

Patent Rights

Pfizer is committed to improving patient health and well-being at every stage of life. Meaningful patent protection worldwide encourages medical progress and further investment in the discovery and development of newer and more effective medicines and vaccines that address unmet medical needs of patients. Pfizer continuously reevaluates its patent filing strategy in all markets to ensure continued innovation and access to medicines for the benefit of patients. Enforcement of patent rights is driven by numerous factors particular to each case; however, Pfizer has a policy of patent non-enforcement in Least Developed Countries.

Background

A patent is a government-issued legal right to exclude others from making, using, or selling an invention for a limited time period. Contrary to expectation, a patent does not grant any right to make, use, or sell an invention; it is only the right to exclude, but this limited right can still have great economic value. One way that patents encourage scientific progress is by requiring that innovators publicly disclose, within the patent document and in great detail, information about the invention. Although patents are granted for a 20-year term, for biologic and pharmaceutical products, it is a stark fact of the industry that a significant part of patent exclusivity terms are used up during the long development and regulatory approval cycles. In many countries, the government may provide a limited extention of the patent term for innovative medicines in recognition of the heavy burden of expense and risk incurred by the R&D and regulatory review process.

Since the property rights under a patent are derived from intellectual activity (acts of invention), they are considered "intellectual property." Patents are treated under the law similar to other property rights in that they can be purchased, sold, made available for use (license), and protected by means of the legal system.

Patents are available for inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step (non-obvious), and are capable of industrial application (useful).¹ Patents are territorial rights, and therefore the exclusive rights are only applicable in the country or region in which a patent has been filed and granted, in accordance with the law of that country or region. Some countries require the payment of maintenance fees to maintain a granted patent in force. Companies take many factors into consideration when deciding if they should file a patent and whether to maintain a granted patent in a particular country.

Once a patent is granted, it can be enforced in a court on the initiative of the right owner. In most systems, a court of law has the authority to address patent infringement. However, monitoring, identifying, and taking action against infringers of a patent is the responsibility of the patent owner. The owner of a patent right will consider many factors when determining its enforcement strategy against infringers.

Key Facts and Figures

- Sectors that rely on intellectual property rights (IPR) represent a significant part of developed and developing economies in terms of GDP, employment, tax revenues, and strategic importance. IPR also promotes foreign direct investment (FDI) and technology transfer in developed and developing countries.²
- Patents often play a critical role in facilitating joint ventures or access to venture capitalists and angel investors. These providers of early-stage capital may provide a 'lifeline'—particularly for small-medium size enterprises—that enable an invention to reach the marketplace.³

• Programs supported by the World Intellectual Property Organization (WIPO) highlight the need for continued use of the patent system to support national innovation goals and contribute to economic growth.⁴

Pfizer's Position

Pfizer is committed to improving patient health and well-being at every stage of life. Meaningful patent protection worldwide encourages medical progress and further investment in the discovery and development of newer and more effective medicines and vaccines that address the unmet medical needs of patients. Pfizer continuously reevaluates its patent filing strategy in all markets to ensure continued innovation and patients' access to medicines.

To demonstrate our commitment to build capacity and advance developing country patent systems, Pfizer supports programs such as the <u>Inventor Assistance Program</u> (IAP), an initiative of the World Intellectual Property Organization in cooperation with the World Economic Forum. The IAP matches developing country inventors and small businesses with limited financial means with patent attorneys, who provide pro bono legal assistance to secure patent protection. Ensuring that as many people as possible have the opportunity to turn great ideas into reality through the patent system is an important part of creating a thriving society that will help move a country to the next stage of development.

Enforcement of patent rights is driven by numerous factors particular to each case. However, the company recognizes the unique level of economic development and social challenges of Least Developed Countries (LDCs); therefore, Pfizer has a policy of patent non-enforcement in LDCs, as defined by the United Nations Committee for Development Policy.⁵

Pfizer also supports patent transparency, as demonstrated by our participation in the Patent Information Initiative for Medicines (<u>Pat-INFORMED</u>), an initiative that seeks to make patent information publicly available for the following therapeutic areas: HIV/AIDS, cardiovascular diseases, diabetes, hepatitis C, oncology, respiratory conditions, and products on the WHO Essential Medicines List. Through this initiative, Pfizer has taken a leading role by taking the additional step to include patents from our entire small molecule portfolio.

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

Our patent filing and enforcement decisions are grounded in our belief that IP protection for biopharmaceutical products advances patient access to medical advances, which ultimately leads to better public health globally.

What It Means for Pfizer

Pfizer is committed to improving patient health and well-being at every stage of life. Meaningful patent protection worldwide is vital as it encourages medical progress and further investment in the discovery and development of newer and more effective medicines and vaccines that address unmet medical needs of patients.

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¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), Article 27.1.

² Dixon, Allen, Intellectual Property: Powerhouse for Innovation and Economic Growth, International Chamber of Commerce (2011).

³ Kalange, Christoper. Consultant, SME Division, WIPO. "Role of Intellectual Property in Innovation and New Product Development" available at https://www.wipo.int/sme/en/documents/ip_innovation_development_fulltext.html#role

⁴ See WIPO Inventor Assistance Program, <u>http://www.wipo.int/iap/en/</u>

⁵ United Nations Committee for Development Policy, List of Least Developed Countries, available at

https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf