America's intellectual property system

The backbone of patient access to critical medicines

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Introduction

Biopharmaceutical research in the United States is a long and uncertain endeavor, driven by the complexity of hard-to-treat diseases, high development costs and stringent regulatory requirements.

Yet patients in the U.S. benefit from biopharmaceutical innovators' ability to invest billions of dollars in research and development because of the backbone supporting American innovation: the U.S. intellectual property (IP) system.

The strength of this system has positioned the U.S. as the world's biopharmaceutical innovation leader, providing patients with:

- ☑ Innovative medicines that have transformed the treatment of many serious and chronic diseases, delivering patients cures and effective treatments.[1]
- ☑ Medicines that have significantly contributed to improved life expectancy in the U.S., accounting for an estimated 35 percent of the total increase in life expectancy between 1990 and 2015. As a result, more people are living longer, healthier lives and spending more quality years with their families.[1,2]
- ☑ The earliest and broadest access to novel medicines of any nation in the world.[3]
- ☑ A thriving generic market that provides patients with access to low-cost medicines.[4]

Unfortunately, misguided critiques of the IP system based on significant misconceptions undermine U.S. biopharmaceutical innovation leadership, global competitiveness and patient access.

To preserve and strengthen this system, it is critical policymakers focus on retaining the careful balance that provides Americans with both the quickest access to new therapies and the most competitive generic market in the world.

Patents are the cornerstone of the American IP system.

Standard patent protections:

20 years

Patents provide innovators with a limited term of protection for inventions and generally provide 20 years of protection from the time they are filed.

Average time protected while in market:

14 years

Because of the time it takes to develop and gain approval for new medicines, the average time a drug approved for the market is protected by patents is around 14 years.[5*]

Competition to first-in-class drugs:

2.5 years**

Patients enjoy the benefits of competition even before a patent has expired. Even medicines pioneering a new drug class face branded competition within that class after 2.5 years** on average, with a quarter encountering competition within just one year. Additionally, novel molecules routinely face market competitors upon launch, such as products from other drug classes and other mechanisms in the indication. IP rights enable and incentivize such competition between innovative products, rather than prevent it.[6]

The framework of balanced IP rights in the U.S. is delivering the twin goals of better treatments and robust generic competition. After the period of exclusivity ends, the Hatch-Waxman Act, a 40-year-old law that unlocked the golden era for patient care, drives further patient benefit by facilitating the entry of low-cost generic drugs. This is a phenomenon with decades of success across many therapeutic areas.[7,8]

* Based on new molecular entities (NMEs) with initial generic entry in 2017-2019.
** First-in-class approvals 2005-2011 with later entries through 2015.

Part 1:

Intellectual property: From innovations to generics

Without balanced IP rights, innovation falters

To sustain the U.S. as a global leader in pharmaceutical innovation, policymakers must preserve the benefits of the existing intellectual property (IP) ecosystem.

Evidence shows that when IP protections are weakened—whether through regulatory overreach or legislative erosion—private-sector investment quickly declines due to uncertainty over whether innovators can realize a fair return for the value of their innovative contributions to society.[8] To spur U.S. competitiveness, support American jobs and advance innovation, the federal government will need to reject calls to weaken the IP system in the U.S. and simultaneously champion a more robust global IP regime.[9]

History provides compelling evidence of what happens when IP protections are undermined. By 1982, Japan had become the world's second-largest investor in pharmaceutical R&D, behind only the United States. However, due to a set of policies weakening the value of IP protections, including excessive price controls, the country squandered its biopharma competitiveness. Japan's share of global value added in the pharmaceutical industry declined 70%, from 18.5 to 5.5, between 1995-2018.[10]

In the U.S., experiments with more invasive IP rules have hampered innovation and were soon dismissed. In 1989, the National Institutes of Health (NIH) mandated that licenses for the use of NIH-funded work include restrictive provisions governing how innovations were commercialized.[11] It didn't take long before that policy was widely regarded as a failure. Companies could not justify investing huge sums in the development of technologies with compromised IP protections, and the provision was rolled back by Harold Varmus, then director of the NIH, in 1995. Such restrictions, Varmus acknowledged, had "driven industry away from potentially beneficial scientific collaborations with PHS (Public Health Service) scientists without providing an offsetting benefit to the public."[11]

Patents promote innovation and enable competition

In addition to providing an incentive for R&D, IP rights promote "innovator vs. innovator competition" by attracting investment and encouraging the development of alternative innovative treatments during the exclusivity period.

While a product is covered by IP protections, competitor companies can learn from innovator patent filings and are free to develop alternative technologies and solutions that benefit patients. As seen in various drug classes with branded competition (see sidebar on the treatment of hepatitis C), this catalyzes the development of new products, increases patient choice and can lead to lower costs—long before the loss of exclusivity of an initial treatment occurs. In short, there would be no branded competition were it not for robust IP protection for new entrants.

Hepatitis C and IP protections

When a product is covered by IP protections, competitor companies can learn from innovator patent filings and are free to develop alternative solutions that benefit patients.

For hepatitis C, a new wave of curative therapies entered the market in 2013. There were initial concerns regarding the budget for health systems to deploy these treatments, but five new competitors very quickly entered the market between 2014 and 2016.[12]

Thanks to U.S. IP protections that fostered competitive innovation, prices declined rapidly, and even better treatments are now available at lower cost than the previous standard of care.

Without this IP framework, such innovations would never have attracted the necessary investment in the first place.

A balanced IP system in the U.S. has delivered world-leading biopharmaceutical innovation and a thriving generic marketplace

Patients benefit through both continued innovation and access to low-cost generics.[13]

In fact, today's innovative R&D pipeline is the foundation from which tomorrow's generic medicines emerge.

To encourage the entry of generics or biosimilars, regulatory agencies like the Food & Drug Administration (FDA) rely upon innovators in the biopharmaceutical industry to perform complex, costly and time-consuming clinical trials. Generic manufacturers are not required to conduct such trials. Thus, there would be no new generics without the groundbreaking research conducted by innovators.[1]

Data exclusivity incentivizes innovators to generate rigorous safety and efficacy data by protecting this information for a limited period.*

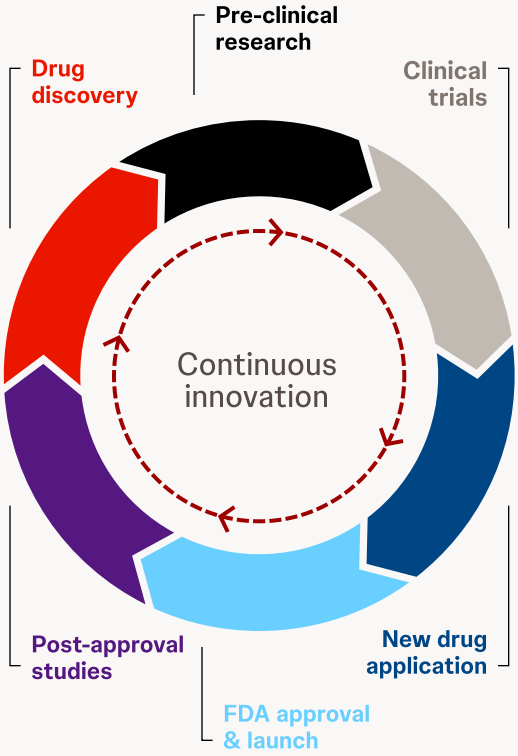
Once exclusivity ends, generic and biosimilar manufacturers use the original data to quickly enter the market with low-cost versions of the original compound at significantly reduced prices.

Today, more than 90% of prescriptions in the U.S. are for generic medicines that were once protected by patents, compared with just 19% in 1984.[14] [15]

Not only do generics routinely take over across various drug classes, but they do so quickly, with market prices falling faster and more dramatically in the U.S. than in peer nations.[16] Among the beneficiaries of this are Americans on Medicare: 90% of Medicare prescriptions are for generics, according to data from MedPAC.[17]

Lifecycle of biopharma R&D

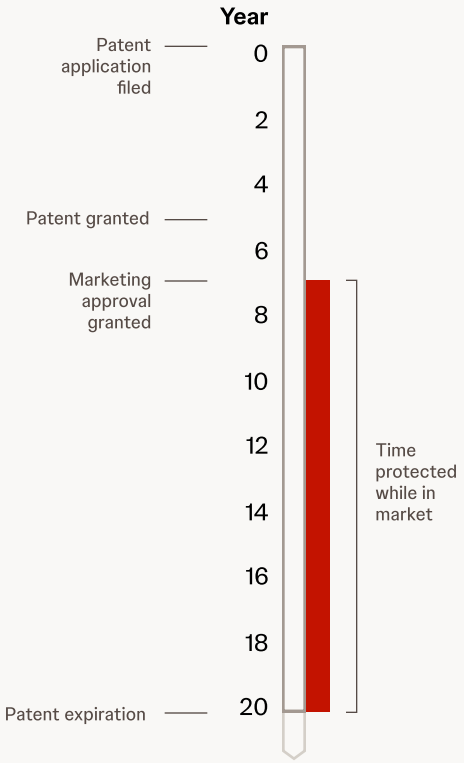
Patent protections ensure innovation can occur throughout the drug development lifecycle. Post-launch, real-world evidence and post-approval studies deepen our understanding of medicines' impact and support continued innovation.



Illustrative timeline: The patent process[18]**

Patent protection lasts 20 years from filing, but much of this protection period is lost due to the time it takes to develop and gain approval for a new medicine.

- Patent protection (20 years)
- Time protected while in market



**Illustrative example for a theoretical product approved seven years after initial patent filing.

*Data exclusivity provides pharmaceutical companies who undertake tolerability, safety, and efficacy testing on their products a limited time where only they can use their clinical data for regulatory approval. Afterward, regulators allow other companies to use those data for generic/biosimilar approval without having to repeat the costly clinical trials, thus enabling lower prices.[17]

IP protections are vital to U.S. competitiveness

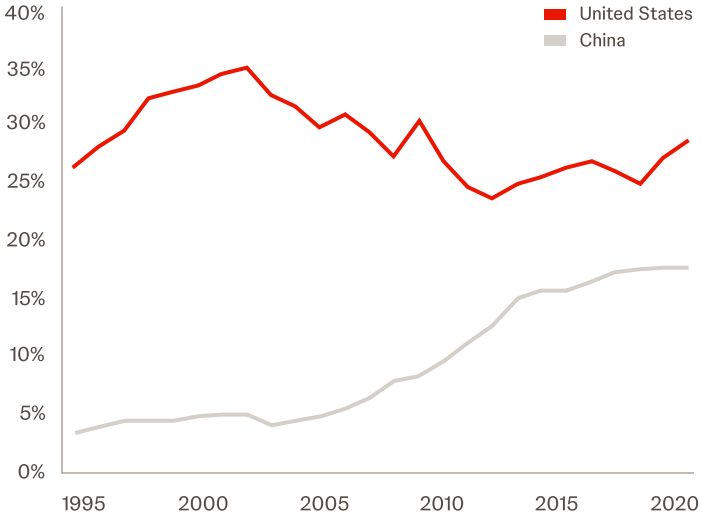
The U.S. remains the global leader in biopharmaceutical development, in large part due to supportive policies including robust IP protections. However, America's continued leadership is not guaranteed without strong IP policy. While China has a smaller base, it has seen a rapid increase in the number of new chemical entities developed.

Between 1995 and 2020, China's global share of value-added biopharmaceuticals increased by 14.4 percentage points, compared with 2.2 percentage points for the U.S.[19]

For the U.S. to retain its current leadership in drug development, it must nurture the IP system that enables biopharmaceutical innovation. America's dominance is jeopardized if diminished patent protections or restrictive IP policies slow the pace of U.S. innovation.

China's relative ascendance on new chemical entities

Global shares of value-added output in pharmaceuticals, 1995–2020[19]



American jobs in the biopharmaceutical industry

The biopharmaceutical industry employs 1,049,839 Americans and generated more than $165 billion in personal income in 2022.[20]

The total economic impact of U.S. biopharma was $1.65 trillion in 2022, including direct, indirect and induced effects.[20]

Biopharmaceutical sector	Estimated sector employment	Share of total industry employment
Biopharmaceutical R&D	408,993	39.0%
Biopharmaceutical manufacturing	359,429	34.2%
Biopharmaceutical distribution	248,374	23.7%
Biopharmaceutical corporate offices	33,043	3.1%
Total	**1,049,839**	**100.0%**

Part 2:

The facts about intellectual property

Clear and accurate information is essential for productive policy discussions about IP, particularly in understanding the crucial role patents play in driving biopharmaceutical innovation. Focusing on data can help us better appreciate the value and purpose of IP protections in advancing medical progress.

Continued product innovation leads to better outcomes for patients

There is a misconception that innovation stops at FDA approval. In fact, post-market research often expands the use and effectiveness of a medication. For example, nearly 65% of oncology drugs have follow-on indications discovered after initial approval—expanding access and improving treatment outcomes.[21]

A U.S. Patent and Trademark Office (USPTO) study documented that the patent system supports the development of improvements that deliver patient benefits, such as safer dosing or new indications. Importantly, the study illustrated how generic versions of the original medicine entered the market even while later patents covering follow-on innovations—such as improved dosing or new uses—remained in effect.[22]

Initial approvals are the first step in identifying the patient populations and indications that will benefit from a medical innovation, but not the last. Undercutting post-approval R&D threatens those improvements. Post-approval research is often focused on innovations to identify and develop safer formulations, pediatric uses or entirely new indications. These innovations deliver enormous benefits to patients, and they deserve protection and support.

Public and private research complement each other

Public-sector research often contributes to foundational basic scientific research, but the reality is that private biopharmaceutical firms are responsible for the vast majority of the development, clinical trials, regulatory approval and manufacturing that brings medicines to patients.[23] Weakening IP protections undercuts the incentive to take on these massive, high-risk investments.[24]

Anything but trivial: Continued innovation

Continued innovation refers to the enhancement of an existing drug or the development of additional drugs within an established drug class.[13]

These types of innovations generally fall into four different categories that are key to advancing health care:[13]

New uses or indications are a form of innovation where drugs are used to treat different conditions than those for which they were initially developed.

A drug that was developed as a chemotherapy agent in the 1940s was later shown to have promise in treating autoimmune conditions.

New patient populations can benefit when existing drugs are adapted to address the needs of new subsets of patients.

An antibiotic was initially developed and approved for adults but was later reformulated to treat pediatric patients through dissolvable tablets.

New formulations involve modifying how compounds are combined to form the medicine to improve efficacy and address side effects.

A glaucoma treatment was reformulated after approval to minimize red eye, improving safety without compromising efficacy.

New dosage forms can increase patient adherence and improve outcomes.

Changing injectable drugs to oral formulations can reduce burdens on healthcare providers and improve patient adherence.

The U.S. innovation model succeeds because of, not in spite of, its IP framework.[25]

The U.S. biopharmaceutical innovation ecosystem was built on a well-calibrated, balanced IP framework, and now supports a competitive pipeline of more than 8,000 new medicines globally being developed across the industry.[26]

The U.S. leads the race to deliver treatments for patients, thanks to the investments in the world's most advanced R&D ecosystem, and more new medicines are launched here than anywhere else.[27]

Part 3:

Actionable policy solutions

The value of medicine extends far beyond clinical outcomes—it profoundly impacts patients by fostering healthier, more vibrant lives. IP protections are essential to medical progress, economic competitiveness and national security. Preserving a strong U.S. innovation ecosystem requires protecting the IP policies that have proven to deliver for patients and society, while refocusing reform efforts on true cost drivers for patients, such as continued patient cost exposure and billions of dollars siphoned away by middlemen.[28]

Policies to promote American innovation

- Strengthen the balanced IP framework that supports the development of innovative medicines and generic entry.
- Stand against initiatives that erode patent protections.
- Demand transparency and accountability from pharmacy benefit managers in the pharmaceutical supply chain.

Policies to promote American competitiveness

- Affirm that robust IP supports competitiveness and improves health outcomes.
- Incorporate IP into trade agreement negotiations and oppose IP waivers.
- Implement robust measures to safeguard emerging technologies from global IP threats.
- Ensure that U.S. trading partners provide IP systems that appropriately protect U.S. innovation.

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