Position on COVID-19 and Intellectual Property Rights

Background

India and South Africa, supported by a number of other countries, have submitted a proposal to the World Trade Organization (WTO) that would essentially eliminate intellectual property (IP) rights for all "health products and technologies … for the prevention, treatment or containment of COVID-19." The United States government has indicated support for a narrower temporary waiver of IP rights for vaccines only. By contrast, WTO members including the European Union (EU), Switzerland, the United Kingdom and South Korea have opposed these waiver proposals, arguing that IP is not a barrier to equitable vaccine access. The EU has proposed instead that WTO members align to open supply chains by facilitating trade and limiting export restrictions, and to expand vaccine production through voluntary license mechanisms and investment in manufacturing capacity, particularly in developing countries.

Our Position

Executive Summary

- Johnson & Johnson fully recognizes the urgency of the COVID-19 pandemic, which is why we mobilized across our Company to swiftly develop a COVID-19 vaccine. We remain dedicated to enabling equitable global access to our vaccine and have committed to make available up to 900 million vaccine doses to the global COVAX initiative and the African Union combined, through 2022. We have also forged new manufacturing partnerships across four continents to scale up global production of our single-dose COVID-19 vaccine.
- We believe that voluntary technology transfers between vaccine manufacturers and carefully selected partners is the most practical, efficient and effective way to expand the global production of COVID-19 vaccines.
- At every step of the way, Johnson & Johnson's response to COVID-19 has been enabled by IP. We simply would not have a vaccine, nor would we be able to scale up production, without a reliable IP framework.
    - 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 have entered into multiple manufacturing agreements, including in India and South Africa.
    - Our agreements with each of these contract manufacturing organizations (CMOs) provide a license to our COVID-19 vaccine IP, and include 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.

- Making IP available to additional manufacturers in an arbitrary and blanket fashion will not shorten the time it takes to get a vaccine to market. To the contrary, the rapid entry of multiple inexperienced manufacturers and production sites unable to manufacture at sufficient scale would further strain existing supply chains, and it could potentially undermine consumer safety.
- In our view, the international community should focus on the following practical solutions:
    - Allow finished vaccines and vaccine components and supplies to **flow freely across national borders**, and explore initiatives to expedite the free movement of goods;
    - Expand vaccine **dose-sharing initiatives** to support countries in need;
    - Provide **technical and financial support** to countries, bilaterally and through COVAX; and
    - Support efforts to improve **global regulatory harmonization.**

Mobilizing Against COVID-19

The pandemic has been extremely sobering for everyone, including the staff and partners of Johnson & Johnson. The situation remains dire in many countries and the massive human toll affects everyone in some way. Yet, our more than 130,000 employees around the world have mobilized with urgency to 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; and
- 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.

We are now shipping our vaccine globally under the terms of our purchase agreements with governments.

Manufacturing the Vaccine

We believe that conducting voluntary technology transfers with carefully vetted partners is the most practical, efficient and effective way to complement our own vaccine manufacturing capabilities and expand global production of our COVID-19 vaccine.

To date, we assessed nearly 100 different potential production sites around the world to identify CMOs with the experience and ability to produce safe, effective and high-quality vaccines at a volume that will meaningfully assist us in meeting global demand. We now have a global network that spans 10 manufacturing sites including partners in the U.S., India, South Africa and Europe. Our agreements with these CMOs provide a license to our COVID-19 vaccine IP, and include 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.

While we are making progress on an unprecedented timeframe, it is important to recognize that the production of our vaccine is a highly complex process that requires very particular capabilities and expertise. It is a common misconception that vaccines can be as quickly and easily mass-produced as small-molecule medicines. In fact, with vaccines, we are 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 the need to maintain end-to-end sterile production.

For example, production of the Johnson & Johnson COVID-19 vaccine requires approximately 200 materials sourced from 67 suppliers that are based across 12 countries. When we account for the varying customization and equipment needs at each of our CMO sites, our vaccine requires approximately 600 different materials across our entire production network. Therefore, 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.

Together with our CMOs, we are addressing these challenges in a collaborative, systematic and efficient manner, working with great urgency to address the global need. Typically, transferring our technology externally is a process requiring at least 24 months. We are now striving to complete these transfers—while maintaining the same good manufacturing practices and quality controls—in just six months.

Importance of IP

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

Our ability to effectively respond to the COVID-19 pandemic is built on years of science and research supported by the IP system. For example, we leveraged 15 years of R&D investments in the Janssen vaccine platform 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.

In our experience, IP is not a barrier to the development of, or access to, COVID-19 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

The proposed IP waiver will not accelerate access to vaccines. 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 vaccine manufacturing challenge. Countries granting vaccine licenses to sites with very limited capacity, or to unqualified or unprepared firms, is likely to result in the diversion and hoarding of critical raw materials, weaken already strained supply chains, and potentially lead to fewer, inferior or even counterfeit or unsafe vaccines.

The fundamental barriers to expanding global vaccine manufacturing capacity have nothing to do with IP. Instead, 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 contribute to vaccine constraints. These challenges will not be resolved, and instead will likely be exacerbated by undermining IP rights.

It should also be noted that global manufacturing capacity for COVID-19 vaccines is coming online with unprecedented speed. Recent independent estimates indicate that total supply capacity for COVID-19 vaccines may reach 12 billion doses by the end of 2021.[1] It is possible that vaccine supply could outpace the ability of countries to absorb and distribute vaccines, thereby creating excess capacity.

We therefore encourage global leaders to focus on the policies and solutions that can best address short-term challenges in the vaccine supply chain:

- Governments can help ensure **essential supplies and equipment flow freely across national borders** to allow manufacturing plants to operate at maximum capacity without disruption or slowdown. Right now, we are seeing multiple impediments on the free flow of critical material, equipment and personnel for vaccine production. These create 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 explore **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.
- **Vaccine dose sharing** is critical for governments to support equitable global access to COVID-19 vaccines. We strongly support initiatives designed to ensure lifesaving COVID-19 vaccines can be redirected to where public health needs are most pressing. Governments should urgently reach out to Johnson & Johnson and other manufacturers to jointly develop dose-sharing plans that are logistically sound, protect consumer safety, and satisfy legal and regulatory requirements.
- Developed nations can also positively impact this health and humanitarian crisis by increasing **technical and financial support to countries in need**, both bilaterally and through multilateral organizations such as COVAX. It is critical to support developing nations in improving their healthcare infrastructure and vaccine education efforts so that vaccine doses can be translated into *vaccinations* going into arms.
- Efforts to support **global regulatory harmonization** are welcome. Currently, the process of getting vaccine doses to different countries is highly complex because countries frequently have different labeling requirements. For example, Johnson & Johnson has three different product labels for our COVID-19 vaccine based on the authorizations received from different regulatory bodies, which complicates efforts to rapidly share vaccine doses between regions and countries.

Johnson & Johnson is committed to helping the global community end this pandemic. We believe IP is critical to respond to this crisis and future health emergencies. Working collaboratively with other manufacturers, governments and international organizations, we can achieve the goal of ensuring that lifesaving vaccines are made available to everyone at risk for COVID-19.

Last Updated: October 2021

[1] IFPMA, based on Airfinity proprietary data analysis. Press release: "Momentum of COVID-19 vaccine manufacturing scale up sufficient for step change in distribution." September 7, 2021. Available here.