



PROTECTING INNOVATION

The Special 301 Report and America's Global Leadership

The 2026 Special 301 Report reveals a growing global divide in intellectual property (IP) policy, with the U.S., China and the EU pursuing sharply different strategies that shape innovation, competitiveness and access to future therapies. The report also helps pinpoint barriers abroad and guides engagement to strengthen IP protection, support jobs and growth, and improve market conditions for innovative industries.

It also marks a significant shift in U.S. trade and enforcement priorities by increasing scrutiny of pricing and reimbursement policies in high-income countries, including Australia, Canada, France, Germany and Japan, that undervalue innovation and push a greater share of global R&D costs onto American patients.

KEY FINDINGS

Strong IP protections are critical to U.S. economic strength. IP-intensive industries support:



63 million jobs;



41% of GDP;

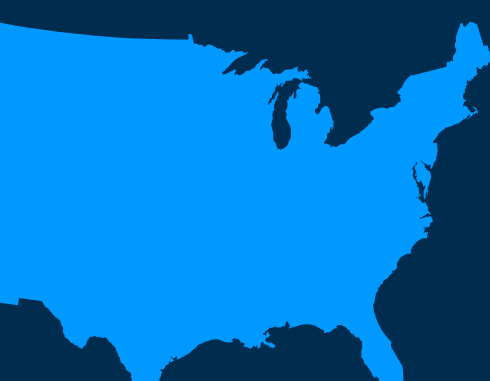


and provide **higher-than-average wages.**

America's Innovation Engine at a Crossroads

The U.S. remains the world's leader in biopharmaceutical innovation, driven by strong IP protections, market-based incentives and a regulatory framework that rewards risk-taking. But continued leadership is not automatic.

- **Risk of weakening U.S. innovation leadership:** As global competition intensifies, policies that mirror foreign price controls risk weakening innovation and shifting more R&D costs to American patients.
- **Global engagement is critical:** The U.S. plays a central role in promoting strong IP standards through multilateral institutions, including the World Trade Organization.
- **Policy choices will shape the future:** Sustaining leadership will require robust IP enforcement, along with transparent and competitive market conditions.





China

Accelerating Innovation, Uneven Rules

China's life sciences growth is reshaping the competitive landscape — but significant concerns remain.

- **Accelerating competition:** China is increasing R&D output and global presence, emerging as a serious competitor in biopharmaceutical innovation.
- **Uneven operating environment:** Weak IP enforcement, limited transparency, pressure to transfer proprietary technology and ongoing counterfeiting concerns continue to disadvantage U.S. innovators.
- **Barriers to market access:** Opaque regulatory approval processes and reimbursement systems can delay or restrict entry, dampening investment in new therapies.
- **IP for strategic dominance:** The close alignment of IP policy with broader economic strategy raises ongoing concerns about fair competition, underscoring the need for stronger enforcement, greater transparency and structural reforms.



European Union

A Cautionary Tale

The European Union has seen a gradual erosion of life sciences competitiveness as sustained price controls and complex regulatory frameworks contribute to slower innovation and delayed patient access to new treatments.

- **Investment headwinds:** Longstanding pricing constraints and regulatory complexity have reduced investment incentives and slowed the pace of innovation.
- **Rising IP concerns:** For the first time in decades, the 2026 Special 301 Report places the EU on the Watch List, citing concerns that proposed reforms could weaken key IP protections, including data exclusivity and effective patent terms.
- **Market access challenges:** Opaque and unpredictable pricing and reimbursement systems continue to create barriers to entry and complicate the pathway for new therapies.
- **A broader warning:** Europe's experience underscores the risks of prioritizing short-term cost containment over long-term innovation, with implications for competitiveness, investment and timely patient access to cutting-edge treatments.

Why It Matters

The report underscores a broader risk: weak IP protections and opaque market practices do more than distort pricing — they reduce investment across biopharma, public health and emerging technologies. Strong, predictable IP systems remain essential to sustaining innovation and expanding access to new medicines worldwide.

To preserve U.S. leadership, policymakers will need to act decisively by strengthening enforcement of global IP standards, rejecting harmful pricing models and deepening engagement with partners that support fair, transparent and innovation-driven markets.