Intellectual Property’s Impact on Global Health & Life-sciences Innovation

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About ITIF

- The world’s leading science and technology policy think tank.
- Supports policies driving global, innovation-based economic growth.
- Focuses on a host of issues at the intersection of technology innovation and public policy across several sectors:
  - Innovation and competitiveness
  - IT and data
  - Telecommunications
  - Trade and globalization
  - Clean energy, manufacturing, life sciences, and ag biotech
Innovation Industries Share Three Distinct Characteristics

1. They compete by inventing next-generation products or services.

2. They are characterized by very high initial fixed costs (e.g., R&D and design), but low marginal costs.

3. They fundamentally embody and depend on intellectual property.
Necessary Conditions for Global Innovation to Flourish

1. Access to large markets (e.g., economies of scale).

2. No excess, non-market-based competition (e.g., subsidies).

3. No forced localization requirements that unnecessarily fragment global production systems.

4. Protection of intellectual property rights.
State of Global Life-sciences Innovation Activity

- Almost 1,000 new active substances have been introduced globally over the past 25 years.
- America’s FDA has approved 500 new drugs since 2000 alone.

About 8,000 Medicines Under Development Globally (4,500 U.S.)

- **VACCINES**: 260
- **Pediatric Diseases**: 560
- **Diabetes**: 160
- **Sickle Cell Disease**: 20
- **Mental Illness**: 138
- **Cell & Gene Therapies**: 362
- **Asthma & Allergy**: 130
- **Neurological Disorders**: 537

Global Health Challenges Increasingly Commonly Shared

- 70% of fatalities in developing world from non-communicable diseases.

- Citizens of low- and middle-income countries bear 80% of the world’s death burden from cardiovascular disease.

- 85% of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.

U.S. Leads in Global Life-sciences R&D and Innovation

Business and Government Investment in Pharmaceutical R&D (in Billions), 2017

![Bar chart showing investment by region]

Number of New Chemical or Biological Entities Produced, 1997-2016

<table>
<thead>
<tr>
<th></th>
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<td>Europe</td>
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<td>Japan</td>
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<td>Other</td>
<td>4</td>
<td>14</td>
<td>12</td>
<td>38</td>
<td>64</td>
</tr>
</tbody>
</table>

Source: ITIF, “How to Ensure That America’s Life-Sciences Sector Remains Globally Competitive”
But It Wasn’t Always That Way

U.S. Share of New Active Substances (NAS) Launched First on World Market

Source: John K. Jenkins, M.D., "CDER New Drug Review: 2015 Update"
Keys to Life-Sciences Innovation Leadership

1. World-leading public/private investment in biomedical research.

2. Aggressive incentives to encourage investment (E.g., R&D tax credit, Orphan Drug Tax Credit).

3. Effective regulatory/drug approval system (E.g., PDUFA).

4. Pricing/reimbursement system allowing innovators to earn sufficient revenues to reinvest in innovation.

5. Robust intellectual property protections.

Source: ITIF, “Why Life-Sciences Innovation is Politically “Purple”–And How Partisans Get It Wrong”
Effective Regulatory Policies Make a Difference

Median Approval Times for New Medicines, Months (CDER, NME NDAs/BLAs)

Reasonable Prices Are Vital for Life-Sciences Innovation

- OECD: “There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.”
- A statistically significant relationship exists between a bio-pharma enterprise’s profits from the previous year and its R&D expenditures in the current year.
- A 50% drop in U.S. drug prices would result in the number of drugs in the development pipeline dropping up to 24%.

Creation of IP Rights Pivotal Driver of Global Economic Growth

IPRs Are Vital to Innovation, As They:

1. Create incentives that empower domestic innovation.
2. Enable a virtuous cycle of innovation.
3. Induce knowledge spillovers that help others to innovate.
4. Boost domestic levels of R&D, exports, and FDI.
5. Facilitate the international diffusion of technology, innovation, and knowhow.
The Biopharmaceutical Research and Development Process

- “The average cost to develop a new drug, including the cost of failure, has increased in six out of eight years.”

- “The average cost in our 2018 drug cohort rose to $2.2 billion, almost double the $1.2 billion required in 2010.”

“I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.”

“Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”

Jack Scannell, Oxford CASMI
Ryan: “Patents provided incentives for biomedical technology entrepreneurs to make risky investments into innovation in Brazil.”

cordia verbenacea

Acheflan

Innovate4Health Initiative

https://medium.com/innovate4health/case-studies/home
IP-driven Innovation in Healthcare is Happening Everywhere

Over 50 case studies.
Innovate4Health: Five Key Challenges

1. Adapting healthcare interventions for environments where resources and infrastructure are challenging;

2. Providing affordable and robust tests for diagnosing diseases;

3. Improving HIV diagnosis and care;

4. Developing affordable interventions to meet basic needs in challenging environments;

5. Getting healthcare to the people in places where access is difficult.

Challenge: Getting Healthcare to People Where Access is Difficult

- 1 billion people lack access to essential health care.
- Global shortage of 7 million public healthcare workers, with that number expected to rise to 13 million by 2035.

Arktek: Passive Vaccine Cooler  

Peek Eye Exam Kit (PEEK)  

Miroculus Portable Cancer Screener

Challenge: Getting Healthcare to People Where Access is Difficult

- Cardio-Pad: World’s first medical tablet facilitating remote heart examinations/diagnosis.

- Tackled lack of specialists in Cameroon while dramatically raising affordability.

“Patents enable you to protect yourself against rivals who simply want to copy your work.”

Stronger Patent Rights Encourage Drug Launches

- Study of 642 new drug launches in 76 countries from 1983 to 2002.
- Finds speed/extent of diffusion strongly associated with countries’ patent and price regulation schemes.
- Moving from a regime of no product patents to long product-patent terms reduces drug launch lags by 55%.

Source: Cockburn, Lanjouw, and Schankerman, “Patents and The Global Diffusion of New Drugs, 2016”
IPRs and the Price of Medicines

- Dutta estimated TRIPS introduction would increase price of medicines 18% in India, with effects on various drugs ranging from 3.5 to 80%.*

- Duggan et al. assessed 6,000+ products consisting of 1,000+ molecules in India.**

- Estimates molecules receiving patents saw average price increase of just 3–6 percent.

“Our results demonstrate that the implementation of product patents for India did not cause either the large increases in pharmaceutical prices or the dramatic consolidation of the market that some predicted prior to its enactment.”

Sources: *A. Dutta, “Intellectual Property Rights and Innovation in Developing Countries, Evidence From India” (2008)
** Duggan, Grathwaite, and Goyal, *The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India*
TRIPS and Public Health


▪ Commits members to provide 20 years of patent protection in all fields of technology, including drug patents/processes, and to protect test data.

▪ Countries may exclude from patentability inventions that would be damaging to human, animal, or plant life and diagnostic, therapeutic, surgical methods.

▪ “Bolar exemption” permits generic companies to study patents.

▪ Developing countries given until 2005 to comply.
Doha Declaration on the TRIPS Agreement/Public Health

- Extended until 2033 LDC TRIPS phase-in period to enact drug patenting.

- Clarified and extended TRIPS’ compulsory license (CL) provisions:
  - CLs permitted in cases of extreme national emergency;
  - CLs permitted if efforts of licensees to gain access to technology on commercial terms have failed, but licensors should receive adequate renumeration;
  - CLs generally meant to supply domestic markets, but countries with generic drug capacity may issue CLs for export at the request of countries without facilities.

- Ecuador, Malaysia, Rwanda, Chile, and Peru have used or are considering CLs.
## Developing Needed Medicines & Access to Medicines

<table>
<thead>
<tr>
<th>Type 1 Diseases</th>
<th>Type 2 Diseases</th>
<th>Type 3 Diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Diseases</td>
<td>HIV/AIDS</td>
<td>Malaria</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Tuberculosis</td>
<td>Chagas disease</td>
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<tr>
<td>Cancers</td>
<td>Meningitis</td>
<td>River blindness</td>
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<tr>
<td>Liver ailments</td>
<td>Dengue fever</td>
<td>African sleeping sickness</td>
</tr>
<tr>
<td>Tobacco-related diseases</td>
<td>Hookworm</td>
<td>Leprosy</td>
</tr>
</tbody>
</table>

- The predominant market/IP-based system appears to be effective for diseases impacting large populations or conditions affecting better-off individuals.

- But challenges exist for rare/orphan diseases and neglected tropical diseases that affect smaller populations and citizens of low-income countries.

Developing Needed Medicines & Access to Medicines

- **Product Development Partnerships (PDPs):** Nonprofits convening PPPs to research and develop treatments to diseases mostly affecting developing countries.
  - Typically grant royalty-free licenses for use in low-income countries or share IP among research partners.

- **Advanced Market Commitments (AMCs):** Guaranteed minimum purchases for new medicines/vaccines that meet predefined safety and efficacy standards.
  - Example: GAVI’s pneumococcal AMC has been introduced in 60 countries, protecting 225 million children through vaccinations.

Developing Needed Medicines & Access to Medicines

▪ **Prizes**: Award prizes to first successful inventors of new drug/vaccine in exchange for IP disclosure.

▪ E.g., U.K. Longitude AMR Prize; ALS Prize

▪ Complement to or replacement for market/IP-based system?

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**R&D Prizes**

<table>
<thead>
<tr>
<th>Disease/Research focus</th>
<th>Design option</th>
<th>Participation</th>
<th>Selectivity</th>
<th>Approach to IP rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC prizes on better use of antibiotics and vaccines</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>UK Longitude Prize on AMR</td>
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<tr>
<td>US AMR Diagnostic Challenge</td>
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<tr>
<td>Prize4Life ALS prizes</td>
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<td>X</td>
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<td>SUDEP institute challenge</td>
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<tr>
<td>Archon Genomics XPRIZE</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Medical Innovation Prize and Prize Fund for HIV/AIDS (Sanders bills)</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Health Impact Fund</td>
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<tr>
<td>TB Diagnostic Prize Fund and Chagas Prize Disease Fund</td>
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<td>X</td>
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<td>Global Health Innovation Quotient Prize</td>
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<tr>
<td>HIV Prize Fund</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Source: IFPMA, “Charting the Course to Sustainable Innovation in Neglected Diseases Globally: An “Optimization Model” for the Use of R&D Incentives”
Developing Needed Medicines & Access to Medicines

- Global Medical R&D Treaty (MRDT): Treaty would place R&D spending obligations on all nations; intl. orgs. like WHO would direct health R&D investment.

- E.g., In 2013 WHO created a Global Observatory on R&D to monitor spending, set priorities, and undertake global health R&D demonstration projects.

- “Delinkage” proponents call for wholesale replacement of market/IP-based drug development system with MRDT & prizes approach.

- Sen. Sanders: Would create an $80 billion Medical Innovation Prize Fund.

James Love, “Inside Views: Delinkage of R&D Costs From Product Prices”
Developing Needed Medicines & Access to Medicines

- Many governments, aid agencies, intl. orgs contributing.

- Innovative life-sciences sector actually #2 global funder of research into NTDs.

### Leading Organizations Funding NTD R&D in 2018 ($ millions)

<table>
<thead>
<tr>
<th>Organization</th>
<th>Funding (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. National Institutes of Health</td>
<td>1,589</td>
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<tr>
<td>Aggregate industry</td>
<td>694</td>
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<tr>
<td>Gates Foundation</td>
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<tr>
<td>European Commission</td>
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<td>UK Department for International Development</td>
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<td>Wellcome Trust</td>
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<tr>
<td>U.S. Agency for International Development</td>
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<tr>
<td>U.S. Department of Defense</td>
<td>77</td>
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<tr>
<td>Unitaid</td>
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</tr>
<tr>
<td>UK Department of Health and Social Care</td>
<td>64</td>
</tr>
<tr>
<td>Indian Council of Medical Research</td>
<td>54</td>
</tr>
</tbody>
</table>

Source: Statista, “Top funders for R&D on neglected diseases by organization 2017”
IPRs Have Been Essential in the COVID-19 Response

- 1/31/21 – FDA has fully approved 1 treatment, granted EUA for 8 other treatments, reviewed 420+ trials, & seen 600+ drug development programs in planning stages.*
- 12/21/20 – There are 221 vaccines (60+ candidates, 170+ in pre-clinical development) and 362 therapeutics in various stages of testing worldwide.**
- Discovered in 1961, decades of study and billions in private funding led to COVID-19 vaccines being the first vaccines to effectively utilize mRNA.**

Sources: *FDA, “Coronavirus Treatment Acceleration Program (CTAP)” (2021)
** Stevens and Schultz, Why Intellectual Property Rights Matter for COVID-19
Getting COVID-9 Vaccines to Developing Countries

- Most companies have committed to making vaccines available to low-income countries as not-for-profit (at cost) rates.
- COVAX, another PDP, is working toward an effective vaccine for all countries, with focus on manufacturing and distribution, as well.
- Licensing agreements allow for production scale-up and quality control.
- Competition regulates prices.
- Innovation is the key, IPR is the enabler:
  - PPE
  - Rapid POC testing
  - Nanobiotech
  - Microneedles
  - Tele-health services
  - Proximity sensors and alerts
  - Contact trackers
  - Robots for healthcare, work, companionship
  - Remote healthcare
  - Drone deliveries
  - VR Education
  - Apps for panic attacks
  - AI protein structure identifier
  - AI for peptide therapeutics
Ensuring Access to Existing Medicines

- Underdeveloped healthcare systems, underinvestment in public health, lack of skilled professionals, and high taxes/tariffs impede access to medicine.

- 90% of WHO essential medicines are off patent, but available in public-sector facilities in developing countries only 40% of the time.
  
  - Regional availability ranged from 29% in Africa to 54% in Asia.

- When combined with VAT taxes on medicines, government-imposed levies account for an additional cost increase of: 55% in India; 40% in Sierra Leone; 34% in Nigeria; and 29% in Bangladesh.

Sources: A. Cameron et al., “Medicine Prices, Availability, and Affordability in 36 Developing and Middle-Income Countries: A Secondary Analysis”; World Health Organization, “Medicine Prices and Availability (2011)”
Eliminate High Tariffs on Medicines: Join “Zero for Zero”

Accelerate Drug Approval Timelines

Average Drug Approval Time, Latin America

Average Drug Approval Time, Asia

Keys to Developing-Country Life-Sciences Innovation Leadership

1. Leverage country’s unique strengths for biomedical innovation.

2. Recognize there are many opportunities to make value-added contributions throughout the drug development process (e.g., clinical trials).

3. Invest in and incentivize biomedical research.

4. Turn universities into engines of innovation.

5. Align drug approval system between safety administration/public heath system.
Conclusion: Why Life-Sciences Innovation Matters

- Global newborn deaths declined from 5 million in 1990 to 2.4 million in 2019.*
- Death within the first 28 days of life is often preventable and caused by lack of quality care or treatment.*
- IPR has enable local and global innovators to solve regional problems in developing and low-income countries:**
  - Remote monitoring system for midwives and obstetricians in Indonesia
  - Neonatal bubble in Peru — Embrace infant warmers

Sources: *WHO, “Newborns: improving survival and well-being” (2020)
**ITIF, Innovate4Health
Conclusion: Why Life-Sciences Innovation Matters

Correlation across countries between 2000-2009 change in life expectancy at birth and change in drug vintage controlling for changes in income, unemployment rate, education, urbanization, health expenditure, immunization rate, HIV prevalence and tuberculosis incidence.

Pharmaceutical innovation accounted for 73% of the 2000-2009 increase in life expectancy at birth in 30 countries (1.27 years of the 1.73 year increase).

Note: size of bubble is proportional to country population.

Conclusion: Why Life-Sciences Innovation Matters

- Helping citizens live longer, healthier lives generates economic benefits.
  - Tuberculosis and malaria cost worst-hit African countries up to 8% GDP annually.

- Opportunity cost of missing work (especially for chronic diseases).
  - 40% of Mexicans applying to work in auto sector aren’t physically able to do so.
  - Poor health in working-age adults costs developing countries an average of 7.4% GDP annually.

- Eliminating heart disease valued at $48 trillion, curing cancer $47 trillion; Alzheimer’s disease will cost $1 trillion annually by 2050.
Thank You

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