EUROPEAN COMMISSION

Cabinet of Executive Vice-President Valdis Dombrovskis
**Head of Cabinet**

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Mr Dimitri Eynikel
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Médecins Sans Frontières
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Dear Mr Eynikel,

Thank you for your letter of 9 October 2020, in which you seek the support of the European Commission for the proposal submitted by South Africa and India to the WTO TRIPS Council regarding a waiver from certain provisions under the Agreement on Trade-Related Aspects of Intellectual Property Rights (the 'TRIPS Agreement') in relation to the prevention, containment or treatment of COVID-19.

I fully share your concerns about the devastating impact of the COVID-19 pandemic on people's health, well-being and economic prosperity, here in Europe and globally. Safe and effective diagnostics, treatments and vaccines are crucial in the fight against COVID-19. In a global pandemic only broad and equitable access to vaccines across the globe will ensure that the public health crisis can be tackled effectively, including in developing countries that have no production capacities or more limited financial resources. We need to find solutions for everyone, whether in developed or developing countries, because it is a challenge we face together and because no one is safe until everyone is safe.

The European Commission has therefore taken a leading role in the Global Coronavirus Response where so far nearly EUR 16 billion have been pledged for universal access to tests, treatments and vaccines against COVID-19 and for the global recovery.

Let me assure you that the European Commission fully supports the ground-breaking and innovative cooperation under the Access to COVID Tools Accelerator (ACT-A), to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines. The EU Health Commissioner, Ms Stella Kyriakides, is our representative in the recently established Facilitation Council that will advise and further promote the activities of the ACT-A.

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In this regard, it is very important to ensure and preserve the necessary incentives to develop innovative solutions and technologies that will be critical to overcome the ongoing pandemic. Researchers and pharmaceutical industry, supported by public funding, have put extraordinary efforts into the development of future treatments and vaccines against COVID-19. The intellectual property rights (IPR) system is crucial to ensure that these efforts are adequately incentivised and rewarded.

There is no indication that IPR issues have been a genuine barrier as regards COVID-19-related medicines and technologies. The fact that isolated examples of shortages in supply that occurred at the early stages of the pandemic, such as the one concerning testing kit reagents in the Netherlands, have been resolved, indicates that the IPR system is fit for purpose and provides the necessary solutions. Making sure that there is a continued supply of medicines and technologies related to COVID-19 is a difficult task. However, inefficient and underfunded healthcare and procurement systems, spikes in demand and lack of manufacturing capacity or materials are much more likely to have an impact on the access to those medicines and technologies than IPR.

A well-functioning IPR system, including its wide range of exceptions and flexibilities, is part of the solution, not an obstacle. In our response to COVID-19 we must concentrate on the key current challenges: (i) rapidly developing safe and effective treatment or vaccine against COVID-19, (ii) increasing manufacturing capacity, (iii) keeping global supply chains open, and (iv) ensuring broad and equitable global distribution of treatments and vaccines once they become available.

The absolute priority and a major challenge now is the rapid development and rolling out of safe and effective treatments and vaccines against COVID-19. Vaccine development is a complex and lengthy process, which normally takes around 10 years. The public funding and support is contributing significantly to accelerating the development of the future vaccines. However, it is the researchers and the industry with their know-how and investment that will be delivering these new vaccines. This include the running of clinical trials in parallel with investing in production capacity to be able to produce millions, or even billions, of doses of a successful vaccine.

Public financing of research and development of the innovative treatments and vaccines can be subject to certain conditions. For example, the European Commission has published a Manifesto for EU COVID-19 research to encourage recipients of EU funding to make research results accessible to all. Recent Horizon 2020 COVID-19 calls have also included a temporary obligation to license results on a non-exclusive basis and at fair and reasonable conditions.

Once the treatment or the vaccine is available, the manufacturing of these treatments and vaccines at an unprecedented scale and within an unprecedented timeline is likely to be the most problematic issue to be tackled. We should collaborate and assist the pharmaceutical sector in ramping up the manufacturing capacity. To tackle current and future supply side shortages, the European Commission has signed and continues discussing further advance purchasing agreements that enable and incentivise the pharmaceutical sector to build and prepare large-scale production facilities once effective treatments and vaccines become available.

Being aware of the importance of the global supply chains in the pharmaceutical sector, the EU is discussing with some WTO partners a possible WTO 'trade and health' initiative with the aim to facilitate global access to affordable healthcare products, including for vulnerable countries without appropriate manufacturing capacities. The

goal is to make supply chains more resilient and diversified and to support efforts to build strategic reserves of critical equipment. This initiative would cover issues such as establishing a scheme of global cooperation in times of health crisis in order to remove unnecessary barriers to trade, abolishing tariffs on pharmaceutical and medical goods, enhanced transparency and trade facilitating measures.

Finally, global collaboration is the only way to overcome a global pandemic. At present, international efforts are being made to ensure equitable distribution of affordable vaccines, in particular to the most vulnerable populations. In addition to leading the Global Coronavirus Response and supporting the Access to COVID Tools Accelerator (ACT-A), in collaboration with the WHO, the European Commission is actively supporting the vaccine pillar of ACT-A – the COVAX Facility. In September, the European Commission announced that it would fully participate in the COVAX Facility for equitable access to affordable COVID-19 vaccines everywhere, for everyone who needs them. As part of a Team Europe effort, the Commission contributes EUR 400 million in guarantees to support COVAX and its objectives in the context of the Coronavirus Global Response.

We make our voice heard in multilateral cooperation and will advocate to close the gaps in pandemic preparedness so that we are globally better prepared at the level of G20 and of the United Nations. In that regard, I welcome the adoption on 18 May 2020 of the COVID-19 Resolution of the World Health Assembly on which the European Union took a leading role, the Omnibus resolution on the Comprehensive and Coordinated Response to the COVID-19 Pandemic by the UN General Assembly on 11 September 2020 and on 17 September the G20 Joint Declaration of Finance and Health Ministers on COVID-19.

The TRIPS Agreement together with the principles endorsed in the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001 ("Doha Declaration"), allows for the necessary flexibilities in relation to IPR protection, including in the case of a health emergency, such as the COVID-19 pandemic. If voluntary solutions failed and IPR became a barrier to treatments or vaccines against COVID-19, mechanisms to address this are already available. The EU has consistently supported the use, where necessary and justified, of the flexibilities provided under the TRIPS Agreement and the Doha Declaration with the objective of ensuring effective access to medicines.

In particular, the TRIPS Agreement provides for the possibility, under certain conditions, to issue compulsory licenses, i.e. a government's authority to grant permission to a party seeking use of a patented invention without the consent of the patent owner. The procedure can be fast-tracked in case of a national emergency. Article 31bis of the TRIPS Agreement provides for a possibility of exporting the needed pharmaceutical products on the basis of a compulsory license to countries having insufficient manufacturing capacities. The TRIPS Council Secretariat has offered its services to any WTO Member that sees itself in the need of getting help to manage the process of Article 31bis. This system is accompanied by other inbuilt TRIPS flexibilities, applying to the various IPR. In addition, least developed countries (LDCs) are not under obligation to implement the TRIPS Agreement until July 2021. The European Union, during the last session of the TRIPS Council, has supported further extension of the transitional period for the application of the TRIPS Agreement by the LDCs.We also note that the LDCs are specifically exempted from implementing the provisions relating to pharmaceutical products until 2033.

Public health in light of the pandemic is a clear and undisputed priority. No effort must be spared to obtain safe, effective and affordable treatments, vaccines, tests and medical

devices necessary to fight this pandemic and to ensure that these products are equitably distributed on a global scale. However, all these efforts must be geared towards addressing genuine challenges in this pandemic with appropriate solutions. The proposal of South Africa and India to pre-emptively waive significant parts of the TRIPS Agreement would not, in our view, address the actual challenges of the pandemic and therefore we cannot endorse it.

The availability of an effective and universally available vaccine against COVID-19 will surely mark the turning point in overcoming this global crisis. We need to keep the momentum and join our efforts to end COVID-19.

Yours sincerely,

Michael Hager