THE TRANS-PACIFIC PARTNERSHIP AGREEMENT

Protecting Biopharmaceutical Innovation Means Hope for New Treatments for Patients

Strong Intellectual Property Provisions in the Trans-Pacific Partnership (TPP) Can Support Patient Health, Sustain Medical Innovation & Spur Economic Growth

The TPP offers an opportunity for governments to encourage patient access to medicines by ensuring that their regulatory and legal frameworks value innovation and the underlying intellectual property (IP) to develop new and improved medicines for patients.

IP is the lifeblood of the biopharmaceutical industry, in that it provides the incentives required for scientists to conduct the research and development (R&D) that produces new medicines for patients globally. It takes approximately 10-15 years to develop a medicine, and for every one medicine that makes it to patients, there are thousands of other drug candidates that have failed.[1]

Without strong incentives for innovation, including a robust global IP protection and enforcement framework, R&D for innovative, life-saving medicines could be stifled.

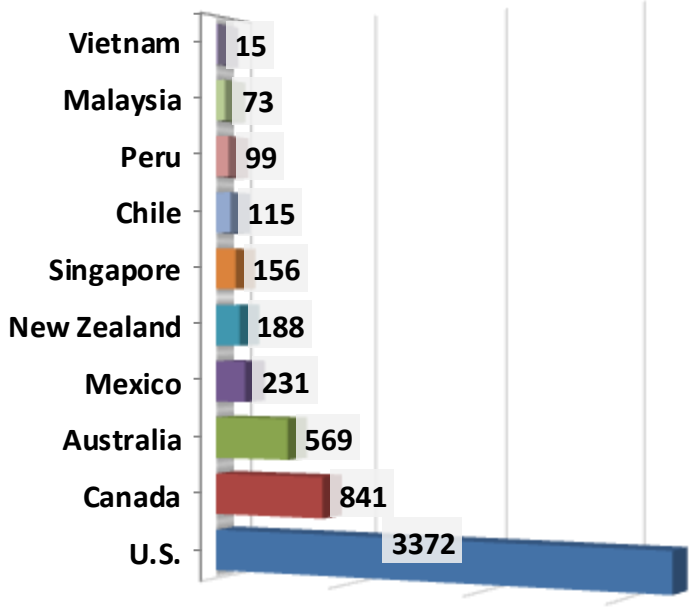
Medical Innovation Has Revolutionized Global Public Health

Strong intellectual property provisions and frameworks that reward innovation within TPP countries can help ensure continued R&D for patients.

Examples of how IP has helped spur innovation and deliver benefits for public health include:

- New cancer drugs developed with IP incentives account for 50% to 60% of increases in survival rates since 1975.[2]
- Due to new medicines, death rates for cardiovascular disease fell a dramatic 33% between 1999 and 2009.[4]
- Since the approval of antiretroviral treatments in 1995, the HIV/AIDS death rate has dropped by 85%.[5, 6]

There are currently approx. 5,600 medicines in development in TPP countries[7]



Strong IP Provisions in the TPP Can Foster Sustained Medical Innovation

Intellectual Property Promotes Access

Intellectual property protection is not a barrier to access in developing countries.

95% of drugs on the World Health Organization's model list of essential drugs lack patent protection. Still, more than one-third of the world's population has limited or no access to these medicines.[8]

Examples of access barriers to patient health include:

- Insufficient infrastructure: i.e., weak healthcare systems; lack of transportation, electricity and trained healthcare personnel—particularly in rural areas
- Inadequate government investment in healthcare
- Significant mark-ups in the distribution chain, as well as high government taxes and tariffs on medicines

Addressing the "real" barriers to access is the responsibility of many stakeholders, including governments, the private sector, and non-governmental organizations.

Intellectual Property Helps Boost Local Innovation & Economic Growth

Strong IP systems provide a key incentive for technology transfer and investment. Where strong IP frameworks are in place, there is greater certainty in the market and greater willingness to transfer technology to stimulate local innovation.

As local biopharmaceutical innovation capacity expands, TPP countries can focus on creating medicines and healthcare products to address diseases prevalent among local populations, including "orphan" diseases—rare diseases that affect small populations.

Local companies may also benefit by being able to produce licensed local versions of drugs, which can help develop their own R&D capacities (i.e., technology transfer).

In many countries, research-based biopharmaceutical companies have undertaken voluntary licensing to enable manufacturers to produce and sell generic versions of products needed to treat severe epidemics.[9]

Innovative Biopharmaceutical Companies Are Committed to Sustainable Solutions[10]

Innovative biopharmaceutical companies support **over 340 initiatives with more than 600 partners** to help shape sustainable solutions that improve the health of all people.

In 2010, the innovative biopharmaceutical industry alone **invested more than $503 million to cure neglected and major diseases of the developing world**, including malaria, tuberculosis, sleeping sickness and dengue fever.

Innovative biopharmaceutical companies are the second largest funder of R&D for neglected diseases in the world, ahead of all countries but the United States.

Almost 100 R&D projects are underway for diseases of the developing world (including R&D for HIV/AIDS).[11]

In the last decade, biopharmaceutical companies provided over **$9.2 billion in direct assistance to healthcare for the developing world**, including donations of medicines, vaccines, and diagnostics equipment, as well as other materials and labor.

Sources

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Despite Myths, Facts Show that Strong Pharmaceutical IP Provisions Can Benefit Patients & Health Systems

Myth	Fact
"Evergreening" delays the availability of generics.	The flawed premise behind this myth is the assertion that companies make minor alterations to their products to indefinitely extend the patent term. As an initial matter, seeking a patent for a follow-in invention does not extend the patent term of the original invention. On the contrary, from a patent perspective, competitors are free to obtain marketing approval for copies of the original invention as soon as the patent term on that invention expires, regardless of whether a patent has been granted for a follow-on invention stemming from the same active pharmaceutical ingredient. Further, this myth fails to reflect the nature of scientific discovery and the value that follow-on or incremental innovations can bring to patients. Science is built on cumulative innovation. Examples of follow-on innovations include improving malaria treatments for developing country conditions, simplifying strict Type II Diabetes treatments, and providing greater flexibility of use and improved diagnostics for neglected tropical diseases such as Chagas disease.
Data protection grants monopoly status to medicines, even when patents no longer apply or exist, and delays generic competition.	Protections for regulatory data and patents are separate and distinct. Data protection does not extend the life of a patent. Data protection is an important right for the biopharmaceutical sector because it provides incentives for the development and launch of new drugs, particularly those not subject to patent protection. If such protection did not exist, innovators would bear the full costs of generating clinical data, while competitors would immediately be able to "free ride" on the data, allowing them to unfairly compete in the marketplace.
Pharmaceutical companies are seeking to extend their 20-year patent monopolies.	First, biopharmaceutical companies are not seeking to extend the 20-year term of protection by a patent. Rather, they are seeking patent term adjustments or restoration (PTA/PTR) to compensate them for that portion of the patent term lost due to either patent office delays or for part of the time during the marketing approval process during which they are unable to market their products. Second, a patent does not prevent competition in a therapeutic area. Due to the complex regulatory approval process, the R&D of an approved pharmaceutical takes, on average, 10-15 years, such that the average time before generic entry is now estimated to be 11.8 years (including PTA/PTR).[12] This R&D, however, does not occur in a vacuum. On the contrary, innovative biopharmaceutical companies are competing against each other to release a first-in kind medicine, such that competing medicines within the therapeutic category are typically launched within less than two years of the first-in-kind medicine.[13]
Patent linkage prohibits national drug regulatory authorities from approving generic medicines until patents have expired.	Patent linkage, as part of a fair and transparent patent enforcement mechanism, helps resolve disputes between innovators and generic manufacturers quickly, providing a smoother and more certain generic market entry process.