Intellectual Property

Introduction

Organon & Co. ("Organon" or the "Company") invests in Research and Development to address the unmet health and medical needs of patients, especially women, and to advance and expand our portfolio of our products. Intellectual property (IP) protections provide a vital framework that enable us to develop innovative and life-changing treatments, cures, and other healthcare technologies for patients and consumers around the world. IP protections ensure companies like Organon can continue to invest in cutting- edge research, especially given the time and high cost it takes to develop new medicines and treatments, some of which may never come to fruition. IP protections also encourage the disclosure of information and data that promote competition and facilitate the introduction of generic alternatives to the marketplace after a limited period of exclusivity. IP protections that promote innovation, access, and affordability are critical to fulfilling our mission of improving the health of women around the world.

We advocate for predictable 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.

Our Approach

Patents

Predictable patent protection is important to the marketing of certain of Organon's products in the United States and in most major foreign markets. In addition to our products themselves, patents may cover pharmaceutical formulations, processes for, or intermediates useful in the manufacture of products, devices for delivering products, or the uses of products. Patent protection for individual products varies from country to country, depending on regulatory activity, the type of patent, and its scope of coverage. The effect of patent expiration also varies depending on other patents, the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product, and the requirements of new drug provisions of the U.S. Federal Food, Drug, and Cosmetic Act or similar laws and regulations in other countries. The protection provided by strong patent systems allows Organon 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 improvement.

Data exclusivity

Unlike other industries where companies can market products soon after getting a patent, new pharmaceutical products must first go through rigorous clinical trials to ensure they are safe and effective 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 is uncertain. To encourage the development of generic products, regulatory agencies such as the U.S. Food and Drug Administration (U.S. FDA) allow the generic to rely upon the clinical work done by the innovator. In exchange, the regulatory agency can provide the innovator an initial period of exclusivity before allowing generics to enter the market using the innovator's clinical data and, in some jurisdictions, an extension of the innovator's product's patent. This period of regulatory data exclusivity simultaneously encourages the development of safe and effective new medicines and facilitates the introduction of generic alternatives. Organon 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. We seek additions to market or data exclusivity in the United States and other countries through new legislation, as well as through legislative reform and implementation of international treaties.

Continuing pharmaceutical innovation

Developing new medicines is an iterative process, producing continued progress that further benefits patients. Ongoing scientific advances and data gathered from product usage can foster additional innovations that make products better, safer, or more useful, each of which has the potential to improve patient outcomes. These innovations include the discovery of new forms and uses of existing chemical compounds or substances better suited to patients' needs. For example, the development of a sustained-release dosage form of a known drug may make patients more likely to stick to their prescribed treatment. Patent and regulatory systems should offer incentives that support and encourage the development of follow-on pharmaceutical innovations, provided they reach established patent or regulatory thresholds.

Trademarks

Organon believes strong and effective trademark protection is in the best interests of consumers, patients, and governments, as well as the innovative healthcare industry. Consumers, patients, and healthcare professionals rely upon trademarks to indicate a certain level of quality and effectiveness and to avoid confusion with similar products. 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. In all markets, Organon's important products are sold under trademarks that are considered in the aggregate to be of material importance. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

Access and pricing

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

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 heart disease, migraine, asthma, and contraceptive methods, as well as other health issues that have a substantial 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 Organon, we are committed to addressing 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.