**South Africa’s Intervention at the formal TRIPS Council meeting of 10 December 2020.**

Madame Chair,

Thank you for giving us the floor, like others we would like to thank you for the report presented this morning as well as your efforts to facilitate discussions on the waiver proposal. At the informal meeting of 20 November and 3 December respectively, proponents reverted to questions posed by several delegations. We would like to ask that our responses during those meetings be made part of the record of today’s formal proceedings. Taken up in our intervention are some of crosscutting issues raised in document IP/C/W/671, which we will revert to in writing. Furthermore, I would like to thank all delegations that took the floor today. We have seen new members take the floor today who had not previously spoken, we are heartened by the level of engagement and welcome Bolivia to the ranks of the co-sponsors. Today some new issues arose from interventions, including questions from the delegation of Norway and Vietnam regarding possible modification of the scope of the waiver. The co-sponsors stand ready to discuss the scope of the waiver proposal. We welcome the United Kingdom’s statement regarding efforts to explore how products and technologies can be made available to the WHO C-TAP initiative. This is one of the avenues that our waiver supports in addition to all efforts to scale up production and access to COVID-19 products and technology. In the interim Madam Chair, there have also been noteworthy developments in policy guidance issued by the European Union through its IP action plan and pharmaceutical strategy which has direct bearing on our discussion in the TRIPS Council, which we will come back to later in our statement.

Those delegations opposing the waiver proposal have repeatedly suggested that voluntary approaches offer the best solution. As would have been emphasized, the TRIPS waiver proposal is supportive of any voluntary licenses issued by companies, however the terms of such licenses are often such that they may restrict access or reserve supply only for wealthy nations. Similarly, for vaccines, bilateral deals are being signed by pharmaceutical companies with specific governments but the details of these deals are mostly unknown. Usually these agreements are for manufacturing of limited amounts and solely supplying a country’s territory or a limited subset of countries. Ad hoc, non-transparent and unaccountable bilateral deals that artificially limit supply and competition cannot reliably deliver access during a global pandemic. These bilateral deals do not demonstrate global collaboration but rather reinforces “vaccine apartheid” and enlarges chasms of inequity. Disparity in access is certain to continue unless concrete steps are taken to address intellectual property barriers. If what the EU, the US and Japan is suggesting, namely that the IP system is responsible for delivery of vaccines in record time, it would fly in the face of the heroic efforts of ordinary people, researchers, scientists and government support and funding to enable this monumental feat. Not companies, but ordinary people have generously donated their skills and efforts to enable global collaboration by participating in vaccine trails, may in developing countries, putting their lives at risk for the greater good of mankind. Yet the irony does not escape us, these very people are denied priority access despite the enormous sacrifices they made.

Several questions were posed as to why the scope of the waiver extends to patents, trade secrets, copyright and industrial designs and what is the evidence that waiver of these aspects are important to contain, prevent and treat Covid-19. The co-sponsors presented elaborate answers during the last meeting.

Other questions were posed as to how the waiver would resolve issues related to Covid-19 prevention, containment and treatment and what is the evidence? Similarly, these were addressed during the last meeting. However, let me briefly recap our intervention on this point.

The co-sponsors have been asked which measures would fall within the scope of the waiver and whether measures that are indirectly related would also be included within the scope of the waiver and who would make this determination. We clarified that the issue is not whether a measure is directly related or indirectly related. It is a matter of what is needed to prevent, contain and treat Covid-19. Any measure that is not in relation to Covid-19 would not be covered by the scope of the Waiver. For instance, a therapeutic for cancer treatment would not fall within the scope of the waiver.The waiver proposal is very specific to Covid-19, its prevention, containment and treatment; and therefore, is proportionate. It does not apply to other diseases, although we are aware of severe access challenges in other disease areas as well. It does not apply to other sectors. We have also been particular in excluding protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement, although it falls within the ambit of copyright, as it would not be relevant to the prevention, containment and treatment of COVID19. The waiver proposal does not cover all aspects of the TRIPS Agreement, for example it does not include GIs, trademarks, layout of integrated circuits etc.

As a further clarification to and issue raised this morning about safety, quality counterfeit medicines, the Waiver request does not extend to trademark and “counterfeit trademark good” as defined in Article 51, footnote 14 of the TRIPS Agreement. And hence TRIPS provisions in relation to these continue to be applicable.

The grant of IP or being a IP holder does not provide any assurance that the protected subject matter is of a particular quality, efficacy of safety standard. Even originator products of multinational pharmaceutical companies have been recalled in the past for failing quality standards, therefore regulatory oversight is required. This shows that the grant of IP has nothing to do with quality.

All medical products marketed in a country has to obtain marketing authorisation from the national medicine regulatory agency which provides authorisation after proper quality checks. The issue of quality of a diagnostic, therapeutic or vaccine is determined by the national medicine regulatory authorities and not the IP system. At the international level, WHO has a member state mechanism that also looks at substandard and falsified medical products.

We urge WTO members not to confuse and conflate issues of quality of a product with issues of intellectual property of medical products. These are separate issues. In the past such conflation has led to seizure of quality generic medicines by the custom authorities such as at European ports, hindering inter alia international aid programmes and public health.

Some countries have queried why TRIPS flexibilities and Covax are insufficient to address the challenge of access posed by COVID. We have addressed this matter extensively at the last TRIPS Council. We reiterate that the targets set by Act-A including the Covax is to provide 2 billion vaccine doses (for 1 billion people) to the world by the end of 2021, 245 million courses of treatment and 500 million diagnostic tests to LMICs (excluding many developing countries) in 2021 are insufficient to meet global needs of the 7.7 billion people of this world. As we seen vaccine rollouts in the developed world, we cannot but continue to wonder when equitable and timely access will become a reality, with more than 90 % of all future production of likely vaccine candidates being reserved for rich developed countries.

With respect to TRIPS flexibilities, as mentioned in our previous statement, these flexibilities have played an important role in promoting access but were never designed to address the access challenge of a pandemic.

Today we would like to revert to a few more questions that were raised on 3 December 2020.

**Some delegations (Brazil, EU, Switzerland) have referred to IP/C/W/670 and asserted at the 3 December informal meeting that the mere existence of patent or patent applications does not amount to a barrier. EU mentioned that it would be interested to know more about these medicines.**

Document IP/C/W/670 presents a preliminary non-exhaustive snapshot of the patent filing and granting status on five selected therapeutics candidates that are under review by the WHO Access to COVID-19 Tools Accelerator (ACT-A) therapeutics pillar. Due to the interval between the time of patent filing and publication, which can take up to 18 months, new patent applications that might have been filed this year may emerge in the coming months.

The first table shows a patent for Regeneron’s new monoclonal antibody REGN10993 + REGN10987 granted in the US in June 2020, and which expires only in 2040. Information on patent applications filed globally should emerge in several months. The access strategy of Regeneron on this therapy remains unknown.

Document IP/C/W/670 also reveals high levels of patent filing and granting on other COVID-19 candidates. Merck’s Molnupiravir (MK-4482) has primary patent applications filed in at least 28 jurisdictions, including two regional patent offices, expiring between 2035 and 2038. Atea pharmaceutical’s AT-527 has primary and secondary patents filed or granted in nearly 60 jurisdictions, expiring between 2036 and 2038. Incety Corp’s baricitinib has primary and secondary patents filed or granted in nearly 50 jurisdictions, expiring in 2029. Roche’s monoclonal antibody therapy tocilizumab has primary and secondary patents filed or granted in nearly 30 jurisdictions, expiring between 2022 and 2028.

IP/C/W/670 also presents the patent landscape for Pfizer/BioNTech and Moderna vaccines.

Patents confers its holder exclusive rights. With this monopoly the patent holder is able to prevent other competent manufacturers from producing and supplying the patented subject matter, as well as to charge exorbitant prices for the patented medicines, hence hindering the timely access to affordable treatment.

The patent landscape in IP/C/W/670 is a warning shot of the existing and emerging patent barriers to access and the need for the international community to take urgent action to overcome these barriers so that supply may be diversified and scaled-up. Access to this type of information is critical to ensure further transparency and accountability. Up the hill at WIPO, we hear that the United States of America, has objected to the update of WIPO's review of existing research on patents and access to medical products and health technologies to extend the publication period of studies up to 2020.  In light of the destruction wrought by the COVID-19 pandemic, one wonders what the United States concerns would be regarding an updated report by the WIPO Secretariat?

**EU has queried what would the domestic implementation of the waiver entail and why would it be easier to carry out than introducing fast-track procedures for compulsory licensing on the basis of the existing system?**

Under the TRIPS Agreement, the flexibilities available are simply insufficient to address the global access challenges that we are facing. In the informal sessions, we have elaborated on this point. With respect to fast-track procedure, under Art. 31 of TRIPS Agreement, there is the option to issue compulsory license on grounds of national emergency or other circumstance of extreme urgency without engaging in prior negotiations with the patent holder. However in practice, its use is dependent on requirements contained in national laws and regulations. Importantly this compulsory license is limited by the condition of Art. 31(f) that it has to be predominantly for the supply of the domestic market, meaning only very limited export is allowed.

To export, the requirements of Art. 31*bis* have to be followed, and this includes issuing compulsory licenses in importing and exporting countries, and compliance with other procedures.

The importing country will in its notification to the Council for TRIPS:

(i) specify the names and expected quantities of the product(s) needed ;

(ii) confirm that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to the Annex of the TRIPS Agreement; and

(iii) confirm that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31bis of this Agreement and the provisions of the Annex to the TRIPS Agreement.

The exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website whereby before the shipment, the licensee is required to post information about the quantities being supplied to each destination and the distinguishing features of the product(s).

Products produced under the licence have to be clearly identified as being produced under the system through specific labelling or marking and suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves.

These are just some requirements of Art. 31*bis*. National laws may include other requirements.

These conditions cannot be referred to as a fast-track process. In fact the process of issuing CLs will have to be repeated again as more effective medical technologies enter the market. They are also not conducive to achieving economies of scale, which are crucial to motivate large scale manufacturing and lower prices of medical products. The current circumstances are especially problematic for countries with insufficient manufacturing capacity.

Also worth recalling that Art. 31 and 31bis only addresses patent barriers while there are also challenges with respect to protection of undisclosed information, a barrier which remains unaddressed. On this especially Art. 39.3 , the EU, US and other developed countries constantly criticise other WTO members especially developing countries for using flexibility allowed by the provision to promote public health. Given this kind of action undermines the ability of governments to respond to a pandemic, a waiver is justified for it would provide all governments legal certainty.

Further if the waiver is adopted, it is a one-time implementation, and may be achieved through executive action. It swiftly addresses all relevant IP barriers. And with its implementation, legal barriers to collaboration, development, production and supply are lifted. A waiver provides legal certainty as to freedom to operate, economies of scale can easily be achieved and with supply expanded, substantial price reduction may be expected, leading to timely affordable access.

Strangely, developed countries are placing emphasis on use of TRIPS flexibilities, but why is pressure been applied on developing countries for implementing public health safeguards in their intellectual property laws and policies, through EU’s annual IP enforcement report and US’ annual “Special 301 Report”, released in the midst of a raging COVID-19 pandemic.

**Concluding remarks and questions to delegations that have raised opposition to the waiver proposal .**

At the 16th October TRIPS Council, the US said: “Where intellectual property rights exist, they can be licensed to companies around the world to scale up manufacturing”. Along the same lines, countries opposing the waiver proposal have argued in favour of voluntary licensing as the main vehicle for expanding global supply.

-If VL mechanisms work, why do various license agreements concluded by companies [such as Gilead] exclude half of the worlds population from supply and only license to a few very specific manufacturers. Why is it that no one knows the full terms of the license?

– If VL mechanisms work, can they provide full details of all voluntary licenses signed with companies all over the world to scale-up manufacturing and for global supply that have been signed by Pfizer/BioNtech and Moderna with respect to their vaccines, and the therapeutics of Regeneron and Eli Lily that recently received emergency approval in the US. We would like to know the full terms of the licenses, with whom these licenses have been signed, which countries will be supplied, when will they be supplied etc.

-If VL mechanism works then why was Oxford/Astra Zeneca license to the COVISHIELD vaccine assigned only to one company in India and public sector manufacturer in Brazil when licenses and tech transfer to any manufacturer who has technical capacity could have been offered?

-If VL works then why are there geographical restrictions in the VL to limit supply to only to low- and middle-income countries (LMICs) under the agreements, excluding supply to other developing countries? Taking note that the issue of classification of countries based on singular criteria such as per capita GDP ignores the deep and persistent structural deficits between developed and developing countries.

Some delegates (e.g., US) asked for data regarding how certain obligations have systematically hindered prevention, treatment, and containment of COVID19 so that a waiver is needed. We consider the discussion of the current proposal is to acknowledge the limitation of the existing legal options and to provide additional flexibility at the international level. We have presented the examples and indications sufficient for members to consider endorsing the waiver proposal, including illustrative examples as per our earlies interventions, and would like to thank Indonesia for sharing its national experiences in this regard – we call on other members to do the same. Improving the readiness of law can be done based on due consideration of the probabilities of events. This has been reflected by a few members who quickly amended domestic laws to get ready based on such probabilities. We would like to ask Canada, Germany and Hungary, when they decided to swiftly amend national laws to enable quicker use of compulsory license, **what kind of data was relied upon at that time - demonstrating the necessity of revising the laws? [we refer to the Secretariat note and compilation of COVID-19 measures.]**

TRIPS flexibilities are important to increase access to medicines and other medical product not just in a pandemic. Why has pressure been applied on developing countries for implementing and supporting public health safeguards in their intellectual property laws and policies  under [EU’s annual IP enforcement report](https://trade.ec.europa.eu/doclib/docs/2020/january/tradoc_158561.pdf) and the annual [“Special 301 Report”](https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf), which was released even amidst the COVID-19 pandemic!

Several delegations highlight TRIPS flexibilities, particularly compulsory license under Art 31 and Art 31bis, as important and need to be used. We recalled how developing countries have been under pressures and discouraged from using those flexibilities for a long time. The EU and Switzerland both highlight the flexibilities as the key measures for members to use, does it mean the EU and Switzerland will from now **on commit not to pressure developing countries when they improve their laws on compulsory license and other TRIPS flexibilities or make use of compulsory license? Would the European Commission from now on exclude compulsory license and other TRIPS flexibilities from its IP enforcement report? Would the USTR do the same to its Special 301 report?**

We notice the recent IP action plan and pharmaceutical strategy published by the European Commission which urges EU members to use fast track compulsory license and explore coordinated compulsory license in EU. In launching the *Pharmaceutical Strategy for Europe*, Vice President Schinas underscored the importance that the transparency of R&D costs plays in ensuring access to affordable medicines.[[1]](#footnote-1) In his remarks to the press on 25 November 2020, Vice- president Schinas said,

"*Equally important, ensuring affordability of medicines will be guaranteed through bolstering transparency on R&D costs and expenditure on medicines in healthcare systems, finding a consensus on costing principles and addressing aspects that impede the competitive functioning of the markets impacting on affordability*."

This principle resonates well with our submission to the October 2019 TRIPS Council and the WHO Transparency Resolution (WHA72.8). Could the European Union provide more details on how it intends to ensure the "affordability of medicines" through the "bolstering of R&D costs"?

The EU IP Action Plan, released on 25 November 2020, reiterates the exigent need to deploy COVID-19 technologies, "not only in Europe but also on a global basis."To this end, the EU IP plan calls for "voluntary pooling and licensing of intellectual property related to COVID-19 therapeutics and vaccines, in line with the recent resolution of the World Health Assembly to promote equitable global access as well as a fair return on investment." Can the European Union elucidate further on how they intend to transform this lofty rhetoric into concrete action?  The EU IP Action Plan notes that the Commission is "**working on mechanisms that would enable and incentivise the rapid pooling of critical IP in times of crisis**". Could the European Union please explicate on these mechanisms that would enable the "rapid pooling of critical IP in times of crisis."

Following on from President Ursula von der Leyen’s State of the Union call for the establishment of an EU BARDA, the EU’s IP action calls for the development of an “effective framework for march-in rights, that should guarantee that publicly funded IP is available in case of critical shortages”. **Could the European Union please provide details on the design of these march-in rights?**

We would counter the EU’s assertion, repeated once again today, that compulsory licensing should be used as  “means of last resort and a safety net when all other efforts to make IP available have failed.” Nonetheless, **could the European Union please provide further details on the EU IP Action Plan's recommendation that EU Member States  "establish fast-track procedures to issue compulsory licenses in emergency situations"?**

The Commission will explore with Member States the possibility of creating an emergency co-ordination mechanism, to be triggered at short notice when Member States consider issuing a compulsory license. **What is the rationale behind this policy decision?**

**In the European Union, data exclusivity and on certain products market exclusivity are granted. How does the EC want to make effective use of CL in this pandemic with these non-patent barriers in place?**

As the European Union has opted out of Article 31bis of the TRIPS Agreement, how would EU member states with no or insufficient manufacturing capacities make effective use of the compulsory licensing provisions of the TRIPS Agreement,  especially in light of the IP Action Plan's emphasis on establishing  "fast-track procedures to issue compulsory licenses in emergency situations"?

1. <https://ec.europa.eu/commission/presscorner/detail/en/speech_20_2212> [↑](#footnote-ref-1)