**South Africa Statements at TRIPS Council Meeting on 16th October 2020**

**First Intervention**

**15 PROPOSAL FOR A WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19**

Thank you Chair for giving us the floor, as you indicated I have the honor to introduce this proposal on behalf of the delegations of Eswatini, India, Kenya and South Africa.

The COVID-19 pandemic is a clarion call for us to answer to the better angels of our nature. High-minded language on solidarity and global public goods however, has not been matched by tangible steps to share know-how and intellectual property rights to facilitate deep technology transfer in the COVID-19 response. Business as usual approaches will not bring back the countless lives that were lost, neither will it ensure that IP barriers to the prevention, containment and treatment of COVID-19 will be addressed effectively.

We have seen this before. At the height of the HIV crisis, prices set for ARVs to treat HIV were simply too high and out of reach for many developing countries. As death rates due to aids plunged in rich countries, infected people across the developing world were left to die

Our leaders vowed that is would never happen again, the Doha Declaration on TRIPS and Public Health reaffirmed flexibilities to accommodate access to medicines. Even in light of this political undertaking and its translation into the paragraph 6 system, prices of many life-saving diagnostics, therapeutics, vaccines and other medical products remain out of reach of most governments and its people.

In 2004 the highly pathogenic avian influenza H5N1 re-emerged, developed countries had priority access, while affected developing countries did not. Within 5 years another pandemic flu (H1N1) emerged and once again rich countries placed large pre-orders of a vaccine buying almost all doses that could possibly be manufactured. Many countries promised to donate vaccines, most of them reneged and moved to secure their own countries’ supply. With COVID-19 history is repeating itself.

Several months into this pandemic there are no meaningful global policy solutions to ensure access. Given this present context of global emergency, it is important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19.

All WTO Members are struggling to contain the spread of the pandemic and provide health care services to those affected. Many developed, developing and least developed countries have declared a national emergency with the aim to curb the growing outbreak, and as advised by the WHO implemented social distancing measures with significant consequences for society and the economy. Notably, developing countries and least developed countries are especially disproportionately impacted.

Madam Chair,

An effective response to COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need. Shortages of these products has put the lives of health and other essential workers at risk and led to many avoidable deaths. It is also threatening to prolong the COVID-19 pandemic. The longer the current global crisis persist, the greater the socio-economic fallout, making it imperative and urgent to collaborate internationally to rapidly contain the outbreak. As new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable price to meet global demand. Critical shortages in medical products have also put at grave risk patients suffering from other communicable and non-communicable diseases. The rapid scaling up of manufacturing globally is an obvious crucial solution to address the timely availability and affordability of medical products to all countries in need. The emerging second wave of the disease underscores the importance to finding global solutions that ensure equitable access.

There are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients. It is also reported that some WTO Members have carried out urgent legal amendments to their national patent laws to expedite the process of issuing compulsory/government use licenses, as evidenced by the updated Secretariat report on national measures taken by WTO Members. Beyond patents, other intellectual property rights may also pose a barrier, with limited options to overcome those barriers. In addition, many countries especially developing countries may face institutional and legal difficulties when using flexibilities available in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). A particular concern for countries with insufficient or no manufacturing capacity are the requirements of Article 31*bis* and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products.

Madam Chair,

Internationally, there is an urgent call for global solidarity, and the unhindered global sharing of technology and know-how in order that rapid responses for the handling of COVID-19 can be put in place on a real time basis. Our joint proposal requests a waiver to be granted to all WTO Members so that they do not have to implement, apply or enforce certain obligations related to COVID-19 products and technologies under Section 1 (copyrights and related rights), 4 (industrial design), 5 (patents) and 7 (protection of undisclosed information) of Part II of the TRIPS Agreement. Let me stress that the proposed waiver would be applicable only to COVID-19. The waiver is limited and does not suggest a waiver from all possible TRIPS obligations, nor does it suggest a waiver beyond what is needed for COVID-19 prevention, containment and treatment.

The waiver should continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity hence we propose an initial duration of [X] years from the date of the adoption of the waiver.

**Second intervention**

**Response to questions and issues raised by Members who took the floor.**

Madam Chair,

It has been exactly three hours since the last time I took the floor, good evening colleagues. It has been a marathon session with many interventions and discussion.

The Cosponsors would like to thank all Members and observers that had intervened. We have heard many concerns raised by Members that intervened. Given the time constraints, the Cosponsors would like to respond to some of the general elements that have emerged out of today’s discussion. There are more direct questions posed by delegation that could be answered at a later stage and we will reach out to delegations concerned.

We want to stress that the protection and enforcement of intellectual property are not absolute, Article 8 of the TRIPS Agreement recognises that countries may adopt necessary measures to protect public health. COVID-19 constitutes an unimaginable global pandemic which requires swift and bold action. COVID-19 is far from over and there is no certainty as to when effective vaccines will be available in sufficient quantities to ensure equitable access. COVID-19 is here to stay, as the EU pointed out in their intervention, vaccines take up to 10 year to develop.

We explained the rationale for our proposal and believe that our proposal demonstrates the existence of exceptional circumstance that justifies our request for a waiver decision, clear terms and conditions governing the application of the waiver.

The Waiver does not imply any change of the substantive treaty obligations; it only temporarily suspends their operation for a period to be agreed by Members and thus will be time-bound. It has a clearly defined scope related to the implementation, application and enforcement of Sections 1 (Copyright), 4 (Industrial Designs), 5 (Patents), and 7 (Protection of Undisclosed Information) of Part II of the TRIPS Agreement which are aspects critical to the diagnosis, prevention, containment and treatment of COVID-19.

We further clarified that the date on which the waiver will continue to apply until widespread vaccination is in place globally, and the majority of the world's population has developed immunity hence we propose an initial duration of [X] years from the date of the adoption of the waiver. This period can be negotiated.

Madam Chair,

**We heard the refrain from the EU and others that the TRIPS Agreement is fit for purpose and its flexibilities are usable without limitation or any problem? We once again contest this this notion.**

Delegations that have taken the floor to condemn this waiver proposal claim that that TRIPs flexibilities already include the option to issue compulsory licenses where necessary.

The proposal for a waiver on certain IP provisions offers an expedited, open and automatic global solution that allows for uninterrupted collaboration in development and scale up of production and supply and that collectively addresses the global challenge facing all countries. Countries should continue to use TRIPS flexibilities to safeguard public health, including issuing compulsory licenses and placing limitations on or making exceptions to exclusive rights.

However, the “case by case” or “product by product” approach required when using flexibilities to address IP barriers at the national level could be limiting during the pandemic. Some countries also face limitations with respect to their national laws, pressures from their trading partners, or lack the practical and institutional capacity required to exercise TRIPS flexibilities during the pandemic quickly and effectively. The existing mechanisms for compulsory licenses under Article31 and Article 31bis of the TRIPS Agreement contain territorial and procedural restrictions that make the practice of issuing product-by-product compulsory licenses a complex process, making it difficult for countries to collaborate. Article 31 requires that compulsory licenses are issued on a case-by-case basis and used predominantly to supply domestic markets, thereby limiting the ability of manufacturing countries to export to countries in need.

Article 31bis requires that any product produced and exported under a compulsory license be identified with specific packaging and quantities, which can lead to unnecessary delays in the context of COVID-19 where countries need urgent access to medical tools. There is even less experience in areas such as industrial designs, trade secrets, algorithms and copyright, applying compulsory licenses to such areas may be legally complicated and novel.

Political pressure from two delegations that oppose the waiver proposal have taken action to ensure that countries do not use compulsory licenses, for example:

* **EU IP enforcement report 2020**, issued right before the COVID19 pandemic, put a number of developing countries, including India, Indonesia, Turkey, Ecuador, under the spotlight of criticism for their laws allowing the use of compulsory license if patent holding companies do not fulfil the obligation of supporting production of medicines locally;
* **USTR 2020 Special 301nreport**, issued right in the middle of the COVID19 pandemic, continue to condemn countries who improve their laws on compulsory license or make use of compulsory license – countries specifically pressured for their law or their use of compulsory license include Chile, Indonesia, Colombia, Egypt, India, Malaysia, Russia, Turkey, Ukraine, El Salvador.

Madam Chair,

**Voluntary Licenses are somehow touted as the solution for COVID-19!**

IP rights can be exercised by their owners to decide on whether to grant a license or withhold from licensing the technology, designs and knowhow required for manufacturing or for further developing the products required for COVID-19. By enforcing exclusive rights backed by IP, such as patents, pharmaceutical companies slow down research and innovation. The use of restrictive voluntary license terms limits the catching up and innovation made by generic competitors.

Nine months into the pandemic voluntary approaches have proven to be insufficient. For instance, despite receiving significant public funding of at least US$70.5 million, Gilead has signed secretive bilateral licenses for Remdesivir (a therapeutic for COVID-19 treatment) with a few generic companies of it choosing that excludes nearly half of the world’s population from its licensed territories. Much of Gilead’s supply has also been reserved for very rich nations. As a result, to date, most developing countries have barely received any supply of Remdesivir. The prices of Remdesivir are also prohibitively high.

On the other hand, to date not a single company has committed to the voluntary Covid-19 Technology Access Pool of WHO.

In cases where companies have made such commitments to issue voluntary licenses, the lack of transparency of license agreements for products to treat COVID-19 is substantial.These initiatives are ad hoc and are not a sustainable way of addressing IP barriers.

While such companies can limit the production, quantity and export of products produced under license to certain geographical areas thereby excluding large parts of the world population. Nonprofit undertakings are time bound, while such companies will decide when they think the pandemic is over.

If we are serious to address access issues, production cannot be concentrated in the hands of only a few manufacturers, in order to scale up production, governments have a critical role to play.

Madame Chair,

**Various Members have asserted that the waiver proposal will impede innovation and that it is improper and ill-conceived on the side of the Cosponsor to bring a waiver proposal at this critical time.**

Never has there been a weaker case for the granting of monopolies.  Governments have been funding the development of COVID drugs and vaccines, and no company is able to meet the global demand. In the context of COVID-19, despite the billions of tax payer dollars invested in R&D, and announcements that COVID-19 vaccines should be considered a public good, no government has openly stated committed to this undertaking.

Monopoly-based and market-driven R&D in biomedical sector ignores unmet health needs - no new medicine was developed for more than 40 years on TB; no effective R&D in addressing antimicrobial resistance (AMR) despite of the constant increasing of number of IP – patents granted in pharmaceutical sector globally for zero value add.

The R&D of drugs is often a joint multi-stakeholder effort, benefitting from significant amounts of public taxpayer money. For COVID-19, the search for an effective treatment or vaccine is a global effort involving by multiple actors – it is not the result of the pharmaceutical industry’s efforts alone. Governments and public funding agencies around the world have poured billions of US dollars of public money to support COVID-19 R&D, especially for drugs and vaccines. However, by and large no conditions for access or affordability have been included as a precondition to any of that funding. Governments must attach strings to any public money given for COVID-19 medical tools to guarantee that, if they prove safe and effective, they are available to everyone. Today some Members have admitted that some conditions had been set on companies, but none of it goes far enough to ensure that IP rights assigned to companies benefiting from taxpayer money do not abuse such rights down the line.

Madam Chair

**It was professed by Members that voluntary cooperative approaches will solve the COVID-19 crisis through generous pledges to multi-stakeholder collaborative platforms. We thank the EU and other delegations for their generous support for these initiatives, including the donation of vaccines and access to COVAX-facility to cooperate in the purchase of future vaccines for the benefit of vulnerable countries.**

* The Cosponsors agree that global cooperation and collaboration is key to addressing the COVID-19 pandemic, initiatives such as the COVAX facility are helpful but insufficient. Our waiver proposal is designed to work synergistically with such initiatives by enabling the rapid scaling of production by multiple producers across many countries, enabling the sharing of knowledge and transfer of technology with the aim of addressing the pandemic

* COVAX at best provides very short-term, limited access to vaccines. Its approach is not sustainable in the medium and long term. The global needs are massive and can only be addressed with global sharing of technology, knowledge and related IP. Not by artificially limiting competition and supply which in turn only results in high prices in the medium and long term.
* Notably wealthy nations representing just 13 percent of the world’s population have already cornered more than half (51 percent) of the promised doses of leading COVID-19 vaccine candidates[[1]](#footnote-1). This creates significant uncertainty for universal access.
  + The EU together with some other wealthier nations and regions, have already pre-booked more than 51% of the global supply capacity of the potential future COVID19 vaccines – leaving limited share for developing countries and least-developed countries to share. It is this conduct that has created huge uncertainty to the guarantee of universal access to COVID19 medical tools and products;
* Global equitable allocation and donation are separate issues from the waiver proposal that we put on the table.
* While some initiatives such as COVAX is aiming to address the initial shortage of supply of medical tools for COVID19 treatment and prevention, its effects can be limited due largely to the following factors:
  + The model and the conducts reinforce the deep inequality in the global health architecture and do not provide a sustainable solution;
  + Both the investment to COVAX and donation commitment cannot solve the issue of the need to diversify, to the maximum level the global capacity of development, manufacturing and supplying COVID19 medical tools;
  + COVID19 reveals the deep structural inequality in access to medicines globally, and one of the root causes is that IP sustains dominating industry’s interests at the cost of lives.

Madame Chair,

**We heard some Members saying that intellectual property is not a hindrance but a help to end COVID-19; …. Suspending key protections of the TRIPS Agreement would send the wrong message to industry investors.**

* Huge public funding has been poured into R&D for COVID-19 – more than 70 billion USD mostly from governments including many developing countries governments; it is taxpayers in different countries who have invested the COVID19 R&D;
* People around the world who are taking huge risk of joining in and supporting the unprecedented R&D process and clinical trials;
* The incentive for people to take substantial risks in supporting and joining clinical trials has nothing to do with IP, but the conscience and common sense of contributing to the finding of a cure for all
* Industry has asked governments to take over their liability and request for indemnity so that industry does not have to bear the risk but can make all the profit without much value add.

**We also heard that intellectual property has enabled collaboration between bio-pharmaceutical innovators and governments, universities and other research partners to speed up progress on our most pressing unmet medical needs, however the Cosponsors strongly contest this notion.**

* It is the pandemic – not IP – that has mobilized collaboration of multiple stakeholders.
* It is knowledge and skills held by scientists, researchers, public health experts and universities that have enabled the cross-country collaborations – not IP!
* It is public funding, again, facilitated these collaborations – not IP!

I will leave it here in the interest of time and as we indicated at the start of this intervention the cosponsors will reach out to other delegations to address more specific issues and questions that may have been raised.

**[Procedural Request]**

**Madam Chair,**

It is clear that Member have different opinions regarding the waiver proposal introduced at today’s TRIPS Council meeting, there is a need to discuss this proposal further. According to Article IX.3(b) a request for a waiver shall be submitted to the relevant Council for consideration during a period which shall not exceed 90 days. We request that this item remain open for discussion for the intervening period. This can be done on the basis suspending this item and reconvening the TRIPS Council formally or informally or through consultations that may be convened by you or a combination of both modalities.

**END**

1. https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19 [↑](#footnote-ref-1)