A Fair Trade: How Intellectual Property Policies Unlock Better Access to Care

A White Paper

Alliance for Aging Research

Introduction

On March 31, the Alliance for Aging Research convened leading patient advocacy organizations, policy experts, academic leaders, and innovation stakeholders for a timely and urgent discussion. The focus: the importance of intellectual property (IP) protections in fostering the research, development, and delivery of groundbreaking medicines that patients rely on.

Amid ever-evolving public discourse and policy debates, the event served as a clarifying forum for shared priorities. It brought together diverse voices committed to a common goal: ensuring those in need continue to benefit from the life-changing innovations driven by American ingenuity.

The convening explored IP's complex yet critical role in the biomedical research and development ecosystem. From the first spark of discovery in a university lab to the moment a patient receives a new, potentially life-saving treatment, IP protections fuel every step of the journey. They incentivize investment, foster public-private partnerships, and turn promising ideas into real-world therapies.

And yet, the system that enables this progress is increasingly under threat. Many policy proposals gaining traction today are driven by understandable concerns — about high drug prices, access disparities, and system inefficiencies. But while well-intentioned, these efforts often target the wrong culprit. Instead of addressing the true structural challenges within the healthcare system, they risk undermining the very IP protections that make innovation possible in the first place. If these safeguards are eroded, the consequences for future access, investment, and patient care would be profound.

Three panel discussions framed the day's conversation. The first examined the importance of technology transfer and the Bayh-Dole Act in bringing federally funded research to market. The second addressed the rise of patent-related myths that distort public perception and threaten the integrity of the system. The third focused on America's global leadership in biopharmaceutical innovation and the growing risks posed by international policy trends.

This white paper distills the key themes, insights, and recommendations from the event. It offers a patient-centered lens on what's at stake — and why IP must remain a cornerstone of American health innovation.

I. Panel One: From the University Lab to the Medicine Cabinet: The Role of Technology Transfer

Moderator:
• **Kate Hudson**, *Deputy Vice President, Association of American Universities*

Panelists:
• **Joseph Allen**, *Executive Director, Bayh-Dole Coalition*
• **Dennis Liotta**, *PhD, Samuel Candler Dobbs Professor of Chemistry, Emory University*
• **Jennifer Luray**, *Senior Vice President, Research!America*
• **John Stanford**, *Executive Director, Incubate Coalition*

Every day, discoveries are made in American labs. But turning those discoveries into accessible medicines requires more than scientific brilliance — it demands a policy environment that supports risk-taking, rewards public-private collaboration, and protects invention. The first panel, moderated by **Kate Hudson**, focused on the foundational role of technology transfer in biomedical innovation — and the pivotal legislation that makes it work: the Bayh-Dole Act.

Passed in 1980, Bayh-Dole empowered universities to retain patent rights to federally funded research. This simple shift unlocked a wave of public-private partnerships, transforming government-funded discoveries into more than 200 FDA-approved drugs and countless medical technologies. As **Joseph Allen** explained, the law corrected a system where promising innovations once gathered dust due to a lack of commercialization pathways.

Dennis Liotta brought this process to life with his story of Emtriva, a groundbreaking HIV therapy that emerged from academic research. He and his colleagues at Emory University developed the drug in response to the devastating HIV epidemic, which was claiming the lives of many in their medical community. But as Liotta explained, the discovery alone wasn't enough. Without strong IP protections and private sector investment, the treatment would have remained in the lab. "If I didn't do a good job in developing intellectual property that would provide that exclusivity, I might find a drug that was really fantastic, but no one would develop it — because they couldn't," Liotta said. "The economics just wouldn't make sense."

Building on that theme, **Jennifer Luray** emphasized Bayh-Dole's far-reaching impact on the innovation ecosystem. The law not only accelerates scientific progress, she noted — it also delivers new products to market, spurs innovative new businesses, and fosters economic development. "Since 1980, American universities alone have generated over $1.3 trillion in economic growth, 4.2 million jobs, and 11,000 startups that can be directly attributed to Bayh-Dole's enactment," Luray noted.

John Stanford followed with the venture capital perspective. Early-stage biotech investment is notoriously risky, often requiring a decade or more before a product reaches the market — if it ever does. As Stanford noted, due to incredibly high rates of failure in the biopharmaceutical field, venture capitalists need to exceed a 1,000% rate of return just to break even. Strong, predictable IP protections are the reason those investments happen at all. "The only thing we have [as investors] is rock-solid confidence that our asset can be protected," he said.

Despite this success, the Bayh-Dole framework is facing new risks. Panelists warned of growing calls to reinterpret Bayh-Dole's "march-in rights"— a provision within the law that allows the federal government to re-license a patent resulting from a federally funded invention if the invention isn't being made accessible to the public. There are those who argue that march-in rights should be used as a tool to allow the government to control or reduce the price of a patented invention. But this reinterpretation fundamentally misunderstands the law's purpose.

Allen clarified that march-in rights are intended to ensure public use of neglected inventions — for example, if a company shelved a promising medical technology and refused to bring it to market — not as a mechanism to retroactively penalize success or dictate pricing. Using it otherwise would undermine investor confidence, jeopardizing future breakthroughs.

The panel closed with a stark warning: Bayh-Dole's public-private structure is one of the most successful innovation policies in history — and tampering with it risks undermining the very cures policymakers aim to make more affordable. "Do you want research papers or do you want cures?" Allen asked the audience. "Under Bayh-Dole, you get both. But if you destroy intellectual property rights, you're just going to get those papers."

II. Panel Two: Patent Myths and Misconceptions: Why Advocacy Must Be Grounded in Facts

Moderator:
• **Chris Israel**, *Executive Director, Alliance of U.S. Startups & Inventors for Jobs*

Panelists:
• **David Kappos**, *Co-founder, Council for Innovation Promotion; former Director, USPTO*
• **David Korn**, *Vice President, Intellectual Property and Law, PhRMA*
• **Brian O'Shaughnessy**, *Partner, Dinsmore & Shohl LLP*

The second panel, moderated by **Chris Israel**, tackled a growing challenge in today's policy discourse: the persistence of patent-related myths.

Terms like "evergreening" and "patent thickets" have become shorthand for abuse. The accusation of "evergreening," for instance, mischaracterizes the practice of obtaining follow-on patents for meaningful improvements — like turning a twice-daily pill into a once-daily extended-release version, or developing a combination inhaler that delivers both a bronchodilator and a steroid for more effective asthma control. Likewise, "patent thickets" is a term often used pejoratively to describe the layering of legitimate patents that protect various aspects of a complex innovation.

In reality, both terms describe legitimate, lawful practices that support continued investment in improving products for patients — they are being mischaracterized to imply manipulation. These narratives, the panel warned, simplify the larger picture and fuel misguided reform efforts.

Opening the discussion, **David Kappos** underscored the role of the U.S. Patent and Trademark Office (USPTO) in driving and safeguarding American innovation. He noted that the patent system includes built-in checks — from opposition proceedings to litigation channels and regulatory review — that guard against abuse.

What critics label as "gaming the system" is, in most cases, a sign that the patent system is working as intended: protecting genuine innovation and incentivizing the continual improvement of medical products. Filing patents on improvements is not a workaround — it's a core element of a functioning innovation ecosystem.

Follow-on patents recognize and reward the ongoing research and investment required to enhance existing therapies for patients' benefit — whether through improved formulations, combination products, or delivery methods. That could mean transitioning a treatment from a daily pill to a monthly injection, or developing an extended-release patch that delivers medication steadily over time. These are exactly the kinds of incentives the patent system was designed to provide: Innovation doesn't stop at a product's initial approval, but continues to evolve in ways that improve patient outcomes.

David Korn explained how such advances made after initial FDA approval — whether a new formulation, extended-release form, or safer delivery method — are anything but trivial. These improvements make medications easier to take, more effective, and better suited to real-world needs, transforming how patients manage chronic and oftentimes debilitating conditions. "The people who say that changes to a medicine are trivial or insignificant don't appreciate the value these improvements make to patients struggling to manage very debilitating illnesses," Korn explained.

Brian O'Shaughnessy added a strategic lens, warning against the oversimplification of IP policy debates. "IP is a war-and-peace industry in a bumper sticker world. And in Washington, the old saying is if you're explaining, you're losing," O'Shaughnessy remarked. He emphasized the importance of patient advocacy groups adding their voices to the discussion, and using real patient stories to underscore IP's impact.

Throughout the discussion, **Chris Israel** emphasized the danger of letting slogans and soundbites shape policy. The panel agreed: when public discourse drifts from fact to fiction, it's patients who ultimately pay the price.

The panelists called on patient advocacy groups to take a more active role in correcting misinformation. Trusted by lawmakers and the public alike, advocates can acknowledge the frustration that fuels these narratives — from concerns about affordability to misconceptions about patents — while explaining how innovation truly works. They can help shift the conversation by grounding debates in the realities of the biomedical ecosystem and the lived experiences of patients who benefit from ongoing improvements.

This isn't just about setting the record straight — it's about preserving the conditions that make scientific progress possible. The solution lies in education and reform that strengthens — not undermines — the engine of progress. To that end, Kappos encouraged support for three key pieces of legislation: the RESTORE Patent Rights Act, the PREVAIL Act, and the Patent Eligibility Restoration Act (PERA).

All panelists agreed that healthcare costs are a serious concern — but advocates must make clear that weakening patents is the wrong tool for the job. "It takes the users of the system, it takes the companies, it takes the patient groups … to explain it to a member or a staffer," Israel concluded. Facts, patient voices, and a clear articulation of what's at stake are the best antidotes to policy built on slogans.

III. Panel Three: Global Leadership Under Threat: IP and America's Biopharmaceutical Edge

Moderator:
• **John Hamre**, *PhD, President & CEO, Center for Strategic & International Studies*

Panelists:
• **Mary Critharis**, *Deputy Chief Policy Officer & Director for International Affairs, USPTO*
• **Patrick Kilbride**, *Former Senior VP, Global Innovation Policy Center, U.S. Chamber of Commerce*
• **Mark Schultz**, *Chair in IP Law, University of Akron School of Law*

The final panel zoomed out to the global stage. Moderated by **John Hamre** of the Center for Strategic & International Studies, the conversation explored how IP leadership in the U.S. shapes not only domestic innovation, but the entire global health landscape.

Hamre opened by drawing a direct line between IP and national security. There is, he said, lowercase "national security" — tanks, troops, and aircraft carriers — and then there is capital "National Security": the strength of our economy, the vitality of our innovation ecosystem, and the cohesion of our society. It is the latter — our ideas industry, our talent, and our creative capacity — that allows us to sustain the former.

With that framing, the panel turned to the question at the heart of the discussion: Why is the United States a global leader in biopharmaceutical innovation, and what's at stake if that leadership is lost?

Mary Critharis emphasized that U.S. policies don't just shape innovation at home — they set the global standard. She outlined the USPTO's work in promoting balanced IP systems through trade agreements and diplomacy, and noted how data exclusivity, trade secrets, and strong enforcement mechanisms form an IP ecosystem that fuels biotech innovation and growth.

Patrick Kilbride reminded the audience that, despite having different backgrounds and levels of expertise, they had one experience in common — that of being a patient. While individual needs vary, he emphasized that all share the imperative to make new therapies available "at the fastest possible speed and at the lowest possible cost." He distinguished between cost and price, which are often conflated in policy debates, and pointed to five key factors that help lower both: investment in research, market-based incentives, regulatory efficiency, supply chain resilience, and fair global pricing.

Kilbride also warned that U.S. companies are increasingly constrained abroad, facing price controls, antitrust threats, and coercion through tools like compulsory licensing — a mechanism by which governments can override a patent and authorize the use or production of a medicine without the patent holder's consent. While typically framed as a way to expand access during public health emergencies, these licenses are increasingly used or threatened as leverage in pricing negotiations.

This trend is part of a broader international movement that questions whether strong IP protections are compatible with affordable healthcare — a damaging narrative that discourages innovation precisely where it's needed most.

"[U.S. companies] need the U.S. government as a partner," Kilbride added, to address these disparities and protect the innovation ecosystem. He sounded the alarm on growing international calls for broad IP waivers — warning that such efforts risk undermining the very incentives that make new medicines possible.

Mark Schultz reinforced that America's leadership is not guaranteed. Until the 1990s, he noted, most new drugs were developed and launched outside the United States. It was only after deliberate policy reforms — including tax credits, regulatory modernization, and IP protections — that the United States became the world's R&D leader. "We're all, as human beings, equally inventive and creative. What makes the difference is institutions," Schultz said, underscoring the far-reaching effect that misguided policies can have.

The discussion also turned to the Trump administration's renewed consideration of tariffs on medicines. Schultz noted that medicines have historically been exempt from tariffs for a reason. "We're bound to see shortages [if tariffs are enacted]. We're bound to see price increases," Schultz stated. "If we have a global trade war on tariffs with medicine, people will be harmed. People will die." Kilbride agreed, adding that while it's vital to build domestic capacity, supply chain resilience depends on collaboration — not isolation. "We have to have a strategic trade policy, not an adversarial one," he said. "Or else we're really doing ourselves a disservice."

Panelists concluded with a call to action: the U.S. must reaffirm its leadership in setting global innovation norms. That includes resisting forced tech transfer, maintaining investment incentives, and protecting core IP rights.

The takeaway was clear: IP is not the enemy of access — it's what makes access possible, both domestically and around the world.

IV. Town Hall Reflections: Elevating Patient Voices and Strengthening Collaboration

The closing town hall session underscored a critical truth: the innovation ecosystem is delicate — and sustaining it will require stronger collaboration between patient advocates, industry, academia, and government. While advocacy organizations are some of the most trusted and effective messengers in policy debates, they cannot carry this work alone. They need committed partners who are willing to elevate patient stories, amplify caregiver voices, and reinforce the policies that make progress possible.

Questions and statements from advocates at the ALS Association, HIV + Hepatitis Policy Institute, Caregiver Action Network, and others highlighted both the urgency and complexity of this effort. Their perspectives brought real-world context to issues like patent eligibility, regulatory certainty, and the barriers that can deter investment in long-term research areas.

Chief among the shared priorities discussed during the town hall was the need to uphold the Bayh-Dole Act. This foundational law is the bridge between public investment and private-sector innovation — and its integrity must be protected. As one speaker noted, for every $1 invested by the National Institutes of Health (NIH), industry contributes another $3 to bring discoveries to market. Undermining this balance risks stalling the development of the next generation of treatments.

Several advocates also drew attention to how different diseases face unique innovation hurdles. In areas like ALS and Alzheimer's, for instance, research often takes longer, patient populations are smaller, and regulatory pathways are more complex. Any changes to patent protections or investment incentives can have outsized effects — making disease-specific advocacy critical to ongoing policy conversations.

Participants called for practical, actionable ways to engage: joining sign-on letters, submitting patient stories to Congress, or participating in briefings that make these complex issues easier to understand. They also highlighted the importance of continued education and user-friendly resources that can translate IP policy into patient-relevant language.

Importantly, speakers stressed the need for industry to continue supporting and engaging with the patient community. Advocacy groups often surface unmet needs or barriers that companies may not anticipate — including caregiver burdens that can be eased by incremental innovations, like longer-acting patches or simplified dosing regimens. These are life-improving advances that reflect the real-world stakes of policy decisions.

As the group reflected on the decades-long erosion of patent rights, the clear takeaway was that preserving this ecosystem must be a collective priority. Progress depends on sustained partnership and a renewed commitment to the policies that enable innovation, access, and better care.

Conclusion: A Call to Action for Patient Advocates

Across all three panels, a unified message emerged: IP protections are not barriers to access — they are the mechanisms that make access possible. They fuel breakthrough science, attract investment in high-risk development, and pave the way for tomorrow's cures.

Unfortunately, the system that enables this progress is under increasing pressure. Efforts to reinterpret the Bayh-Dole Act, persistent myths that downplay the value of incremental innovation, and global pushes for broad IP waivers all threaten to undermine the delicate balance that sustains medical progress.
These attacks are often rooted in frustration over drug prices and access barriers — systemic issues that deserve serious attention. But dismantling IP rights in response is not the answer. These time-limited, transparent, earned protections reflect the significant risk, investment, and scientific effort required to bring a therapy to market — and they are not to blame for the broader challenges in our healthcare system.

Policymakers must tread carefully, ensuring that reforms do not sacrifice long-term innovation for short-term optics. We can and should pursue affordability — but reforms should be aimed at the real drivers of patient costs. Blaming patents for these issues is both inaccurate and counterproductive.

Patient advocacy organizations have both the power and the responsibility to defend this innovation engine. By championing evidence-based policy, challenging misleading narratives, and keeping the patient perspective front and center, they can help protect the progress of the past fifty years — and ensure the next fifty deliver even more.

The Alliance for Aging Research and its partners remain committed to safeguarding the IP protections that benefit patients. But we cannot do it alone. We invite policymakers, researchers, advocates, and industry leaders to join us in reaffirming that strong IP rights are not only compatible with access, they are essential to it.

Access and innovation are not opposing forces. They are two sides of the same coin. Weakening IP won't build a better system for patients. Strengthening it — and pairing it with smart, equitable policy — is the path forward.

Ultimately, this isn't just a conversation about law or economics. It's about ensuring scientific discoveries reach those who need them most. It's about delivering cures and saving lives.