

## Global Intellectual Property Rights

Pfizer believes that intellectual property (IP) is critical to driving innovation and stimulating economic growth in countries throughout the world. IP rights are a type of property right that give the creators of knowledge the right to benefit from their unique work and contributions. Strong IP systems foster an innovative culture, where innovators can develop new products and technologies knowing that their inventions and creativity are secure. Strong IP protection afforded by effective patent systems provides incentives for increases in technology transfer, foreign direct investment, and local research and development (R&D) capacity. Other mechanisms including data exclusivity and patent linkage help provide legal certainty for innovators to sustain R&D efforts, paving the way for generic medicines.

### Background

IP rights allow people and entities to own their innovations in the same way that physical property can be owned. Governments establish and enforce IP protection primarily to stimulate investment in knowledge-intensive industries and to encourage the production of useful goods and services arising from knowledge-based inventions. The innovative biopharmaceutical industry is especially reliant on intellectual property rights. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) outlines minimum IP standards to which WTO members must comply. These include provisions with respect to patents, data exclusivity, enforcement procedures, remedies, and dispute resolution.

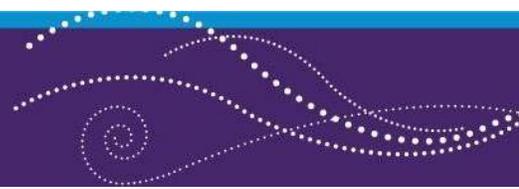
Patents, a form of IP rights, grant innovative companies the exclusive right to exclude others from manufacturing and marketing their products for a certain number of years. Without this important protection, other entities would be able to replicate new inventions immediately, and most innovator companies would not be able to sustain R&D investments to develop new medicines for patients.

Data exclusivity is a mechanism by which clinical research, test data, and relevant safety information submitted by an innovator for biopharmaceutical products is protected for a limited time from referencing by competitors when they submit their products for regulatory review. That is, data exclusivity can limit government regulatory agencies from accepting applications from generic manufacturers based on the test data that innovator companies submit to government regulatory agencies. After the period has expired, reference to the data is permitted by generic companies—this allows protection of the innovator's substantial investment in generating the data, while at the same time preventing unnecessary repetitive tests and trials. The TRIPS Agreement does not specify a timeline for data exclusivity, but it requires that WTO members ensure protection of data from disclosure and unfair commercial use (Art. 39.3).

In addition, the TRIPS Agreement contains provisions with respect to compulsory licenses (CLs), enabling countries to issue CLs under certain circumstances (Art. 31). A compulsory license results when a government allows an entity to produce a patented product or process without the consent of the patent owner. In the biopharmaceutical industry, CLs have been issued to allow generic versions of patented drugs. Recently, countries have begun granting CLs targeting non-communicable diseases and are seeking new policies to promote the use of CLs to support industrial policy objectives aimed at favoring domestic industries or as a cost containment measure. The 2001 Doha Declaration on TRIPS and Public Health confirms that the TRIPS Agreement should not stop countries from taking action to protect public health and that countries are free to determine the grounds for granting a CL.

Other IP rights of relevance to the innovative biopharmaceutical industry include patent linkage and patent term extensions. Patent linkage refers to the “linking” of marketing approval for generic pharmaceutical products to a review of the patent status of the medicine by government regulators. Linkage requirements ensure that regulatory agencies do not inadvertently contribute to patent infringement by approving market authorization for drugs that are still protected under patents and that parties can resolve patent disputes before potentially infringing pharmaceutical products are launched on the market. Relatively few countries have patent linkage mechanisms; however, they are included in some U.S.-negotiated free trade agreements.





Patent term extensions, also known as patent term restoration (PTR), may be given to biopharmaceutical products to compensate patent owners for delays in the regulatory approval process, as well as for undue delay in the patent examination process. Countries including Australia, Japan, Korea, Israel, the United States, and many of the member states of the European Union provide PTR for up to five years for pharmaceuticals.

## Key Facts and Figures

- The OECD has found that a 1% increase in the strength of patent protection in developing countries correlates to nearly a 1% increase in domestic R&D.<sup>1</sup>
- A recent study concluded that use of CLs in developing countries to lower drug prices was not as effective as voluntarily negotiating prices with manufacturers.<sup>2</sup> Recent analysis found that economies with beneficial IP protection see 9–10 times more life sciences investment than those with weak IP.<sup>3</sup>

## Pfizer's Position

Pfizer believes that establishing and enforcing IP policies is critical to driving innovation to meet medical needs while stimulating global and local economic growth. While the extent to which a country benefits from IP depends on several factors including poverty, infrastructure, political stability, and respect for the rule of law – it is widely recognized that where countries have strong and effective IP protection regimes in place, there is significant connection between increased incentives for local innovation and the transfer of technologies that foster local innovation and economic growth.

Pfizer shares the goal of facilitating access to medicines for patients and supports implementation of the 2001 WTO Doha Declaration on TRIPS and Public Health and the flexibilities therein—if applied as intended in the agreement. In limited circumstances, countries may choose to use a compulsory license to respond to a health crisis or emergency. However, such licenses must be limited to these specific circumstances and abide by provisions established in TRIPS Art. 31 so that pharmaceutical research companies can continue to develop innovative, lifesaving new drugs to meet global health challenges. Resorting to a compulsory license as a routine matter of public policy is not the best way to achieve the goal of facilitating access.

## How Patients, Health Care Professionals, and the Health Care System Benefit

Strong IP protection for biopharmaceutical products facilitates patient access to medicines, which leads to better public health.<sup>4</sup> Strong IP systems play an essential role in fueling innovation and economic growth in emerging markets. IP protections help facilitate medical progress by providing incentives to sustain R&D and innovation for a wide range of therapeutic areas including to address currently incurable conditions or other unmet medical needs prevalent in the developing world. Strong IP protection also lowers barriers to the timely launch of innovative pharmaceutical products and paves the way for generic medicines. The generic medicines that lower healthcare costs today are the innovative medicines of yesterday that have since come off-patent.

## What It Means for Pfizer

Pfizer is committed to improving patient health and well-being at every stage of life. Strong IP rights provide the foundation to ensure continued medical innovation for patients and improve patients' quality of life.

<sup>1</sup> Cavazos Cepeda, R., Lippoldt, D. and Senft, J., Policy Complements to the Strengthening of IPRs in Developing Countries, OECD Trade Policy Working Paper No. 104, p. 21 (14 Sept. 2010),

<sup>2</sup> Reed F. Beall, Randall Kuhn and Amir Attaran, "Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement," *Health Aff.*, 34, 493–501, (2015).

<sup>3</sup> Global Intellectual Property Index, 2015 at <http://www.theglobalipcenter.com/gipcindex/>

<sup>4</sup> See, e.g. Ernst R. Berndt and Iain M. Cockburn, "The Hidden Cost Of Low Prices: Limited Access To New Drugs In India," 2014; Cockburn, Iain M., Jean O. Lanjouw, and Mark Schankerman. 2016. "Patents and the Global Diffusion of New Drugs." *American Econ. Review*, 106(1): 136-64; Margaret Kyle and Yi Qian, "Intellectual Property Rights and Access to Innovation: Evidence from TRIPS," National Bureau of Economic Research, Dec. 2014, <http://www.nber.org/papers/w20799>; Margaret Kyle, WIPO 23rd SCP <http://www.wipo.int/webcasting/en/index.jsp> (Wed 2 morning session, 15:50).

