

# Position on Intellectual Property

Intellectual property (IP) protections provide a vital framework to help enable the development of innovative and life-changing treatments, cures and other healthcare technologies for patients and consumers around the world. IP protections help ensure innovative healthcare companies can continue to invest in cutting-edge research, especially given the expense and time commitment necessary to develop new medicines and treatments.

IP protections also encourage the disclosure of information and data that promote competition and facilitate the introduction of generic alternatives into the marketplace after a limited period of exclusivity.

At Johnson & Johnson, we combine research and development (R&D), novel access programs and business model innovation, advocacy, and the power of multi-sectoral partnerships to help deliver innovative treatments and technologies to the world's most underserved populations.

Throughout the lifecycle of our products, Johnson & Johnson facilitates access for patients in need by working with governments, non-governmental organizations and other private-sector companies using tools like equity-based tiered pricing, voluntary licensing, healthcare system capacity-building, and patient assistance programs. We adhere to the following principles regarding IP:

**Patents:** We advocate for strong and effective patent systems that support, protect and promote innovation. These systems encourage scientists, entrepreneurs, doctors, academics and companies to develop new life-enhancing and lifesaving products. They also enable economic growth and promote the disclosure of information among competitors. The protection provided by strong patent systems allows Johnson & Johnson the freedom to disclose information about its inventions openly, which speeds the development of competing technologies by other companies and organizations, creating an ongoing cycle of innovation and product improvement.

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Pharmaceutical innovation is an iterative and continuous process that delivers new and improved medicines that benefit patients. Substantial research, development and innovation is required to develop each new medicine. In addition, ongoing scientific advances and data gathered from product use can foster additional innovation that makes products better, safer or more useful, each of which has the potential to improve patient outcomes. These product improvements may include the discovery of new forms and uses of existing chemical compounds or substances better suited to patient needs. For example, the development of a sustained-release dosage form of an existing drug may result in an increase in patient adherence, which can deliver a significant therapeutic benefit. Incentives should be provided by patent systems to support and encourage the development of pharmaceutical innovation that benefits patients.

**Data exclusivity:** Unlike industries where products can be marketed soon after securing a patent, new pharmaceutical products must first undergo rigorous clinical trials to ensure they are safe and efficacious before being prescribed to patients. These clinical trials often cost hundreds of millions of dollars and require several years to complete, and the likelihood of success after that significant investment of time and resources is uncertain.

To encourage generic entry, regulatory agencies such as the U.S. Food and Drug Administration (FDA) do not require generic manufacturers to perform these risky, costly and time-consuming clinical trials, but rather allow the generic to rely upon the clinical work done by the innovator. In exchange for allowing generic manufacturers to use the clinical work of the innovator, the regulatory agency provides the innovator an initial time period of exclusivity to the innovator's data.

During this limited period, only the innovator company can use this proprietary clinical trial data for product approval purposes. Afterwards, generic manufacturers may use the data in support of their own regulatory filings. In this way, data exclusivity simultaneously encourages the development of safe and effective new medicines and facilitates the introduction of generic alternatives.

Johnson & Johnson believes that data exclusivity periods should be provided for all new drugs, and the length of those periods should reflect the significant time and investment required to develop and test these treatments. Longer periods of exclusivity for biologic medicines such as monoclonal antibodies are appropriate given their complexity and the greater investment required to develop and test.

**Trademarks:** Trademarks differentiate a product or service of one party from those of another. Consumers, patients and healthcare professionals rely on trademarks to indicate a certain level of quality and effectiveness, and to avoid confusion. Accordingly, we believe a robust trademark registration and enforcement system is essential, not only to enable confident purchasing decisions and encourage fair competition, but also to protect the health and safety of consumers and patients worldwide.

**The importance of IP in developing countries:** IP is an important facilitator of accessible and affordable healthcare in developing countries. IP protections are the foundation of a system that has developed important new treatments for patients in need, including diseases that have the greatest impact on developing countries. To promote access to these medicines, we work closely with governments, non-governmental organizations, and other stakeholders around the world.

**Compulsory licensing:** At Johnson & Johnson, we have a longstanding commitment to address unmet medical needs in developing countries around the world. We recognize and support international agreements, including the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the Doha Declaration, that provide for the use of compulsory licenses in certain limited circumstances. However, we are concerned about the growing use of compulsory licenses, particularly for the purpose of favoring domestic industries. Doing so threatens the overall IP system, which has enabled the development of lifesaving medicines for millions of patients today and has the potential to create new therapies for millions more in the future.

## Application

This Position is relevant for the Johnson & Johnson Family of Companies, as detailed in our [governance materials](#). We provide updates on matters relating to IP in our annual [Health for Humanity Report](#) when relevant.

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