

Confronting Biomedical Progress

IPSC 2025

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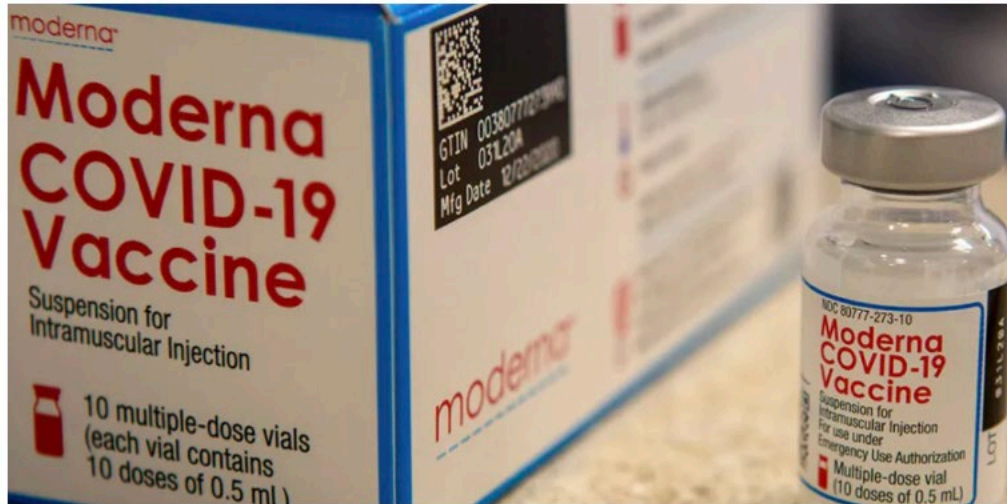
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Roadmap

1. The Problem
2. Research Design
3. Findings
4. Normative Claims



University of Michigan Journal of Law Reform

Volume 56

2023

Inequitable by Design: The Patent Culture, Law, and Politics Behind COVID-19 Vaccine Global Access

Ximena Benavides
Yale University

PLOS GLOBAL PUBLIC HEALTH

RESEARCH ARTICLE

‘Our project, your problem?’ A case study of the WHO’s mRNA technology transfer programme in South Africa

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Published: September 23, 2024 • <https://doi.org/10.1371/journal.pgph.0003173>

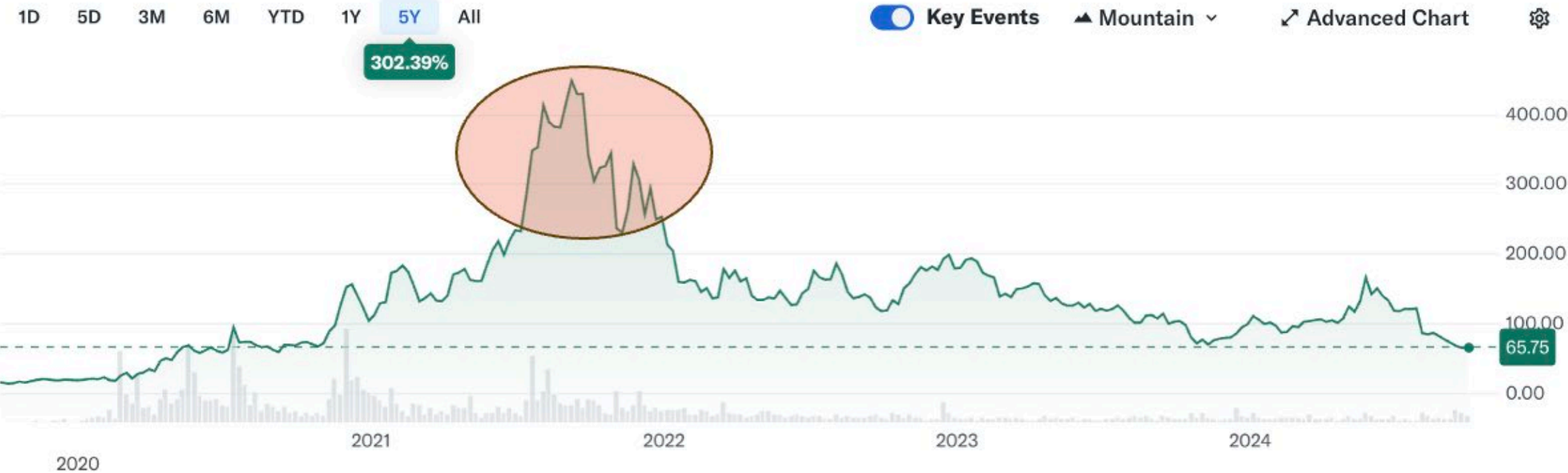
Moderna, Inc. (MRNA)

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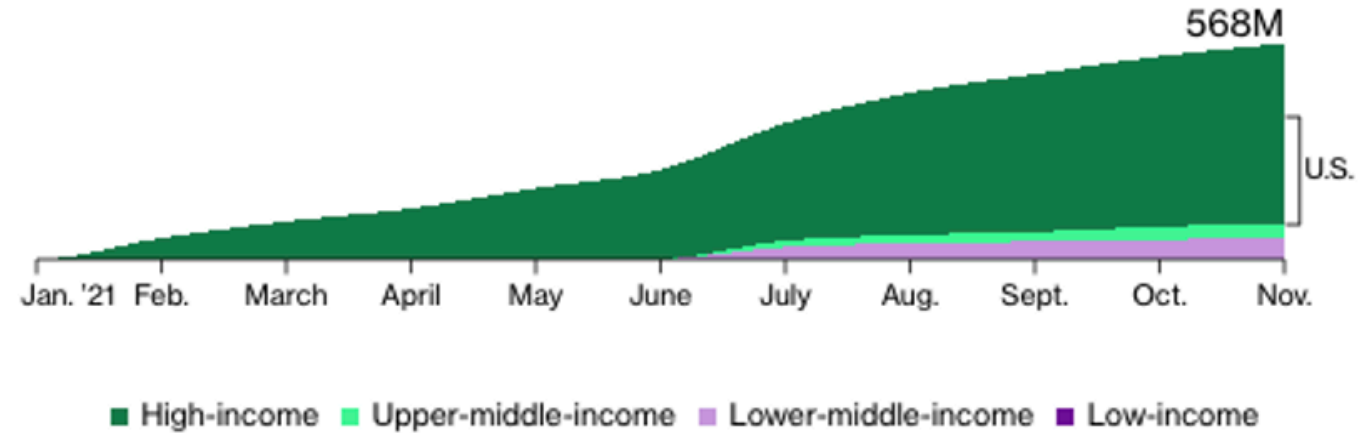
THE PROBLEM

RESEARCH DESIGN

FINDINGS

NORMATIVE CLAIM

Moderna Global Vaccine Distribution



Moderna Makes Milestone Pledge To “Not Enforce Our Patents” On COVID-19 Vaccine Technologies During Pandemic & Issue Open Licenses Afterward

Intellectual Property 08/10/2020 · Raisa Santos & Elaine Ruth Fletcher

Moderna/NIH

Moderna is advancing a new approach to vaccines that uses mRNA. The company's founders partly developed the idea in a scientific paper that relied on public funding.^[15] Many investors initially considered the idea too speculative.^[16] But the Department of Defense took significant risk early-on.^[17] In 2013, the agency awarded the corporation \$25 million to test the approach. In 2016, BARDA awarded Moderna \$125 million to develop a Zika vaccine, which helped increase confidence in the new technology.^[18] NIH was recently working with Moderna to develop a vaccine for another kind of coronavirus, helping jumpstart the new response.^[19]

When the new coronavirus emerged in December, an international public and private collaboration, the Coalition for Epidemic Preparedness Innovations (CEPI), provided funds to develop the vaccine for COVID-19.^[20] NIH scientists then began testing the vaccine and ran a Phase I trial.^[21] Moderna was recently awarded a \$483 million BARDA contract to support further vaccine testing and to scale-up manufacturing to enable large-scale production.^[22]

Business | Throwing a jab

A dispute over covid-vaccine technology ends up in court

Moderna takes on Pfizer and BioNTech

NEWS EXPLAINER | 30 November 2021

What the Moderna–NIH COVID vaccine patent fight means for research

Collaborators are locked in a high-stakes dispute over which researchers should be named as inventors on a key vaccine patent application.



Pharma CEOs Face Scrutiny Over Drug Prices in Senate Hearing

By [Savannah Hulsey Pointer](#)

2/8/2024

Updated: 2/8/2024

THE PROBLEM

RESEARCH DESIGN

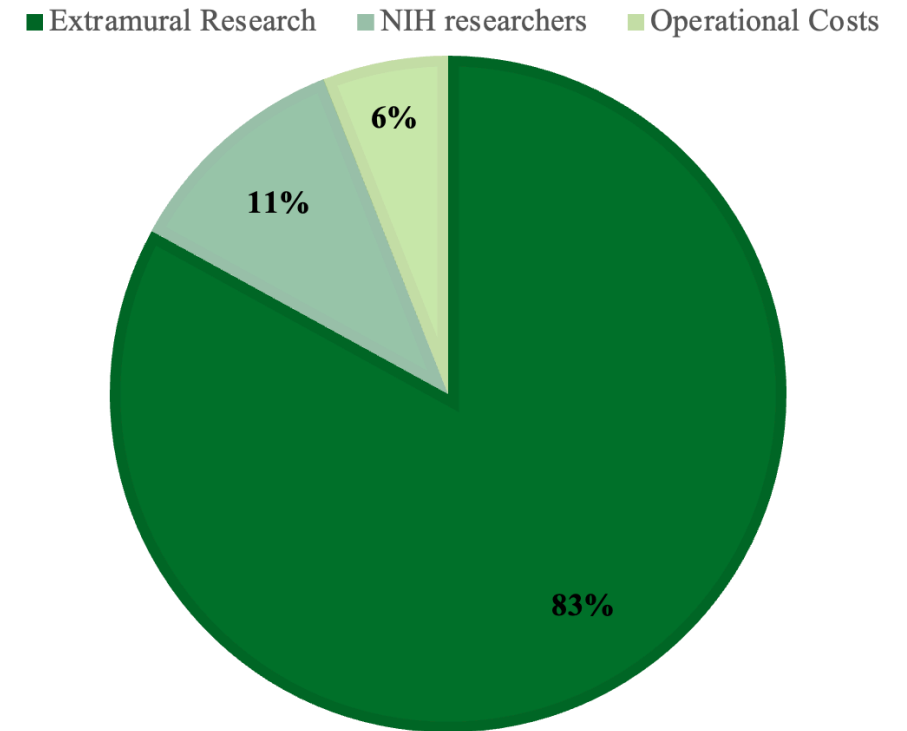
FINDINGS

NORMATIVE CLAIM

Federal Funding

- ✓ NIH is the largest single federal funder of the nation's biomedical enterprise —and globally.
- ✓ NIH assigns \$48 billion annually to R&D (>3x NASA's research funding).
- ✓ The majority of funds benefit labs outside NIH control.
- ✓ At least 20% of American productivity since WWII comes from R&D government funding
- ✓ **Key supporter of fundamental, pre-commercial basic science research**

NIH FUNDING





September 12, 2024 06:00 AM EDT Updated 09:33 AM R&D

Moderna plans \$1.1B in R&D and program cuts, delays break-even point to 2028

This year's plan provides **cost-cutting concessions desired by some investors**, but not large enough to achieve a previously stated forecast of breaking even by 2026. The company is now targeting 2028 to break even on an operational basis, excluding stock-based compensation, depreciation and amortization expenses. Bancel said the summer review considered more drastic cuts that could achieve break-even by 2026, but they determined these weren't the right steps in **creating value**.

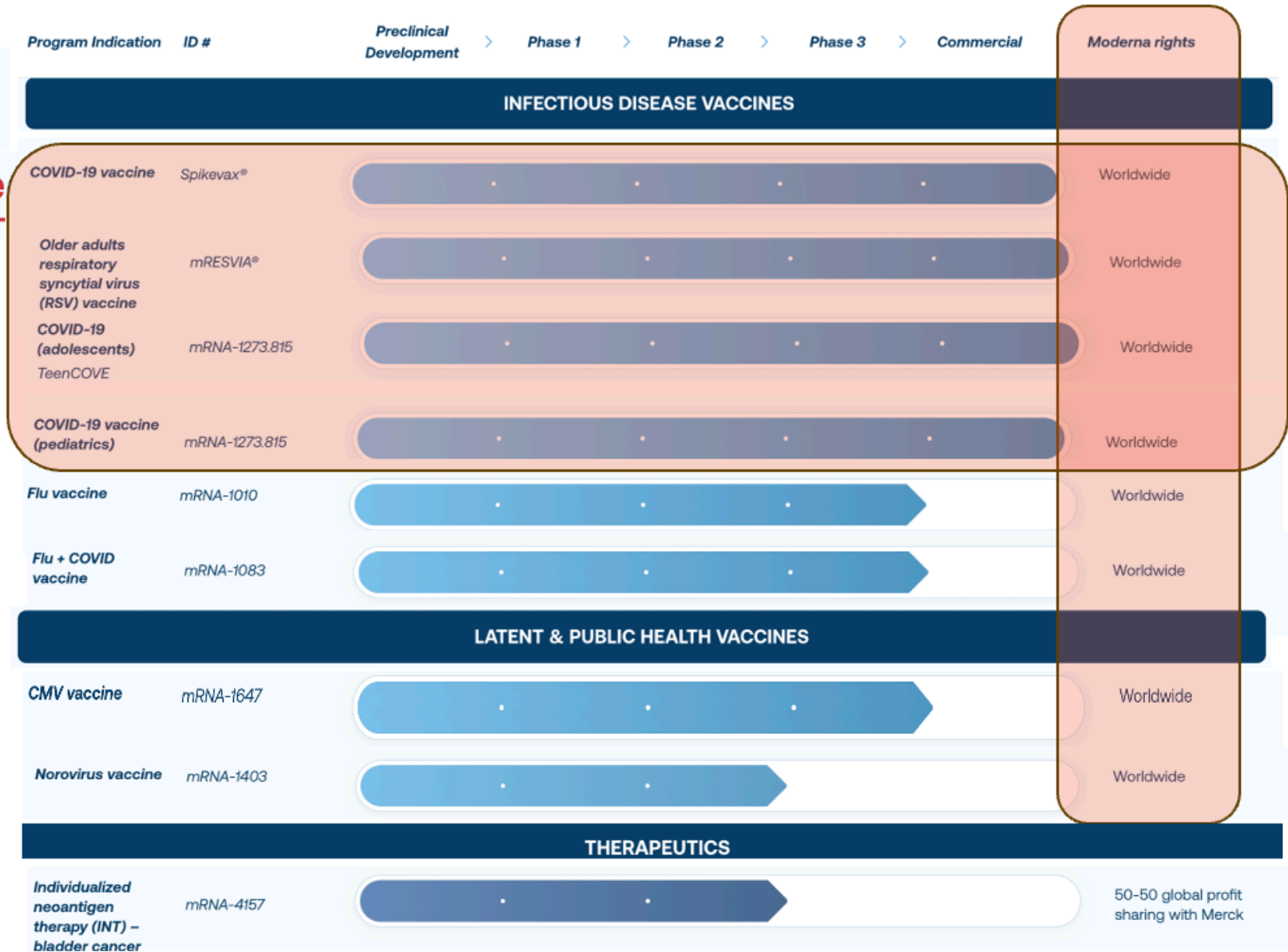
"The scenario of cutting for the sake of cutting to **drive profitability** we think was destroying **enormous amounts of shareholder value** and also being the wrong outcome for patients," he said.

"We're not saying we will never develop them," Bancel said, noting the company **could resume development if sales accelerate** or it strikes **a deal with a pharma** company. But their near-term future remains uncertain.

"**That's what investors want us to do** more than being profitable next week but not **creating the return**," he said.

moderna[®]

mRNA pipeline



THE PROBLEM

RESEARCH DESIGN

FINDINGS

NORMATIVE CLAIM

HEALTH AND SCIENCE

Moderna to slash 10% of workforce as biotech cuts costs, Covid shot sales slow

PUBLISHED THU, JUL 31 2025•7:15 AM EDT | UPDATED THU, JUL 31 2025•8:37 AM EDT



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NEWS | 03 October 2024

Nearly 50% of researchers quit science within a decade, huge study reveals

Twenty years of publishing data across many countries and disciplines show women are more likely than men to leave research.

By [Miryam Naddaf](#)

US cancels more than \$700 million funding for Moderna bird flu vaccine

By Patrick Wingrove

May 29, 2025 11:58 AM EDT · Updated 6 days ago



UNITED STATES · HEALTH

Trump administration cancels contract with Moderna to develop bird flu vaccine

The \$590 million contract, signed days before Trump took office, was scrapped by Health Secretary Robert F. Kennedy Jr, who has spent decades promoting misinformation about immunization.

Le Monde with AFP

Published on May 29, 2025, at 8:25 am (Paris) · 🕒 1 min read

HEALTH | PHARMA

How Moderna Went From Pandemic Hero to Vaccine Victim

The biotech's mRNA vaccines were lauded by the first Trump administration but now are caught up in government changes to vaccine rules

By *Jared S. Hopkins* [Follow](#) and *Peter Loftus* [Follow](#)

Updated June 3, 2025 7:59 am ET

THE PROBLEM

RESEARCH DESIGN

FINDINGS

NORMATIVE CLAIM

More than 1 in 5 US adults can't afford prescription drugs

Article by [Sara Lebow](#)
Jul 5, 2022

September 12, 2024 06:00 AM EDT Updated 09:33 AM R&D

Moderna plans \$1.1B in R&D and program cuts, delays break-even point to 2028

KFF Health News As Big Pharma Loses Interest in New Antibiotics, Infections Are Only Growing Stronger

By [Arthur Allen](#)
JULY 15, 2022

Senate, FTC cracking down on pharma patent shenanigans

By [Dick Durbin](#) and [Lina M. Khan](#) July 2, 2024

Pharma CEOs Face Scrutiny Over Drug Prices in Senate Hearing

By [Savannah Hulsey Pointer](#)
2/8/2024 Updated: 2/8/2024

Progress of Science

THE PROBLEM

RESEARCH DESIGN

FINDINGS

NORMATIVE CLAIM

1. Access Concerns Addressed with Drug Pricing Policies

- Price Regulation (IRA)
- Guidelines for Compulsory Licensing

2. War on Science

- Abrupt funding cancellations (delay or freeze grants)
- Hampered grant processes (staffing cuts and agency disruptions)
- Wide-ranging attempts to take apart funding mechanisms for scientific research.



Progress of Science

- Constitutional Law
- Intellectual Property Law
- Antitrust Law & Policy

Article I, Section 8, Clause 8 of the U.S. Constitution.

It grants Congress the power "...to **promote the Progress of Science** and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

This clause **does not explicitly** define the term "**progress**"; rather, it sets a constitutional purpose or goal for intellectual property laws. The phrase "**the Progress of Science and useful Arts**" indicates that the **motivation** behind granting exclusive rights **is to encourage innovation and dissemination of knowledge**, thereby fostering **societal advancement**.

Progress of Science

- Constitutional Law
- Intellectual Property Law
- Antitrust Law & Policy

- American Political Economy
- Moral Political Economy
- LPE

- *How has 'Progress' been promoted?*
- *Who has driven its promotion?*
- *What outcomes have been sought? and,*
- *Have those aspirations been fulfilled?*

Progress of Science

- | | |
|---|--|
| <ul style="list-style-type: none">- Constitutional Law- Intellectual Property Law- Antitrust Law & Policy | <ul style="list-style-type: none">- American Political Economy- Moral Political Economy- LPE |
|---|--|

Biomedical Innovation Industrial Policies

	1878-1950	1950	1980	1990	2025 - forward
PATENTS		Law typically encouraged or required open science or government ownership of publicly funded research	Bayh-Dole Act: allowed government-funded research be privately patented	Congress promote the progress of science with IP legislation (any of the means outlined in the IP Clause).	
FEDERAL FUNDING	Government funds intramural science primarily for military purposes	Government funds includes basic science in extramural research institutions		While federal funding doubles, financial institutions (venture capital, private equity, venture philanthropy) become progressively attracted to biomedical industry. SVM principle governs.	NIH grants cut or terminated. Reliance on greater philanthropy. New ultrawealthy funding era?
PROGRESS	The purpose of trademark law is not to promote the progress of science but rather to support fair competition and consumer protection	The purpose of greater public funding is to maintain U.S. competitive position globally	Improve commercialization through universities (extramural)-industry collaborations	Progress is quantified by more products in the market or holding IP exclusivities (even no commercialized products)	
		Suboptimal private investment: ownership problem		Suboptimal private investment: unexploited IP exclusivities and evergreening	
COURTS	SCOTUS 1879 Trade-Marks Cases		Fed. Cir. 1988 (Constant v. Advanced Micro-Devices, Inc.): SCOTUS has expansively interpreted the Spending Clause and might not allow the IP Clause to limit Congress's spending power.	SCOTUS 2003 Eldred v. Ashcroft	Pending litigation against the Trump administration re: grant terminations

Progress of Science

Biomedical Innovation Industrial Policies

1950s (Pre Bayh-Dole Act)	1980s (Bayh-Dole Act) Corporatization	1990s (Post Bayh-Dole Act) Financialization	2010s High-Tech Industrialization	2025 Gold Standard Science
<i>Academic Institutions</i>	<i>Big Pharma</i>	<i>Big Finance</i>	<i>Big Tech</i>	<i>Big Philanthropy?</i>



CAPITALIZING
A CURE

HOW FINANCE CONTROLS

THE PRICE AND VALUE

OF MEDICINES

VICTOR ROY



**CAPITALISM, POWER
AND INNOVATION**
INTELLECTUAL MONOPOLY
CAPITALISM UNCOVERED

Cecilia Rikap



THE PROBLEM

RESEARCH DESIGN

FINDINGS

NORMATIVE CLAIM

Finding 1

Progress in Quantitative Terms

- ✓ Progress is measured in a market-driven, predominantly **IP-law-governed** domain.
- ✓ As IP law assigns ownership to scientific discoveries to promote innovation, the **governance** of biomedical research is **transferred** to commercially motivated actors.
- ✓ IP law is instrumentalized for **short-term value extraction** rather than long-term innovation, undermining the very rationale for patents that U.S. courts frequently invoke.

Finding 1

Progress in Quantitative Terms (cont'd)

- ✓ Often operating with **limited accountability**, market actors accumulate patents, shield knowledge from the market, and arrange research priorities to align with business plans (“**Progress Is More**”).
- ✓ Even when U.S. courts attempt to limit the issuance of patents by applying restrictive standards of patentability, patents continue to proliferate in a **dysfunctional patent system** characterized by insufficient restrictions, inadequate discerning filters, and an abundance of bad patents.

Finding 2

Progress in Value-Neutral Terms

- ✓ Concerns about **corporate power** concentrations have been broadly dismissed and considered irrelevant.
- ✓ **Access demands** have often been channeled as **consumer welfare issues** of high pricing under the influence of antitrust policy and the economic style of reasoning. Indirect access concern policies (e.g., consolidate high-skilled workforce or manufacturing capacity) have been sidelined.

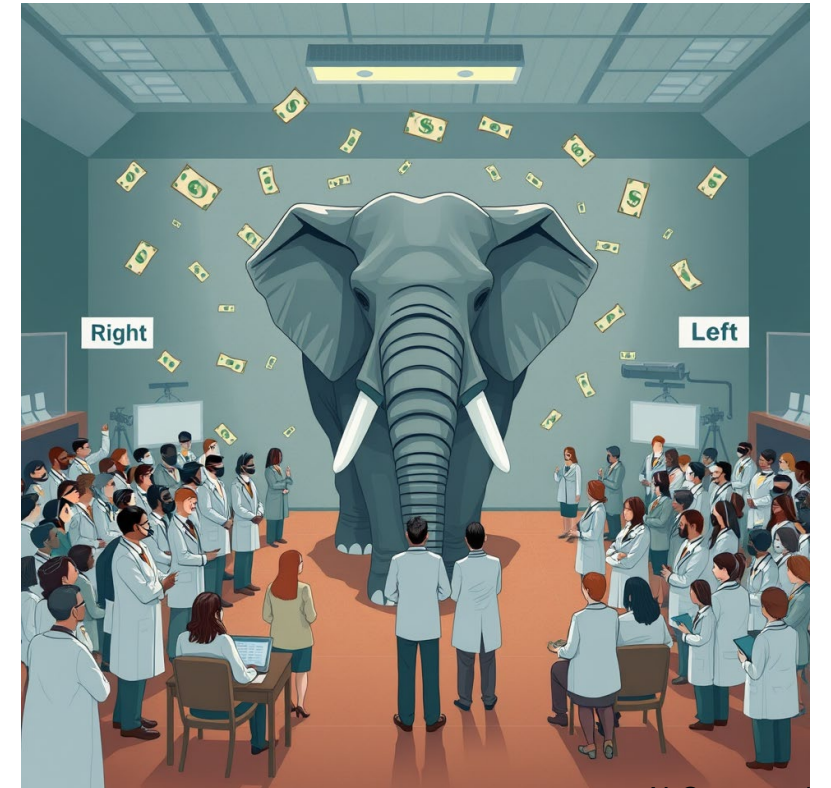
Finding 2

Progress in Value-Neutral Terms (cont'd)

- ✓ Federal funding has served to entrench private control further.
- ✓ Ideals of accessibility and competition are stripped from the advancement of progress since the earliest stages of public funding structuring.
- ✓ The result is a narrowed definition of 'Progress' in value-neutral and unidirectional terms, in a largely anticompetitive environment.

Normative Claims

- ✓ Progress is focused on **products rather than processes** (Relational Innovation)
- ✓ Competitive Biomedical Innovation (IP Race Theory, M. Lemley)
- ✓ NIH funding is the elephant in the room: Grants as Relational Contracts



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Questions & Comments

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