Public Policy Statement | February 2024

Intellectual property

As a research-intensive biopharmaceutical company, MSD works to save and improve lives around the world by inventing breakthrough medicines and vaccines and by striving to make them available and affordable to those who need them. Strong intellectual property (IP) systems are the cornerstone of innovation, catalyzing the investment needed to embark on the long, costly, and high-risk process of developing new and improved medicines and vaccines. IP systems not only reward innovation, but also allow scientists to build on each other's discoveries and provide a framework for collaboration and partnership. IP is an enabler and not a barrier to access to and affordability of innovative, quality-assured medicines and vaccines. IP enables us to pursue a continuum of approaches to both develop novel products and facilitate patient access to them around the world, including through voluntary licenses and other IP-grounded partnerships.

Background

Intellectual property (IP) protections are a fundamental part of the research and development (R&D) ecosystem, enabling and incentivizing scientists from across different sectors – academia, biotech, government, and the biopharmaceutical industry – to innovate, generate new knowledge and evidence, and ultimately create new and improved medicines and vaccines that address unmet healthcare needs.

The biopharmaceutical industry invests more in R&D than almost any other industry with one of the greatest R&D intensity ratios (i.e., ratio of R&D investment to sales) across sectors.[1] This has resulted in the creation over the last 20 years of vaccines that prevent over 30 diseases and over 430 medicines that have changed the course of diseases like HIV, hepatitis, and cancer.[2] These successes came out of a complex, decades-long, costly, and risky process that builds on the IP generated by scientists from across sectors and around the world. IP protections help scientists at companies, big and small, secure the investment needed to drive this R&D. IP protections provide the certainty that should an innovation successfully be developed, the innovators and the investors will be able to realize a return on their investments. These returns are essential to incentivize continued reinvestment in ongoing R&D on expanded indications and new patient groups, as well as R&D to develop new medicines and vaccines that will address other unmet medical needs.

In exchange for time-limited IP protection, IP systems require innovators to publicly share information about their innovations. This requirement enables scientists to conduct research to improve upon existing medicines and facilitates generic medicines to enter the market after IP protections expire.

A recent assessment by the World Intellectual Property Organization (WIPO) found that IP protections enabled developers of COVID technologies to share and advance technical information, and that without it, the developers would not have been able to in-license scientific contributions or out-license to contract manufacturing organizations.[3] The assessment found that the absence of IP protections and legally enforceable mechanisms "would have resulted in substantial inefficiencies and almost certainly would have delayed the introduction and distribution of vaccines."[4] Simply put, strong IP systems serve as a cornerstone of biopharmaceutical innovation.

Critical IP protections and incentives that enable innovation

As a research-intensive company, we rely on a set of IP rights:

- **Patents** protect and incentivize ongoing investment in innovation. MSD supports patentability criteria that are consistent with the World Trade Organization (WTO) and other international rules, which determine what is genuinely new, improved, inventive, and useful, and therefore patent worthy. National laws, regulations and judicial decisions that prohibit patents on certain types of inventions or impose additional or heightened patentability criteria can restrict patient access to new innovations, stifle competition, and undermine investment in future treatments and cures.
- **Patent term extensions (PTEs)** restore time of patent protection that is lost during the period of clinical trials and regulatory review necessary for regulatory approval, helping to offset this lost period of exclusivity before the product can be used by patients. PTE is an important mechanism to protect against arbitrary regulatory delays. PTEs enable further investment in clinical research, such as studies to treat new types of cancers or to test safety and efficacy in children and incentivize further discovery efforts that will benefit society. They are not used to extend the life of a patent without further investment, innovation, and new or improved application.
- **Regulatory Data Protection (RDP)** creates a powerful incentive for innovator R&D investment while allowing generic and biosimilar companies to eventually rely on an innovator's proprietary data and avoid investing in their own independent, duplicative clinical studies. RDP ensures that sensitive and proprietary information submitted for regulatory approval remains confidential for a defined period of time. RDP is especially critical for biologic molecules, which are generally more complex to develop and manufacture than small molecules and are therefore dependent on both patents and the data submitted to regulatory agencies.

- **Patent linkage** conditions marketing approval of a follow-on biopharmaceutical product to the expiration of the reference product's exclusivity and is critical for enforcement of IP rights. Effective linkage systems ensure that a regulatory agency does not approve the marketing of a follow-on product that infringes IP rights. Patent linkage promotes cooperation between two critical agencies that govern biopharmaceutical products – regulatory and IP agencies.

In addition to these overarching incentives, several targeted protections exist to further encourage R&D of medicines for specific patient populations:

- **Orphan exclusivity laws and special programs** encourage development of medicines for patients suffering from rare (i.e., orphan) conditions and are critical to address unique unmet medical needs. Orphan designation typically provides exclusivity for a defined period and can also enable additional measures to shorten the time it takes for an innovative drug to obtain regulatory approval.
- **Pediatric exclusivity laws** encourage R&D investment in and availability of new medicines for children. Pediatric exclusivity provides an additional extension of market and regulatory data exclusivity and helps offset the additional costs of conducting clinical studies on safety and efficacy in pediatric populations.

Patents alone are not sufficient to ensure an innovator's IP rights will be respected. Effective protection of IP also relies on a government's judicial and administrative institutions to ensure effective enforcement and adjudication against acts of potential infringement.

IP and access to medicines

An effective IP system is one part of a broader ecosystem that supports the discovery and delivery of innovative medicines and vaccines to patients. Ensuring that patients have access to innovative medicines requires all components of the ecosystem to work effectively, including regulatory, procurement, supply chain, healthcare financing, and delivery systems. Enhancing access to our medicines and vaccines is core to MSD's mission, and we partner with a range of stakeholders, including multilateral organizations, non-governmental organizations, donors, and governments, to strengthen the broader ecosystem and improve timely, affordable, and equitable patient access to our medicines and vaccines, particularly in low- and middle-income countries (LMICs).

As outlined in the IP PACT, patient and societal benefit inform our approach to IP throughout a product's life cycle. For example, our strategy to enable global equitable access to our COVID-19 therapeutic, LAGEVRIO (molnupiravir), underscores the importance of IP-grounded partnerships. We entered into non-exclusive voluntary licensing agreements with established generic manufacturers (i.e., those with a history of supplying quality-assured medicines to global public health programs) and the Medicines Patent Pool (MPP) to facilitate availability of molnupiravir in more than 100 LMICs. Through these licenses and local manufacturing

partnerships, we provide supply coverage for approximately 90 percent of the population in LMICs. More courses of molnupiravir were available to LMICs in the first quarter of 2022 (immediately after regulatory authorization) through our supply agreement with UNICEF and through our generic licensees than were supplied to high-income countries in this timeframe.

MSD has also entered into IP-grounded cross-sectoral partnerships in efforts to improve pediatric HIV medicines through the Pediatric HIV Treatment Initiative (PHTI), a multi-stakeholder initiative of PEPFAR, UNITAID, Drugs for Neglected Diseases Initiative (DNDi) and the MPP.

We assess the potential to enter into similar multi-stakeholder mechanisms based on the nature of the access challenges, the commitments of partners, and the potential for meaningful impact.

IP challenges globally

The weakening of IP rights and protections undermines the R&D and collaborations that ultimately turn breakthrough science into new medicines and vaccines for patients. Currently, there are several proposals being deliberated through multi-lateral forums and in national legislatures around the world that would undermine the foundation of innovation that effective IP protection provides. For example, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the most comprehensive multilateral agreement on IP, sets a minimum global benchmark for IP and trade that has enabled the sharing of knowledge, technology, and innovations. However, in 2022, WTO members agreed to waive certain commitments to protect IP for COVID-19 vaccines and have been considering expanding the waiver further to cover specific treatments. This weakening of IP provisions needlessly jeopardizes innovation and risks inadvertently hurting preparedness for future pandemics by discouraging investment into new technologies to fight global health emergencies.

At MSD, we continue to believe that the most effective way to provide better access for patients around the globe is to collaborate with governments and other stakeholders and leverage IP-grounded partnerships, such as voluntary licensing, and not to waive IP rights and leave supply and quality of supply to chance. For example, there were more than 330 voluntary IP-grounded partnerships to bolster manufacturing capacity, facilitate technology and knowledge transfer, and drive R&D to find vaccines and medicines against COVID-19.[5]

Evidence indicates that legal requirements or actions undermining IP, such as compulsory licensing, are not effective in fostering a healthy ecosystem for biopharmaceutical investment and innovation and do not necessarily result in improved access or availability of lower-priced products and may even hinder equitable access.[6]

IP and ongoing innovation in cancer care

The importance of IP protections is reflected in our innovation strategy for KEYTRUDA and our company's commitment to continue to investigate how patients can benefit from our medicines after they are first approved. Since 2014, when KEYTRUDA was first approved to treat advanced or unresectable melanoma, MSD has worked tirelessly to expand its use in treating different types of cancers. Because each cancer is unique, regulatory agencies require that innovators prove their products work by testing them in clinical trials in patients with each distinct type of cancer. Each trial can take two to five years to conduct with no guarantee of success. As of March 2023, KEYTRUDA has received 50 approvals from the U.S. Food & Drug Administration (FDA) alone, including indications in 16 specific tumor types and 2 indications that are tumor-agnostic.

Despite the challenges and commercial risks of conducting clinical trials, our company is currently conducting or supporting hundreds of clinical trials involving KEYTRUDA to provide options to cancer patients who do not presently have choices for effective treatments. Importantly, patents directed to, for example, additional indications or combinations do not extend the patent life of earlier patents covering the initial innovation associated with a product. It is incorrect to characterize additional patents filed on subsequent innovation around KEYTRUDA as extending the life of earlier patents on the initial discovery of pembrolizumab, the active ingredient in the product. A biosimilar manufacturer does not need to "copy" the subsequent innovation that our company has protected with patents to bring its version to the market, and we continue to expect biosimilar manufacturers will offer biosimilar options for that initial discovery by late 2028 when those patents expire.

[1] European Commission (2023), 2023 EU Industrial R&D Investment Scoreboard; https://publications.jrc.ec.europa.eu/repository/handle/JRC135576
[2] IFPMA. Intellectual property - IFPMA
[3] Abbott, Frederick M. Intellectual Property and Technology Transfer for COVID-19 Vaccines: Assessment of the Record. Executive Summary. Geneva, Switzerland: World Intellectual Property Organization, 2023. Accessed from: wipo-pub-rn2023-39-exec-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf
[4] Abbott, Frederick M. Intellectual Property and Technology Transfer for COVID-19 Vaccines: Assessment of the Record. Executive Summary. Geneva, Switzerland: World Intellectual Property Organization, 2023. Accessed from: wipo-pub-rn2023-39-exec-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf
[5] IFPMA. Applying Lessons Learned from COVID-19 to Create a Healthier, Safer, More Equitable World. Accessed from: https://www.ifpma.org/publications/applying-lessons-learned-from-covid-19-to-create-a-healthier-safer-more-equitable-world/
[6] Pugatch Consilium. Separating Fact From Fiction – How Localization Barriers Fail Where Positive Non-Discriminatory Incentives Succeed. A global assessment of localization policies and incentivizing life science investment and innovation. 2016. Accessed 16 February 2023 from: http://www.pugatch-consilium.com/reports/Localization%20Paper_US_FINAL.pdf