Position on COVID-19 and Intellectual Property Rights

Background

Since the start of the COVID pandemic, numerous proposals have been made in a variety of multilateral forums, particularly the World Trade Organization (WTO) and the World Health Organization (WHO), that would limit or eliminate intellectual property (IP) rights for products related to COVID-19. These proposals have expanded to include potential restrictions on IP rights for future pandemics. Discussions on these proposals are ongoing.

Our Position

Executive Summary

Acting with urgency at the onset of COVID-19, Johnson & Johnson galvanized resources to help halt the pandemic through developing an easy-to-deploy vaccine, obtaining regulatory authorizations, building supply chain capabilities and engaging with partners around the world to support health systems and healthcare providers involved in combatting COVID-19. Information on our activities follows.

- Johnson & Johnson worked with urgency to advance a vaccine for COVID-19 that served populations globally, with special consideration given to some of the most vulnerable communities. Johnson & Johnson developed a vaccine that could be stored and shipped around the world through standard vaccine distribution channels, and to date has shipped over 85% of the Company's vaccine doses to low- and middle-income countries (LMICs). As part of our commitment to global access, we offered our vaccine at a single, non-profit global price during the pandemic period.
- To scale up global production of our single-dose COVID-19 vaccine, we also forged new voluntary manufacturing partnerships across four continents.
- We believe that voluntary technology transfers with carefully selected partners is the most practical, efficient and effective way to expand the global production and ensure the safety of COVID-19 vaccines and treatments. Our actions included the following:
    - We leveraged 15 years of R&D investments in the Janssen vaccine platform to swiftly develop our single-dose COVID-19 vaccine.
    - To expand our global manufacturing network and increase our capacity to deliver the highest-quality COVID-19 vaccine on a global scale, we entered into multiple manufacturing agreements.
    - Our agreements with contract manufacturing organizations (CMOs) provided a license to our COVID-19 vaccine IP and included a technology transfer mechanism to facilitate the sharing of confidential manufacturing know-how, enabling each CMO to fulfill its manufacturing obligations in our global supply network.

- Limiting IP will not increase global access to vaccines or treatments. To the contrary, a strong global IP framework facilitates the rapid development of voluntary partnerships with organizations that have the capabilities to deliver safe and effective vaccines. The rapid entry of multiple inexperienced manufacturers and production sites unable to manufacture at sufficient scale can strain existing supply chains, equipment, materials and personnel, and could undermine consumer safety.
- Johnson & Johnson delivered more than 268 million COVID-19 vaccines in 2022, with more than 85% launch-to-date shipped to low- and middle-income countries. In fact, when abundant vaccine supplies became available in 2022, challenges emerged such as the ability of low-income countries to absorb and administer available vaccine doses and turn vaccines into vaccinations. In many low- and middle-income countries we worked closely with supranational agencies, governments and non-governmental organizations to help strengthen national health systems and infrastructure, overcome vaccine hesitancy and help improve immunization rates.

Mobilizing Against COVID-19

The pandemic has been extremely sobering for everyone, including the staff and partners of Johnson & Johnson. The massive human toll affected everyone in some way. Yet, our more than 140,000 employees around the world mobilized with urgency to develop a vaccine that could address the critical needs of families, communities and healthcare providers globally.

Starting in January 2020, we:

- Conducted an intensive evaluation of vaccine candidates culminating in the selection of a lead candidate for a single-dose regimen;
- Launched multiple Phase 1, 2 and 3 clinical studies, including ENSEMBLE, our large-scale, pivotal Phase 3 clinical trial;
- Gathered, analyzed and released topline Phase 3 interim efficacy results;
- Filed for and received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), and achieved emergency or conditional authorization for use of our COVID-19 vaccine in more than 80 countries around the world; and
- From the beginning, we identified new and impactful ways to optimize clinical trials, reach diverse communities, and ensure appropriate representation from all populations in our research.

Manufacturing the Vaccine

We believe that conducting voluntary technology transfers with carefully vetted partners is the most practical, efficient and effective way to complement vaccine manufacturing capabilities and expand global production of vaccines and treatments.

- Bringing forward a safe, effective and accessible vaccine was at the forefront of our pandemic response from day one.
- We developed our COVID-19 vaccine to be easily transported and stored using standard refrigeration.

Johnson & Johnson delivered more than 268 million COVID-19 vaccines in 2022, with more than 85% launch-to-date shipped to low- and middle-income countries. For our COVID-19 vaccine, we assessed nearly 100 different potential production sites around the world to identify Contract Manufacturing Organizations (CMOs) with the experience, infrastructure and ability to produce safe, effective, high-quality vaccines at a volume that would meaningfully assist us in meeting global demand. We also set up a network that spanned manufacturing sites in the U.S., India, South Africa and Europe. Our agreements with these CMOs provided a

license to our COVID-19 vaccine IP and included a technology transfer mechanism to facilitate the sharing of confidential manufacturing know-how, to enable each CMO to fulfill its manufacturing obligations in our global supply network.

It is important to recognize that the production of vaccines is a highly complex process that requires very particular capabilities and expertise. For Johnson & Johnson, this includes managing biologic products and processes, a vast array of consumables (raw materials that are used or consumed in the production process and need to be repeatedly reacquired) and end-to-end sterile production.

For example, production of the Johnson & Johnson COVID-19 vaccine requires more than 160 different materials sourced from numerous suppliers based across multiple countries. When we account for the varying customization and equipment needed at each of our CMO sites, our vaccine required approximately 600 different materials across our entire production network. Consequently, when we work with new partners, their existing manufacturing technology needs to be adapted; in turn, we support key suppliers as they expand their capacity to produce the materials we need.

Additionally, increasing supply is not just about hardware and materials. Vaccine production is an intensely high-tech process, and experienced professionals with expertise in biotech production are imperative. We have teams of highly trained Johnson & Johnson employees at each manufacturing site in our global supply chain network validating production processes, verifying quality assurance protocols, and supervising the production scale-up process.

Typically, transferring our technology externally is a process requiring at least 24 months. We worked to complete these transfers for our COVID-19 vaccine—while maintaining the same good manufacturing practices and quality controls—in just six months.

Importance of IP

Every step of the way, Johnson & Johnson's response to COVID-19 has been enabled by IP. We simply would not have a vaccine without a reliable IP framework; nor would we be able to scale up production.

Our ability to effectively respond to COVID-19 and potential future pandemics relies on years of investments in science and research supported by the IP system. For example, we leveraged 15 years of R&D investments to develop our single-dose COVID-19 vaccine in just over a year. IP also enabled us to scale up global manufacturing. Without the integrity and legal certainty of the IP system, we could not have entered into contractual relationships to establish our global manufacturing network.

We were the first major vaccine manufacturer to transfer our COVID-19 vaccine technology to an African manufacturer, Aspen SA Operations (Pty) Ltd, based in South Africa. In an expansion of our existing partnership, in March 2022 we announced the completion of a landmark agreement with Aspen to enable the first COVID-19 vaccine to be manufactured and made available by an African company for people living in Africa, with the goal of increasing COVID-19 vaccination rates across the continent. The agreement enables Aspen, using COVID-19 vaccine drug substance supplied by Johnson & Johnson, to produce Aspen-branded finished vaccine and make doses available to the public sector in Africa, including all 55 Member States of the African Union and key multilateral entities supporting Africa's COVID-19 vaccination drive, inclusive of the African Vaccine Acquisition Trust (AVAT), and the COVAX Facility.

IP is not a barrier to the development of, or access to, pandemic treatments and vaccines. To the contrary, IP is essential to the rapid development of innovative solutions and global partnerships to address this crisis and future infectious disease threats.

Productive Solutions

Proposed restrictions on IP will not accelerate access to diagnostics, vaccines or treatment. In the same way that giving the wrong medicine will not cure the patient and could worsen the disease, the wrong policy response could inadvertently inhibit our ability to address the global access challenge. Countries granting licenses to sites with very limited capacity, or to unqualified or unprepared firms, can divert critical raw materials, weaken already strained supply chains, and potentially lead to fewer, inferior or even counterfeit or unsafe products.

The fundamental barriers to expanding global vaccine manufacturing capacity during the COVID pandemic were unrelated to IP. Limited availability of bioreactors for production globally, supply chain constraints with regard to consumable raw materials (such as biobags and filters) and a shortage in highly trained manufacturing professionals all contributed to vaccine constraints. These challenges would not have been resolved, and instead would likely have been exacerbated, by undermining IP rights.

We recognize that the challenge of implementing vaccination campaigns in pandemic situations is highly complex, encompassing structural issues in resource-limited settings such as a lack of cold storage capabilities and a shortage of healthcare professionals available to administer shots. All stakeholders involved, including manufacturers, supranational agencies, governments and NGOs need to work in close collaboration to strengthen national health systems and infrastructure to expedite vaccine deployments. Johnson & Johnson assessed various initiatives being pursued by governments and NGOs to support COVID-19 vaccine delivery, to identify where we could effectively complement and contribute to existing efforts. Based on this, we engaged in a number of initiatives to address vaccine absorption challenges in three areas: supply chain and distribution, in-country cold chain capacity, and vaccine confidence.

Looking at the long-term and sustainable functioning of the global supply chain for diagnostics, vaccines and treatment for pandemic use, we encourage governments to focus on the following policies and solutions:

- Governments can help ensure **essential supplies and equipment flow freely across national borders** to allow manufacturing plants to operate at maximum capacity and speed without disruption or slowdown. During the pandemic, we saw multiple impediments on the free flow of critical material, equipment and personnel for vaccine production. These created major delays in the manufacturing process and supply chain—not just for Johnson & Johnson, but for the entire vaccines industry. We ask that governments resist protectionist policies such as export controls and restrictions.
- Conversely, governments can put in place **initiatives that expedite the free movement of goods**. Relatively simple interventions such as establishing expedited customs procedures and shipping green lanes can allow greater quantities of vaccine to reach more people more rapidly.
- This pandemic has shown that developed nations can also positively impact health and humanitarian crises by increasing **technical and financial support to countries in need**, both bilaterally and through multilateral organizations. It is critical to support developing nations in improving their healthcare infrastructure so that vaccine doses can be translated into vaccinations going into arms.
- Efforts to support **global regulatory harmonization** are needed. Currently, the process of getting vaccine doses to different countries is highly complex because countries frequently have different

labeling requirements, which complicates efforts to rapidly share vaccine doses between regions and countries.

Johnson & Johnson is committed to helping the global community address this and potential future pandemics. We believe IP is critical to responding to this crisis and to future health emergencies. Working collaboratively with other manufacturers, governments and international organizations, we can achieve the goal of ensuring that lifesaving diagnostics, vaccines and treatment are made available to everyone at risk during a pandemic.

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