

# Position on Intellectual Property

## Background

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 also help ensure innovative healthcare companies can continue to invest in cutting-edge research, especially given the high cost and time it takes 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.

## Relevance

As the world's largest and most broadly based healthcare company—with operations in more than 60 countries, reaching more than a billion patients and consumers each day with its medicines, consumer health products and medical devices—Johnson & Johnson plays a major role in advancing health and well-being. Each year, we invest billions of dollars in R&D to address the unmet health and medical needs of patients around the world. IP protections that promote innovation, access and affordability are critical to fulfilling our mission of changing the trajectory of health for humanity.

## Guiding Principles

We believe we are uniquely positioned to bring together science, technology, people and ideas to help us in this mission. Our scale and reach come with a huge sense of responsibility—every decision we make can have an enduring impact across the world. Every decision is anchored in [Our Credo](#) and in our commitments to patients and all who use our products and services, to employees, to communities around the world, and to our stockholders.

## Our Position

At Johnson & Johnson, we are building on our 130-year legacy of blending heart, science and ingenuity to tackle some of the world's most pressing public health challenges. Our Global Public Health division is the first fully dedicated organization within a healthcare company that combines R&D, novel access programs and business model innovation, in-country operations, advocacy, and the power of multi-sectoral partnerships to help deliver innovative treatments and technologies to the world's most underserved populations.

Throughout the lifecycles of our products, Johnson & Johnson works 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 to facilitate access for patients in need. We are transparent about our position relative to various aspects of IP, as follows:

**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.

**Data exclusivity:** Unlike other industries where products can be marketed soon after getting a patent, new pharmaceutical products must first go through 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 take several years to complete, and the likelihood of success after spending that time and financial investment is uncertain.

To encourage generic entry, regulatory agencies such as the U.S. Food and Drug Administration (FDA) do not ask generics 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 before the generic can use it.

Regulatory data exclusivity protects proprietary clinical trial data for a limited time period. During this limited period, only the innovator company can use this 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 time for biologic medicines such as monoclonal antibodies are particularly important given their complexity and the higher levels of investment required to develop and test.

**Follow-on pharmaceutical innovation:** Developing new medicines is an iterative process, and makes continued progress that further benefits patients. Ongoing scientific advances and data gathered from product usage can foster "follow-on" innovations (sometimes called "incremental" innovations) that make products better, safer or more useful, each of which has the potential to improve patient outcomes. Follow-on innovation includes 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 a known drug may result in an increase in patient adherence, which can deliver a profound patient benefit. Incentives should be provided by patent systems to support and encourage the development of follow-on pharmaceutical innovations, provided they reach established thresholds of being new, useful and non-obvious in order to be granted a patent.

**Trademarks:** Johnson & Johnson believes strong and effective trademark protection is in the best interests of consumers, patients and governments, as well as the innovative healthcare industry. Trademarks function to differentiate a product or service of one party from those of another. Thus, consumers, patients and healthcare professionals rely upon 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.

**Access and affordability of healthcare in developing countries:** We believe that IP protection is not a barrier to accessible and affordable healthcare. To the contrary, IP protections are the foundation of a system that has developed important new treatments for patients in need, including those for HIV, tuberculosis and other 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.

**Access and pricing:** Johnson & Johnson works closely with governments and other organizations around the world to facilitate access through equity-based tiered pricing, healthcare system capacity-building, patient assistance programs and voluntary licensing arrangements. We believe that these mechanisms are effective in providing access while also promoting an IP framework that enables the development of new treatments for patients.

## 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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