At a glance:

America's intellectual property system: The backbone of patient access to critical medicines

Why it matters

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

IP fuels innovation and competition

IP rights promote 'innovator vs. innovator competition' by attracting investment and encouraging the development of alternative groundbreaking treatments during the exclusivity period.

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

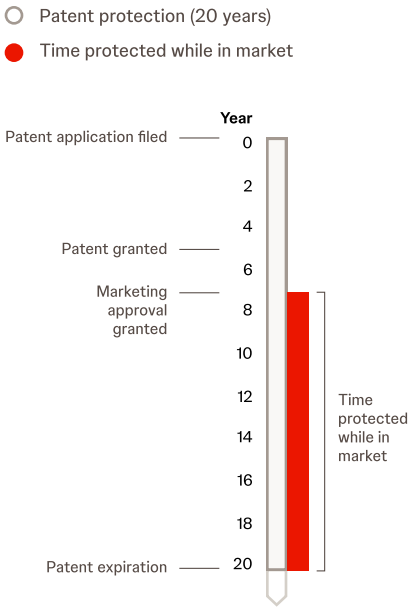
The U.S. IP framework delivers for patients

A balanced IP system in the U.S. has delivered world-leading biopharmaceutical innovation and a thriving generic marketplace.[4]

The strength of this system has positioned the U.S. as the global leader in biopharmaceutical innovation, providing patients with the earliest and broadest access to novel medicines of any nation in the world.[5]

Illustrative timeline: The patent process[6*]

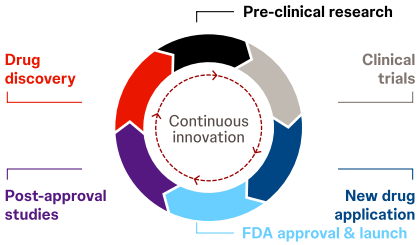
Patent protection lasts 20 years from filing, but much of this protection period is lost due to the time it takes to develop and gain approval for a new medicine.



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

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.



Actionable policy solutions

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.

By the numbers

90%

Of Medicare prescriptions are for generics, reflecting a thriving competitive marketplace.[1]

65%

Of oncology drugs gain new indications post-approval.[2]

14 years

Average time a drug remains protected on the market.[3*]

*Based on new molecular entities (NMEs) with initial generic entry in 2017-2019.

Citations

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