are who should benefit from publicly funded science discoveries, and what controls should governments have regarding the pricing of vaccines and other drugs that directly benefit from those discoveries?

The science that allowed for the speed and success of the various COVID vaccines raises complicated questions regarding IP and the right of the private sector to make money off therapies built on the foundation of academic and government lab research. Many of the big pharmaceutical companies that ventured to develop therapies and a vaccine, like the Pfizer/BioNtech collaboration and Moderna, have promised to provide the vaccine "at costs" but will then seek unspecified profits once the pandemic has ebbed – a determination on the course of the virus that has yet to be defined.

The Bayh-Dole Act not only provided an incentive for government funded research to be brought eventually to the market, including pharmaceuticals; it also gives the government "march-in" rights. Under such rights, the government can require that the owner of the subject invention grant to the federal government "a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants," if the patent holder has not taken "effective steps to achieve practical application" or "to alleviate health or safety needs." In order for the federal government to invoke this compulsory license, a federal agency must determine that "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees." If such a determination is made, a contract is created containing "terms that are reasonable under the circumstances."[14]

Pharmaceutical industry lobbyists and both Pfizer and Moderna have insisted that the march-in rights of the federal government were never intended to control the price of drugs or other discoveries. And as one industry publication warned: "Many activist groups that are asking the government to seize the patent rights of those developing vaccines may not understand how much this would disrupt the innovation ecosystem."[15] When and how the federal government might invoke its march-in rights has been a long subject of debate.

A July 2003 General Accountability Office report addressed this issue and concluded that,

> The government is not entitled to automatic price discounts simply because it purchases products that incorporate inventions in which it happens to hold a license. Furthermore, the government's rights attach only to the inventions created by federally funded research and do not necessarily extend to later inventions based on them. Thus, the government may have no rights in a next-generation invention that builds on federally funded technology if the new invention were not itself created by federally sponsored research. Few of the biomedical products that federal agencies most commonly buy appear to incorporate federally funded inventions.[16]

It is important to note that, thus far, march-in rights have never been used by federal officials. There was lengthy debate over their possible use in the development and pricing of HIV-AIDS medications, including a 2004 lawsuit, but they were never invoked.[17]

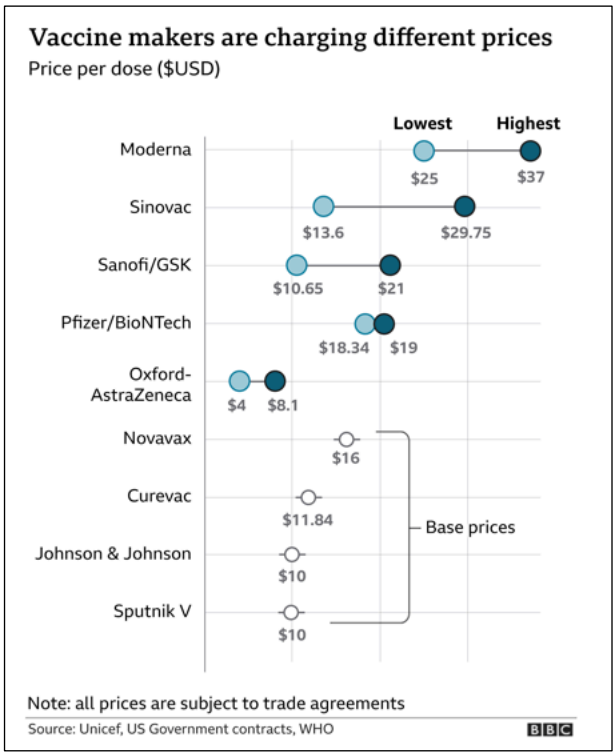
Vaccines, in general, are not usually big money makers – they tend to have one-time, if massive, use compared to highly profitable drugs taken regularly over years and decades. That is why private sector drug makers have not generally invested much into vaccine development. Pharma representatives have noted that the COVID pandemic has reduced the profit motivation: "the big pharma players are more interested in the volume of vaccines needed," notes Erin Herdeman in *Firm News*, "and in regaining the trust of consumers by providing these vaccines as quickly and reasonably priced as they can."[18]

WHO OWNS WHAT?

But public advocacy groups and many scientists beg to differ regarding the possible profit motivation of drug makers, and the right of the federal government to control vaccine prices. Unlike innovations in computing and areas such as materials, the timeline from discovery to an actual product in biomedical and biotechnology is generally much longer and more complex. The remarkable short period of just a year from discovery of the COVID virus to not one but a group of different vaccines was the result of decades of biomedical research.

For example, the Pfizer and Moderna vaccines are both based on what is called mRNA research: The messenger RNA (or mRNA) encodes a key protein of SARS-CoV-2, the scientific name for the strain of coronavirus that causes COVID-19; once the mRNA gets inside our cells, our bodies produce this protein that then acts as the antigen that triggers an immune response. "The basic research on DNA vaccines began at least 25 years ago, and RNA vaccines have benefited from 10 to 15 years of strong research," said immunologist Akiko Iwasaki at the Yale School of Medicine.[19] Researchers at the National Institute of Allergy and Infectious Diseases (NIAID) in Bethesda, Maryland, working with university counterparts, found ways to use RNA sequencing to attack earlier coronavirus strains, including MERS and SARS. Using this technology, Moderna also collaborated with Harvard and the University of Pennsylvania on its vaccine.

The AstraZeneca vaccine, made in partnership with the University of Oxford, does not use mRNA. "Instead, a viral vector (or carrier) holds extra genetic material that codes for the SARS-CoV-2 spike protein. This, too, benefited from years of research to select the vector," explains an article in *Nature*.[20] The Johnson and Johnson vaccine is based on similar technology. Both appear to be similar in effectiveness to the Pfizer and Moderna vaccines, and both do not require the level of deep refrigeration of the mRNA that complicates distribution of the Pfizer and Moderna vaccines. They are also much cheaper to produce and priced, thus far, lower. And emerging COVID therapies are also based on publicly financed research at university and government labs. Since 2014, Gilead has partnered with various universities, led by the University of Alabama, for research into remdesivir , an antiviral medicine approved as a COVID treatment.



In addition, the search for a vaccine in the U.S. included an initial federal investment of around $10 billion as part of the "U.S. Operation Warp Speed" vaccine program, an unprecedented government stimulus package to pharma companies. Presumably to avoid possible federal control of IP and pricing, Pfizer choose not to take any federal money. But those companies that did were then able to quickly scale-up costly clinical trials and simulations the mass production of promising vaccines, whether they worked or not. Funding from Bill Gates' foundation and other philanthropies also helped supercharge research.

And in the rush to secure vaccine supplies, the U.S. government and the EU made multibillion-dollar contracts that protect pharmaceutical companies from liability, patent ownership, and leeway on delivery dates and pricing. The terms of most of these contracts have not been open for public view, seemingly at the insistence of private sector drug makers, but perhaps also political leaders who may not want to deal with the debate they would generate.[21]

Thus far, drug makers are also not sharing information on the actual cost of manufacturing vaccine doses. However, there is some indicators that the Pfizer deal with the U.S. and other countries is among the most lucrative. "Pfizer expects to sell $15 billion worth of Covid-19 vaccines in 2021," notes an industry newsletter. "That would make it the second-highest revenue-generating drug anytime, anywhere, according to industry reports."[22]

ARGUING FOR MARCH-IN RIGHTS

Public Citizen Litigation Group, a public interest law firm co-founded by Ralph Nader, claims that the federal government should have at least partial rights to Moderna and other coronavirus vaccine patents: "It's a classic example of taxpayers paying twice for medicines."[23]

Kathryn Ardizzone, a lawyer with Knowledge Ecology International, a nonprofit public interest group, has stated that the failure of the Trump administration to leverage federal subsidies to avoid large scale profit making after the initial period of "at cost" pricing promised by big pharma participants was a major mistake. "The reality is that this is not just a free market arrangement," she said. "The U.S. government has put up a billion dollars towards the development of the vaccine, and in doing so, should have realized

that it has significant leverage and [negotiated] contract terms that are favorable to the American public and worldwide."[24] Indeed, big pharmaceutical companies showed little interest in developing a vaccine until government funding came into play.

"I think it was unwise of our governments to hand over that money without strings attached," said Ellen Hoen, director of research group Medicines Law and Policy.[25] House Democrats agreed and pushed for march-in rights to be included in the first emergency funding bill passed by Congress last February, but the Trump administration and Senate Republicans successfully blocked this provision. "The industry is concerned that any pricing provisions in the bill could be a 'camel's nose' that could lead to broader efforts to control prices," stated lawyers at BakerHostetler, a firm that represents drug companies.[26]

Unless march-in rights are invoked, it appears that Moderna and other vaccine producers will claim exclusive rights to profits from their COVID vaccines. The Trump administration seemingly dismissed any interest in negotiating terms for public ownership of vaccine IP or in invoking this clause in the Bayh-Dole Act.

In an August 2020 letter to Health and Human Services Secretary Alex Azar, 33 state attorney generals asked that the Trump administration use the provision, but in this case against Gilead Sciences, the maker of the COVID therapeutic remdesivir, which initially charge $2,340 for a five-day treatment course. "Remdesivir has benefited from millions of dollars of public funding, including a $30-million NIH-funded clinical trial estimated for this fiscal year alone," stated the letter authored by California Attorney General Xavier Becerra and Louisiana Attorney General Jeff Landry.[27]

As noted, the march-in provision is untested, and IP law is a complex and convoluted pathway to control drug prices, even in a pandemic. Yet it is also true that simply having this prerogative under the Bayh-Dole Act may allow the new Biden administration to bargain for a lower cost for production and distribution of vaccines. In addition, there other emerging vaccine producers, creating a competitive market, eventually, for different vaccines, although with different efficacies.

VACCINE DIPLOMACY

As early as March 2020, the World Health Organization listed 52 other vaccine candidates.[28] China's CanSino Biologics was the first to launch small clinical trials in a number of nations, including Brazil. Russia has its own "Sputnik Vaccine" with an efficacy claim similar to the Moderna vaccine – although without providing data needed for an international confirmation of effectiveness.[29] Both are based on human adenoiral vectors, like the AstraZeneca vaccine, that are cheaper to produce and administer. This is a huge advantage for mass vaccinations, and particularly in distribution and cost containment for developing economies. But these vaccines may also be significantly less effective than the more complex and costly mRNA based vaccines.

China has already brokered deals with 15 other countries on five continents for distribution of their vaccine. Sinovac, another China-based biopharmaceutical company, has contracted to supply 50 million doses to Turkey, 46 million to Brazil, and 40 million to Indonesia. Meanwhile, CanSino Biologics has agreed to supply 35 million doses to Mexico, as well as to supply its vaccine to Argentina, Chile, Pakistan, and Russia. Recent data from Brazil indicates, however, that the Sinovac vaccine is only 50 percent effective.[30] If so, this could be a major blow to the emerging pharmaceutical industry in China, which is attempting to establish itself as a rival to the U.S. and the EU.

The international race for successful vaccines, and therapeutics, is about defeating a global pandemic; it is also about global influence that vaccine makers, and their governments, can wield. Some nations are openly using their development and distribution of vaccines to further their international political priorities; others who are not actually producing vaccines are securing doses as part of larger deals with governments and drug makers to then distribute to selectively to other nations. Both India and the United Arab Emirates, for example, have purchased doses from the UK and China respectively, and then sent a portion to their allies. This story of "vaccine diplomacy" is evolving rapidly as the world, and particularly developing nations, search for effective vaccines at a manageable cost.[31]

BIDEN, VACCINES, AND IP

For now, the focus of the U.S. federal government under the new Biden administration is to ramp up vaccine production and distribution, which has lagged behind promises of the Trump administration. It is one more legacy of a President who failed to marshal federal resources to effectively battle the pandemic. The Biden strategy includes invoking the Defense Production Act, in an attempt to insure that vaccine makers have priority in the supply chain of chemicals and equipment needed to ramp up vaccine production, and instituting a national plan for giving 100 million or more shots in the first one-hundred days of his administration.[32] Cost containment, it appears, is a secondary issue in the depths of a health and economic crisis in which only a widespread distribution of two or more vaccines will bring salvation.

Back in March 2020, when still in the heat of the Democratic presidential primaries, Biden, unlike a number of other candidates, stated that he did not embrace the use of march-in rights. Instead, he outlined a plan for legislation that would allow the Department of Health and Human Services Secretary to approve the price of vaccines developed with federally funded research – a possibility now that Democrats control both the House and Senate.[33] Controlling overall drug prices is on the agenda of the new Biden administration, along with the larger issue of expanding the Affordable Care Act.

But again, price is not the main concern at the moment; the focus is on increasing supply of doses and vaccinating a larger percentage of Americans, fast. As of early January 2021, the federal government has purchased or pre-purchased over 200 million doses of the Pfizer/BioNTech vaccine at a cost of around $20 a dose, and another 200 million doses from Moderna at around $25 a dose (see Figure on vaccine prices). The promise is that the vaccinations will be free for patients, and thus the cost will be borne by taxpayers.

The goal of rapid vaccine distribution faces challenges. The Pfizer and Moderna vaccines require deep refrigeration, Pfizer's at extreme low temperature (at least initially), that increases the cost of production and delivery, and as well as two doses per patient. Another 300 million doses have been ordered from AstraZeneca at a much lower cost per dose, but with lower efficacy. Yet in the waning days of the Trump administration, supposed federal stockpiles of the Pfizer and Modena vaccines promised to states under the "Warp Speed" program seemed to be missing or simply non-existent.

BAYH-DOLE IN RETROSPECTIVE

The Bayh-Dole Act, along with other federal legislation related to IP, was a major catalyst for expanding America's innovation system. In moving from a federal support system for science that was largely focused on national security needs, to a broader agenda of supporting a more innovative economy that harnessed university and government conducted research, great gains in science and technology have been achieved. The federal government, in the past and today the largest funder of basic research, allowed more explicitly for a link of academic and government lab research with private sector development, incentivized by the promise of financial gain for inventors and universities.

An alternative path that critics have voiced over the years: patents generated via public taxpayer funding remain in the public domain and therefore available to any and all to profit from or use for the public good. The failure for most federally generated discoveries to make it into commercial products, and the free market ethos of the pre-Bayh-Dole era, resulted in the Bayh-Dole legislation that provided incentives for universities, and research and entrepreneurs, to innovation and profit that has been hugely successful.

But the act, the spectacular pace of science and technological advances, and evolving IP law and regulations raise questions regarding who should profit from taxpayer funded research. "Some argue, particularly with respect to pharmaceuticals and biotechnology, that under the Bayh-Dole Act companies are receiving too many benefits at the expense of the public," stated a 2016 Congressional Research Service review of the Act and its impact.[34] The federal government currently provides over $100 billion each year for scientific research through grants and government labs.

Drug prices have long been the major focus of this debate over IP ownership, in part because they are almost always the result of a long period of accumulated discoveries, many made with no idea originally of their applicability and opportunities for commercialization. The COVID pandemic, and the worldwide toll it is taking on the health and economy of nations, provides perhaps the most important test of the concept that profit making in a crisis should be limited or even eliminated, particularly when such profits are significantly based on publicly funded research and incentives. This is the case at least in the U.S. which has not had a tradition of government-controlled drug prices.

The argument against greater regulatory controls? Pharmaceutical companies are driven by profits, spend enormous sums, and take years, sometimes decades, in developing a new drug; take away the financial incentive, and you severely diminish future innovation in biomedicine. The irony is that U.S. taxpayers pay the highest prices in the world for most drugs, many produced based on federally funded research in past decades. Part of the problem is that Americans do not have a national health care system that would help the federal government negotiate better prices. Other countries, including Canada, as well as the European Union, have used their bargaining power to reduce prices. The free market ethos, and the powerful lobbying influence of the mega-rich pharmaceutical industry, has also made American lawmakers reluctant to intervene more directly in controlling drug prices.

Worries also remain over how the Bayh-Dole Act has influenced the behaviors of university researchers away from fundamental research and more toward areas with the promise of commercial applications Corrosive claims of patent ownership of early discoveries can later impede further development and commercialization by others. Entrepreneurial researchers and commercial

enterprises, particularly in biotechnology fields, have filed patents for natural phenomena that could be used for broad claims of ownership and demands for compensation for actual commercially viable products – part of a larger trend toward so-called "patent trolls."[35] It is not an exaggeration to say that Bayh-Dole, and subsequent legislation and legal judgements, helped to initiate a patent frenzy that did not always bolster innovation.

VACCINE NATIONALISM

The Bayh-Dole Act was built around the concept of the primacy of national systems of science and economic policies. It significantly bolstered an existing national research ecosystem now mirrored throughout much of the world, with each country intent on enhancing its own economic competitiveness. But science and innovation are an international enterprise in which discoveries, and patents and licenses, cross national boundaries and include global companies and international collaborations of researchers. Particularly over the last three decades, a global science system has emerged based on a cross-border network of scientists sharing data and collaborating, fueled largely by the interaction of universities and by world organizations and pan-regional alliances, such as the World Health Organization and the EU, respectively.[36]

This emerging modern reality was not a focus of the Bayh-Dole Act. The act encouraged those who received U.S. patents to then seek foreign patents as well. International patent systems are complex, including individual nations with their own patent laws (that require filing at often a significant cost) and pan-regional patent organizations. U.S. universities and pharmaceutical companies alike have filed foreign patents generally in more wealthy countries first for any worldwide distribution. But in the case of a drug needed to address a health crisis in a developing economy, for example, they will seek patent and licensing approval in a country first before allowing production by a third-party, limiting the supply and sometimes blocking the development of lower-cost generic drugs.

Based often on federally funded research and patents, drug makers have generally charged more in more wealthy countries (with the U.S. seemingly having always charged the most) and a lower but still profitable price in developing economies. In the case of drugs developed with university owned patents, universities also profit.

In the midst of the AIDS crisis in South Africa, Yale held a patent and license for an HIV drug that Bristol-Myers produced and then sold at a similar price charged in the U.S. The license generated significant income for Yale, but the price per dosage was simply unmanageable for fighting AIDS in South Africa. In 2001, under political pressure, Yale allowed for the generic making of the drug at a substantial lower cost.[37] Partly in response to this and other cases involving university IP ownership, in 2007, over 100 research-intensive universities signed a declaration promising that they would pursue "responsible [patent] licensing includ[ing] consideration of the needs of people in developing countries and members of other underserved populations."

Two years later a smaller group of universities stated that they were "committed to implementing effective technology transfer strategies that promote the availability of health-related technologies in developing countries."[38] It is difficult to assess if these promises have had a significant impact on, for example, global drug manufacturing and distribution.

The strong adherence to national ecosystems of scientific research and patents and licensing means a complicated path for producing and distributing one or more of the emerging varieties of COVID vaccines (with also the worry of new strains of the virus) throughout the world. University and government lab research, and patents and licenses, are only one part of the story of the decades of research that has led to the remarkable year-long process of developing some ten or more potentially viable COVID vaccines. There is also the story of their worldwide distribution and the costs and politics involved.

By late November 2020, some 10 billion doses of the various vaccines that had or promised efficacy were pre-ordered. Over half of the pre-orders, and now distribution, is to the 27 members of the European Union, along with Canada, the U.S., the UK, Australia, and Japan. In late January, President Biden announced the purchase of an additional 200 million more doses of the Pfizer/BioNTech and Moderna vaccines, bringing the U.S. total anticipated doses paid for by the federal government to 600 million, with the hope of having most Americans vaccinated by summer.[39] Johnson and Johnson and Novavax, both of which received U.S. federal emergency funding, have announced that their vaccines had sufficient levels of efficacy and, perhaps just as importantly, mitigate the severity of those who do catch the virus after a vaccine.

Meanwhile, EU leaders are complaining that delays in the distribution of the AstraZeneca/Oxford vaccine are purposeful, and that the UK is giving priority to its citizens. Having multiple effective vaccines will help mitigate the COVID virus and its mutations and help to contain prices. But the largely undisclosed deals made by governments to secure supplies will secure profits as well for drug makers.

It also evident that demands of the U.S., the UK, and EU to secure doses, and the price they are willing to pay, leaves dwindling short-term supplies of vaccines for low- and middle-income countries. In December 2020, the governments of India and South Africa asked COVID vaccine producing companies, via the World Trade Association (WTO), to suspend their IP rights to ensure the production of the vaccine in less wealthy countries. "What this waiver proposal does is it opens space for further collaboration, for the transfer of technology, and for more producers to come in to ensure that we have scalability in a much shorter period of time," stated a representative of the South African Permanent Mission to the WTO.

The U.S., UK, Canada, and the EU rejected the proposal with the argument that it would stifle further innovation in biomedicine.[40] Under an "emergency license," India and Brazil have become a major producer of the AstraZeneca vaccine, but with no public information on the financial agreement. (India is also developing its own Covaxin vaccine based on adenoiral vectors.) There remains a movement to suspend international IP laws to facilitate vaccine production and distribution.

The scale of the challenge to vaccinate some 80 percent of the world's population is immense. As of this writing, only about two billion doses of COVID-19 vaccines have been promised for the 190 low and middle-income countries that signed onto a World Health Organization-led partnership called COVAX.[41] Some of the contracts with the U.S. and EU restrict sending vaccines to other parts of the world.[42] So-called vaccine nationalism is emerging as a major international controversy. By early February, COVAX had contractually secured only some 330 million doses of the Oxford/AstraZeneca and Pfizer/BioNTech vaccines for 145 countries that, it is estimated, would cover an average only 3.3 percent of each country's population by June 2021 – unless more vaccines are distributed.[43] The Biden administration announced at a meeting mid-February meeting of the G7 that the U.S. will contribute a total of $4 billion to COVAX, and urging other nations to increase their contributions.[44]

The long-term prospects may be better, as the number of effective vaccines grows, production ramps up, and worldwide distribution becomes more effective. But the lag gives the virus time to spread in much of the world and for new variants of the virus to emerge. Administration of COVID vaccines will not be a one-time event, but likely an on-going, multi-year endeavor with boosters and required modifications. A pandemic cannot be defeated if in only one portion of the world the virus is contained. Countries seeking to inoculate their citizens at the expense of everyone else are chasing a false promise, notes Yasmeen Serhan in an article in *The Atlantic.*[45]

Bayh-Dole helped launch a revolution in science and technological innovation built on the foundation of national science ecosystems that made universities, government, and the private sector partners and that incentivized patenting and licensing. In many areas of technological development and commercial application, this system has been extremely successful. But as noted, it remains unclear how well this system serves the larger public good especially in the midst of a global health crisis. In the aftermath of the COVID pandemic, one might assume that the issue of the strengths and weaknesses of the IP world set out by the Bayh-Dole Act will be debated and focused on these questions: who profited from the pandemic and at what global public expense?

ENDNOTES

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7 This was much of the reason for the formation of the Council for Chemical Research, the generation of which is described by Ivan Legg [https://pubs.acs.org/doi/pdf/10.1021/bk-1992-0478.ch002]

8 The statute specifies that any grant agreement must contain a "requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to administration of subject inventions, be utilized for the support of science research or education." 35 U.S.C. §202(c)(4

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sympathizers. This debate was carried out at meetings of the National Academy of Sciences, during which a number of NAS members threatened to resign from the Academy unless the Academy disassociated itself from advising the federal government on its prosecution of the Vietnam War. In the end, I think only one member of the Academy resigned due to these concerns.

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