



Public-Private Partnerships Need Predictable IP Rules

Many breakthrough therapies emerge from partnerships among the federal government, research institutions, and private companies. These collaborations work only when the rules governing resulting intellectual property are clear and reliable.

In several cases, however, federal agencies have asserted ownership or other patent rights *only after* a company invested substantial resources and successfully brought a treatment to market. These retroactive claims strain public-private partnerships and discourage future investments.

Public-private partnerships help turn scientific discoveries into medicines.

- Federal funding often supports foundational scientific research.
- Private companies contribute specialized expertise and assume the substantial risks of development, including clinical trials, regulatory approval, and manufacturing.

Retroactive assertion of patent rights can undermine the predictability these partnerships require.

- Drug development is lengthy, expensive, and uncertain. Companies make investment decisions based on agreements established at the outset of a collaboration.
- Moving the goalposts after a product succeeds makes companies more reluctant to collaborate with government researchers in the future.

Case study: Pre-exposure prophylaxis (PrEP) therapy for HIV/AIDS

- Beginning in 2004, Gilead and the CDC collaborated to evaluate whether Gilead's HIV medicines, including Truvada, could prevent infection as [PrEP therapy](#). Gilead supplied drugs and compounds at no cost under agreements governing the parties' IP rights.
- The CDC nevertheless sought patents covering the use of those medicines for PrEP. The Court of Federal Claims later held that the government had breached its agreements.
- After federal agencies encouraged Gilead to obtain FDA approval for Truvada as PrEP, the government sued the company for patent infringement and sought more than \$1 billion in damages. A jury later found the asserted patent claims invalid, and the parties reached a [final settlement in 2025](#).

Public-private partnerships can accelerate lifesaving innovation, but only when both sides know the rules before committing resources. Federal agencies should negotiate any ownership, licensing, pricing, or access conditions at the outset — and honor those agreements after a product succeeds. The government should be a reliable partner in drug development, not a source of uncertainty that makes companies think twice before collaborating.

This one-pager is based on an Eira Initiative working paper by Christopher Holman, "Biomedical Public-Private Partnerships That End in Patent Disputes."