



Global Intellectual Property Rights

IP rights are a type of property right that incentivizes and enables creators of knowledge to produce and make public their unique and valuable 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. Pfizer believes that intellectual property (IP) is critical to driving innovation and stimulating economic growth in countries throughout the world. 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 early resolution mechanisms, help provide legal certainty for innovators to sustain R&D efforts for the benefit of patients, 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 IP regimes 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 concerning patents, data exclusivity, enforcement procedures, remedies, and dispute resolution.

Patents, a form of IP rights, grant the right to exclude others from exploiting for a limited time the invention covered by a patent, but only if the patent has complied with stringent legal requirements. In order for an invention to be patentable, it must be new, non-obvious, and sufficiently well described to ensure that when the patent expires, the invention is available to society. Without this important protection, others would be able to copy 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 an innovator's pre-clinical and clinical research, test data, and relevant safety information for biopharmaceutical products are protected for a limited time from referencing by generic 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. Data exclusivity is one of the protections available to drug innovators in exchange for making their extensive regulatory data available for reference by generics companies, thereby saving the generic companies from generating their own evidence of safety and efficacy for their products. The TRIPS Agreement does not specify a timeline for data exclusivity. Still, it requires that WTO members ensure the protection of data from disclosure and unfair commercial use (Art. 39.3) and five years has generally been accepted as a minimum for small molecule products whereas greater terms of protection are typically sought for biologics (e.g., 12 years in the U.S.).

In addition, the TRIPS Agreement contains provisions with respect to compulsory licenses (CLs), enabling countries to issue CLs under certain limited circumstances (Art. 31). A compulsory license results when a government allows an entity to produce a patented product or process, primarily for supply of the domestic market, without the consent of the patent owner. In 2017, the "Paragraph 6" amendment to the TRIPS Agreement entered into force. It made permanent previous waivers allowing countries with insufficient or no manufacturing capacity to import medicines under a CL in certain circumstances. The 2001 Doha Declaration on TRIPS and Public Health recognizes the public health problems facing developing and least developed countries and states that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. It also stresses the need for the TRIPS Agreement to be "part of the wider national and international action to address these problems." It recognizes that IP protection is important for the development of new medicines.

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. A patent linkage system provides an



opportunity for innovators and generic manufacturers to resolve patent disputes in an efficient, timely, and fair way before generic medicines can be launched. Relatively few countries have patent linkage mechanisms; however, they are included in several U.S.-negotiated free trade agreements.

Many governments provide a limited extension (or restoration) of the patent term for innovative medicines in recognition of the heavy burden of expense and risk incurred by innovators as a consequence of government requirements imposed during the R&D and regulatory review process. That is, a patent term extension (PTE) allows patent holders to capture economic benefits that could not be obtained during the approval procedure.

Key Facts and Figures

- The Organization for Economic Co-operation and Development (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.¹
- Economies with effective IP protection are 39% more open for business and attractive to foreign investment; 70% more likely to produce more innovative output; and have 26% greater global competitiveness.²
- A study concluded that use of compulsory licenses in developing countries to lower drug prices was not as effective as voluntarily negotiating prices with manufacturers.³

Pfizer's Position

The incentives provided by the IP system have enabled Pfizer to build an infrastructure that allows us to apply science and our global resources to bring therapies to people that extend and significantly improve their lives. Pfizer believes that establishing and enforcing IP policies is critical to driving innovation to meet medical needs while stimulating global and local socio-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, which recognizes countries' right to protect public health, while also acknowledging that IP protection is important for the development of new medicines.

Pfizer welcomes the "Paragraph 6" amendment (Article 31*bis*) to the TRIPS Agreement that entered into force in 2017, and we understand that the limited, narrow use of a compulsory license to address a national health emergency may be appropriate if all other options have been exhausted and the problem is truly urgent. However, Pfizer has been and will continue to work directly with governments and other stakeholders to ensure Pfizer's treatments and vaccines are accessible to those who need them. Resorting to a compulsory license as a routine matter of public or industrial policy is not the best way to achieve the goal of facilitating sustainable access to medicines.

Pfizer also supports IP provisions such as regulatory data protection as a condition of obtaining marketing approval against both disclosure and unfair commercial use as required by TRIPs and patent linkage, which provides for the early resolution of patent disputes before potentially infringing follow-on products enter a market. These provisions may be included in bilateral and plurilateral trade agreements by countries to build on their TRIPS obligations to better reflect the characteristics of their respective healthcare and economic systems. Recognizing the unique level of economic development and social challenges of Least-Developed Countries (LDCs), Pfizer is supportive of the extended deadline for LDCs to comply with the provisions of the TRIPS Agreement.

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.⁴ 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 and effective IP rights provide the foundation to ensure continued medical innovation for patients and improve patients' quality of life.



¹ 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),

² U.S. Chamber International IP Index, "Art of the Possible", 8th Edition (2020), available at https://www.theglobalipcenter.com/wp-content/uploads/2020/02/GIPC_IP_Index_2020_FullReport.pdf

³ 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).

⁴ 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).

