Pfizer's Patent Policy & Commitment to Access to Medicines

Pfizer's purpose – *Breakthroughs that change patients' lives* – fuels everything we do and reflects our passion for science and our commitment to patients. Alongside passion and commitment, a strong system of intellectual property protection provides the economic incentive necessary to achieve sustainable scientific advancement and enable companies like Pfizer to apply its science and global scale to research, develop and distribute medicines around the world. We are thrilled our COVID-19 vaccine was delivered to over 180 countries and has the potential to change more lives than any other breakthrough from the past century, and we are just as proud of our other discoveries – big and small – that deliver meaningful value to patients and society.

The Patent System Advances Our Purpose

By providing inventors with a limited period of exclusivity for each new invention, the patent system encourages inventors to persist in their research and progress the science necessary to discover the next breakthrough. The patent system also fosters competitive innovation and facilitates collaboration amongst inventors – both integral to scientific advancement – by mandating the disclosure of inventions. It is the combination of incentive and disclosure provided by a robust patent system that enables Pfizer and other life science companies to spend the time, energy and resources to discover, research and develop new life-changing medicines. As a signatory to the "IP Principles for Advancing Cures and Therapies" (IP PACT), Pfizer is committed to patient and societal benefit as guiding principles in our IP practice. Learn more about these ten (10) principles here: **IP PACT.**

Patent Filing on Genuine Innovation

When assessing whether an invention may be patentable, we evaluate whether the invention reflects a genuine innovation that will ultimately support the needs of patients. We do not file patents for discoveries that lack genuine innovation or for the purpose of limiting competition. We also continuously assess the patentability of our inventions as new information becomes known and, as required by law, disclose all such relevant information to the relevant patent offices. We also engage in a careful and continuous review of our patent portfolio, which may result in the withdrawal of granted and pending patents when the maintenance of that patent or application is no longer supported by our development efforts.

As is often the case, Pfizer's research and development efforts do not end after the initial invention discovery, nor does it stop once we file a patent application on that discovery. Our researchers are continuously looking for ways to significantly improve and enhance the health, wellbeing and quality of life of patients by, for example, discovering improvements to existing medicines. These

advancements include researching new diseases that could be treated by the medicine, improving dosing or administration, and reducing side effects or adverse drug reactions. To the extent that these advancements represent genuine innovation, Pfizer may file a patent application covering the latest invention.

Before being granted as a patent, all patent applications go through the same rigorous process and must meet the exact same patentability criteria. To receive a patent, any invention must demonstrate novelty, inventive step, and utility – no matter when the application is filed during the research and development process. Patients benefit from a patent system that incentivizes and protects the continuous pursuit of improvement.

The term of protection provided by a patent is 20 years from the date of filing the patent application, subject to extension in some jurisdictions to compensate for delays at the patent office and/or regulatory delays. In some (but not all) cases, the exclusivity period of patents filed later in a product's lifecycle may extend beyond the exclusivity period of an earlier filed patent. Pfizer committed in the IP PACT to "acting responsibly, ethically and professionally during the course of all proceedings concerning the securing, enforcement and defense of patents." This includes not delaying or gaming the filing of a patent application in order to achieve a longer exclusivity period. Patient access to our medicines and vaccines is considered and evaluated at different stages during drug development and commercialization. Since patent filings often occur before clinical trials, access is more realistically assessed after approval/commercialization. However, access is also taken into account during the patent filing and enforcement process, as patents may be licensed or the subject of settlements with competitors.

We also support patent transparency, as evidenced by our participation in the **Patent Information Initiative for Medicines** (Pat-INFORMED), an initiative hosted by WIPO that seeks to facilitate easy access to medicine patent information. Through this initiative, Pfizer has taken a leading role by listing the patents from our entire small molecule product portfolio.

The patent rights we consider most significant in relation to our business as a whole, together with the year in which the basic product patent expires, can be found in our annual filings on Form 10K, including our most recent 10-K. Additionally, as required by U.S. law, the Food & Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the **Orange Book**), contains patents "for which a claim of patent infringement could reasonably be asserted" against a company seeking to make a generic version of the medicine (21 355(b)(1)). In March 2023, for example, there were five (5) patents listed in the Orange Book for Ibrance (palbociclib) tablet.

Responsible Approach to Patent Enforcement

Enforcement of our patent rights is driven by numerous factors particular to each case. We are committed to continually acting in a responsible, ethical and proportionate way when protecting our inventions and resolving patent disputes, which includes careful consideration of the legal remedies available to us in a given situation. We respect validly granted patents, while being prepared to challenge the patents of third parties when appropriate.

In addition, we recognize the unique level of economic development and social challenges of Least Developed Countries (LDCs), as defined by the United Nations Committee for Development

Policy; therefore, Pfizer has a policy of patent non-enforcement in LDCs. In that same spirit, we are supportive of a time-limited extension for LDCs to comply with the provisions of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

Pfizer shares the goal of facilitating access to medicines for patients and we support implementation of the 2001 WTO Doha Declaration on TRIPS and Public Health, which recognizes countries' right to protect public health, while also acknowledging that IP protection is important for the development of new medicines. We welcome the "Paragraph 6" amendment (Article 31bis) to the TRIPS Agreement that entered into force in 2017, and we understand that the limited, narrow use of a compulsory license to address a national health emergency may be appropriate if all other options have been exhausted and the problem is truly urgent. However, Pfizer has been and will continue to work directly with governments and other stakeholders to help ensure our treatments and vaccines are accessible to those who need them. Resorting to a compulsory license as a routine matter of public or industrial policy is not the best way to achieve the goal of facilitating sustainable access to medicines.

The Patent System Facilitates Collaboration

Our ability to rely on patent laws that protect intellectual property from being misappropriated enables us to enter collaborations and partnerships where we can share proprietary information in an effort to speed up progress on the most pressing unmet medical needs. The **2022 Access to Medicine Index** recognized Pfizer as performing "above average" in terms of sharing IP assets with third-party researchers.

Most recently, we engaged in voluntary licensing agreements with th**e Medicines Patent Pool (MPP)**, a United Nations-backed public health organization, to help facilitate the production and supply of generic versions of our **oral COVID-19 treatment** to the most vulnerable populations, as well as an agreement to facilitate the clinical development of **sutezolid**, an investigational medicine for the treatment of tuberculosis.

To demonstrate our commitment to build capacity and advance developing country patent systems, Pfizer supports programs such as the **Inventor Assistance Program** (IAP), an initiative of WIPO in cooperation with the World Economic Forum. The IAP matches developing country inventors and small businesses with limited financial means with patent attorneys, who provide pro bono legal assistance. We believe that the more people who can turn great ideas into reality through the patent system, the greater the chance of creating a thriving society that allows countries to move to the next stage of development.

Additionally, Pfizer was a founding member of the **WIPO Re:Search** program, a public-private partnership hosted by the World Intellectual Property Organization (WIPO) that aimed to accelerate the discovery and development of technologies for neglected tropical diseases (NTDs), malaria, and tuberculosis by sharing IP with the global health research community. We're proud of the impact this 11-year collaboration, which came to a close in 2022, had in the fight against NTDs, malaria and tuberculosis.

Regulatory Data Protection Strikes a Proper Balance

Pfizer further supports regulatory data protection (RDP) as a means of ensuring the protection of innovative data against both disclosure and unfair commercial use as required by the TRIPS Agreement. RDP enables the approval of lower cost generic medicines, by preserving an incentive for innovators to generate safety and efficacy data, while allowing generic companies to refer to and rely on that data in seeking approval once the RDP period expires. We believe RDP provisions should meet the highest international standards in terms of eligibility, predictability and duration, and should be measured from the date of approval of the product by each country's respective regulator.

Evidence-Based Policymaking Based on Facts

Undesirable outcomes and unintended consequences can arise as the result of false and misleading information. This is particularly relevant in complex and technical fields, such as policymaking pertaining to the development of a new drug. To help ensure the protection, conservation, and proper understanding of the laws governing the intellectual property system, access to dependable and accurate information is of the utmost importance. At Pfizer, we encourage evidence-based policymaking based on the facts. See, for example, inaccurate statements posted by the Initiative for Medicines, Access, and Knowledge (I-MAK), regarding Lyrica® (pregabalin), with the corresponding truth (**view Lyrica Infographic**). We are dedicated to helping people find accurate, science-based information as they make healthcare decisions that impact their lives. Learn more here: **The Facts**.

Commitment to Access to Medicine and Closing the Health Equity Gap

The IP system is the foundation for new medicines and vaccines for patients, and at Pfizer, we measure ourselves not just by the creation of breakthrough medicines and vaccines, but by the accessibility of those critical innovations within populations in need. Our vaccines and medicines are not able to benefit patients if they cannot reach or afford them. To change patient's lives, Pfizer applies a modernized approach to access, focused on affordability and delivery for patients with the greatest coverage gaps and out-of-pocket exposure.

Pfizer's Access Approach

Our broad-based core methods to reduce the number of people who cannot afford our medicines include:

- Advocating with payers, governments, and others in the health care system on behalf of patients to identify affordable access to our medicines.
- Patient assistance and donation programs when insurance or reimbursement systems fail to provide affordable access to our medicines.
- Innovative financing mechanisms, including differential pricing, microfinancing, peer-topeer lending, subscription models, and flexible payment options, to help reduce out-ofpocket costs for patients on a sustained basis.

- New technologies that reduce barriers to care and digital wallets with the potential to pass rebates directly to patients at the point of sale.

- Global commercial access partnerships with organizations like Gavi, the Vaccine Alliance, where we've agreed to supply up to 930 million doses of pneumococcal conjugate vaccine (PCV) through 2027 at its lowest access price. In 2022, Pfizer extended this work through a bid with UNICEF to supply Prevenar 13 to Gavi at its lowest access price.

We set the price of our medicines and vaccines guided by the value our products bring to patients and society, achieving the broadest possible access. Our goal is to create long-term solutions that take into consideration the environments and health systems in which we operate, using flexible payment models designed for differing markets. Pfizer has engaged in numerous outcomes-based agreements globally, with additional agreements in development. Alternatively, to achieve faster and broader access to our medicines, we have over 150 financial-based agreements currently implemented or in development in emerging markets. In the 2022 Access to Medicine Index, Pfizer ranked No. 6 overall, but led in the governance of access category for an integrated accessto-medicine strategy and board-level responsibility.

In 2022, we also launched an Accord for a Healthier World, which is focused on closing the health equity gap that persists between wealthy nations and many lower income countries. Alongside governments and multi-sector partners, Pfizer is working to co-create scalable, sustainable solutions to enable greater access to health care innovation for 1.2 billion people living in 45 lower-income countries around the world on a not-for-profit basis.