

# Intellectual Property Statement

Intellectual property (IP) protections provide a vital framework that enables the development of new, innovative and life-changing treatments, cures and other technologies for patients and consumers around the world. IP protections provide incentives that ensure innovative companies like Johnson & Johnson can continue to invest in cutting-edge research, especially given the high cost and time it takes to develop new medicines and treatments. In 2017 alone, Johnson & Johnson invested US \$10.6 billion in Research and Development to address the unmet medical needs of patients around the world.<sup>1</sup>

In addition to incentivizing the development of innovative medicines and technologies, IP protections encourage the disclosure of information and data that promote competition and, upon expiration of time-limited exclusivity periods, facilitate the introduction of generic alternatives into the marketplace. By carefully balancing each of these considerations, IP protections serve the healthcare interests of patients and consumers.

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.

## Patents

Johnson & Johnson advocates 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 life-saving products, 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 like the US 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, one that 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 health care industry. Trademarks function to differentiate a good 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 to not only enable confident purchasing decisions and encourage fair competition, but also to protect the health and safety of consumers and patients worldwide.

## **IP and Access & Affordability of Healthcare in Developing Countries**

At Johnson & Johnson, we are building on our Company's 130-year legacy of blending heart, science and ingenuity to tackle some of the world's most pressing public health challenges. Today, we are undertaking even greater steps to unlock the potential of innovation for everyone, everywhere. By harnessing our Company's collective breadth, scale and legacy of scientific innovation, we strive to live up to Our Credo responsibilities and change the trajectory of health for humanity.

Charting a bold new, self-sustainable approach, Johnson & Johnson Global Public Health is pushing boundaries as the first fully dedicated organization within a healthcare company that combines Research & Development, 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.

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 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 life-saving medicines for millions of patients today, and has the potential to create new therapies for millions more in the future.

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 more effective at providing access while also promoting an IP framework that enables the development of new treatments for patients.

*Last updated: July 2018*

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<sup>1</sup> For more information, see <http://healthforhumanityreport.jnj.com/innovation/research-and-development>