South Africa's statements at the TRIPS Council Meeting of 30 July 2020

ITEM 1

Madame Chair,

My delegation takes the floor to congratulate you on your appointment of chair of TRIPS Council. We thank you for the good work that you have done so far, in particular in conducting informal consultations and holding open-ended informal meetings of the TRIPs Council in an inclusive and transparent way. We want to assure you of our fullest support for the remainder of your tenure, we have a heavy workload ahead of MC12 and will call on your cooperation and leadership to facilitate our work in the TRIPs Council.

ITEM 2

Questions raised to delegations' certain delegations

Chair,

We thank the Secretariat for the overview of notifications received under this item. As rightly pointed out some of the notifications overlap with the list of verified measures which was published by the Secretariat. South Africa wishes to raise some questions on COVID related notifications under item two. We look forward to study Australia's notification and for the short explanation of the amendment. Also, we the intervention from Canada has been well noted. We have some further questions of clarification regarding Canada's notification. The EU also discussed the notification of Hungary about which we also have some questions. For brevity I will focus only on a few questions and submit the remainder in writing.

Canada: IP/N/1/CAN/30 (Canada: Laws and Regulations)

a. Does the scope of the amendment allow compulsory licenses to be sought by the Minister of Health for purposes of importing generic versions of patented medical products to respond to public health emergencies?

b. The amendment limits the duration of the CL to a maximum of one year. As is now apparent, pandemics and other public health emergencies can go on for much longer, how will Canada address this gap? Can the CL be renewed or can the Minister of Health reapply for a new CL to cover the same products. Would this not disrupt access during an emergency?

c. Do patent holders have the right to apply for an injunction or any other relief that may halt implementation of the CL sought by the Minister of Health?

d. Why has Canada limited the right of a Minister of Health to apply for and be granted a CL only in situations of public health emergencies. How will the Minister of Health address patent challenges in other situations of public health need in Canada?

Hungary: IP/N/1/HUN/3 (Hungary: Laws and Regulations

The TRIPS Agreement reaffirmed by the Doha Declaration on TRIPS and public health recognize that each WTO Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. The right to issue compulsory license be it to address public health or any other national concern should be a common feature in national patent legislation.

a. Why has the Government of Hungary decided to rely on its emergency powers to issue a Government decree for public health compulsory licenses.

b. Section 1(4) of the Decree states the period for which a public health compulsory licence is granted shall not last longer than until 31 March 2021. Given that the Covid-19 challenge is expected to continue for a number of years, and shortages are likely, what other provisions exist in Hungary's patent law that will allow Hungary to issue compulsory or government use license to import or manufacture patented medical products.

c. The public health CL decree allows exploitation of patented inventions presumably including importing from other countries. How will the opt-out of Hungary as an eligible importing country in connection with the 30th August 2003 and Article31bis mechanism impact the utility of Hungary's public health compulsory license decree.

d. What circumstances informed the government's decision to terminate the special legal order (State of Danger) on 18 June 2020?

ITEM 3

General Statement on COVID-19

Madam Chair,

More than 16.5 million cases and 650 thousand deaths of COVID-19 have been confirmed globally. The global community is facing an extraordinary challenge. No country has been spared the devastating effects of Covid-19. Health and human toll are substantial and expected to continue to grow.

In this context we recall Resolution WHA73.1 of 19 May 2020, which recognises that COVID-19 pandemic has a disproportionately heavy impact on the poor and the most vulnerable, with repercussions on health and development gains, in particular in low-income countries. It further calls on cooperation between multilateral organisations and other stakeholders and the WHO Director General to identify and provide options that respect the provisions of relevant international treaties, including the provisions of the TRIPS Agreement and the flexibilities within the Doha Declaration on the TRIPS Agreement and Public Health, to be used in scaling up development, manufacturing and distribution capacities needed for transparent equitable and timely access to quality, safe, affordable and efficacious diagnostics, therapeutics, medicines, and vaccines for the COVID-19 response. South Africa welcomes the launch of the Trilateral Study on Access to Medical Technologies and Innovation, but notes with disappointment that it does not cover issues related to COVID-19.

Madam Chair,

The list of verified measures prepared by the Secretariat already indicate some steps taken by Members and supplemented by views Members will express during this TRIPS Council meeting and further meetings. A further step in concretizing this commitment is to hold a workshop as requested by the ACP Group which will give Members and other participants an opportunity to further discuss IP challenges with respect to access and to explore approaches to deal with COVID-19 in the context of intellectual property rights.

Curbing the pandemic and limiting the social and economic fallout is dependent on an unprecedented timely roll out of sufficient quantities of medical supplies to all countries in need including masks, personal protective equipment, ventilators, diagnostic kits as well as therapeutics and vaccines as they are identified. This requires global solidarity to transfer of technology and massively scale-up manufacturing globally. At present there are vast shortages of medical products within a country as well as between developed and developing countries. In light of possible second waves of the coronavirus, countries must take measures to ensure that they are able to restock medical products that will be needed to fight the virus.

The WHO estimates that at least 500 million tests are needed over the next 12 months in low- and middle-income countries.[1] Testing if deployed in a timely way could contribute to saving at least 9 million lives and avert at least 1.5 billion COVID-19 infections. The challenge with testing is to develop new rapid diagnostic tests and to scale up the production of such reliable, affordable tests to a volume sufficient for all countries to access them. Similar shortages can be seen with respect to personal protective equipment and ventilators. Bloomberg reports that the world demand for ventilators is ten

[1] WHO COVID-19 ACT Accelerator Technical Update and Virtual Press conference of 26 June 2020 <https://www.who.int/docs/default-source/coronaviruse/transcripts/act-accelerator-technical-update-and-press-briefing-26th-june.docx?sfvrsn=b88700e1_0>

times the current supply capacity.[2] Manufacturing ventilator parts for e.g. using 3D printing raises a number of intellectual property issues such as patents, industrial design and copyright.

The challenge of intellectual property is most apparent in the area of therapeutics. Several of the therapeutics under investigation do have patents granted or pending in many countries. A recent case that has widely been reported is Remdesivir, approved in several jurisdictions as preliminary results showed that it shortened the recovery period. Earlier this month, it was reported that Gilead had agreed to supply the US its projected production for the next three months, raising concern about supply of Remdesivir to other countries. Gilead has entered into 9 licensing agreements with generic manufacturers from 3 countries for the supply to 127 countries.[3] These limited, non-transparent exclusive licenses seem to be an attempt to contain competition by creating an oligopoly.[4] Generic manufacturers globally that can contribute to expanding global supply have been excluded. The lack of transparency, and accountability in the present dire times is extremely worrying and dangerous. It is an indicator of the IP and access challenges ahead of us, that the WTO Members need to address effectively and swiftly.

On the subject of vaccines, there are already news reports of intellectual property disputes that could hinder the development and production of COVID-19 vaccines.[5] We observe with great apprehension the rush by developed countries to sign deals to gain preferential access to vaccines, leaving many countries behind. Vaccine nationalism may address short term political demands of a country but drastically falls short of what is required to contain this pandemic. World leaders from the north and south have referred to vaccine as a global public good, that should be fairly and equitably available globally, leaving no one behind. Now is the time to put it into action.

The challenge before us is to produce an effective vaccine to meet the needs of the world population of 7.8 billion in as short a time frame as possible. This will require the sharing of knowledge and technology of successful vaccines so that the widest distribution at lowest cost can be achieved. Even the European Parliament Resolution entitled "*The EU's public health strategy post-COVID-19*" which was adopted on 10 July 2020 acknowledges its importance as it calls for "maximum sharing of COVID-19 health technology-related knowledge, intellectual property and data to the benefit of all countries in the context of WHO's Technology Access Pool (C-TAP).[6] It also calls for strong support for the WHO'S Technical Access Pool (C-TAP), while incorporating collective safeguards in favour of the public regarding public funding, such as transparency, accessibility and affordability clauses and non-exclusive licences for exploitation of final products, in all current and future calls for funding and investment. It further calls for enhanced dialogue with third countries and the issuance of compulsory licences in the event that such countries do not share their vaccines or therapeutic knowledge.[7]

In a July 2020 paper, MSF documented how exclusive rights and monopolies granted to pharmaceutical corporations, resulting in high prices and blocking generic competition has had a negative effect on MSF's medical actions in different countries. This has affected that ability of countries to provide access to treatment of HIV/AIDS, tuberculosis, hepatitis C and cancer for patients who need them. Beyond access to pharmaceuticals and biosimilars, the effects of patents have also hindered the introduction of affordable vaccines in developing countries, with the focus on pneumococcal conjugate vaccines (PCV) and human papillomavirus vaccine (HPV).[8] The 'fair shot' report found that the patents increase

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[2] Bloomberg (2020), *World Ventilator Demand Now 10 Times What's Available, Says Maker*, <https://www.bloomberg.com/news/articles/2020-03-25/world-ventilator-demand-now-10-fold- what-s-available-says-maker.>

[3] See <https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir>

[4] See <https://www.latimes.com/world-nation/story/2020-07-01/gilead-patent-limits-access-to-covid-19-drug-remdesivir>

[5] See <https://twn.my/title2/intellectual_property/info.service/2020/ip200704.htm; https://www.fiercebiotech.com/biotech/moderna-stock-sinks-as-patent-case-spurs-concern-for-covid-19-vaccine>

[6] European Parliament <https://www.europarl.europa.eu/doceo/document/TA-9-2020-0205_EN.html>

[7] Ad par. 8.

[8] The full text of MSF report 'A fair shot for vaccine affordability: understanding and addressing the effects of patents on access to new vaccines' is available from: <https://msfaccess.org/fair-shot-vaccine-affordability>

uncertainty, costs and delays in competition resulting in high prices for low-and-middle income countries. We cannot afford a similar scenario when dealing with COVID-19.

In short, we are of the view that the WTO should be cognizant of IP obstacles across essential medical products needed to contain the pandemic and take urgent steps to address these barriers in a comprehensive manner. The WTO-TRIPS Agreement does provide a number of flexibilities that may be utilized by member states to overcome IP obstacles. In anticipation of such barriers, some WTO members have undertaken urgent changes to national patent legislation to make it easier to issue compulsory licenses. However, there are a number of challenges:

Firstly, IP barriers go beyond patents, and often flexibilities in other intellectual property such as industrial designs, copyright and trade secrets is often less understood and implemented nationally.

Secondly, developing country Members may face legal, technical and institutional challenges in using TRIPS flexibilities. This is especially true for countries that have never utilized flexibilities such as compulsory licenses.

Thirdly, when an exporting country is producing under a compulsory license mainly for export, the mechanism established by the 30 August 2003 decision, and later translated into an amendment of the TRIPS Agreement as Article 31*bis*, would be applicable. This mechanism waives the condition in Article 31(f) that a compulsory license should be predominantly for the supply of the domestic market. However, experience in using this mechanism is largely non-existent. In 2006, *Medecins Sans Frontieres* (Doctors without Borders) attempted to use the procedures to export HIV medicines from Canada to Rwanda but it concluded that the mechanism is neither expeditious nor workable. We also note that implementation of the Article 31*bis* mechanism at a national level is rather limited or may not achieve its intended objectives. Further some countries have opted out of using this system as importers, which may pose a challenge to access.

Several voluntary initiatives have emerged since the outbreak of COVID-19 including pledges and voluntary licenses. Some of these are commendable, but these are ad hoc initiatives, simply inadequate to systematically and comprehensively address IP barriers. IP holders of essential technologies may also decide not to participate in such initiatives.

The World Health Organization has launched the COVID-19 Technology Access Pool (C-TAP) calling IP holders to voluntarily issue global non-exclusive licenses or to voluntarily surrender intellectual property rights, to facilitate the widescale production, distribution, sale and use of such health technologies throughout the world. However, to date no company has committed to doing so. Instead limited, exclusive and often non-transparent voluntary licensing seems to be the preferred approached and these are insufficient to address the needs of the current COVID-19 pandemic.

"Business as usual" approaches are simply inadequate to tackle COVID-19. We need to consider new bold measures that will comprehensively and expeditiously address IP challenges. The following approaches can be considered:

Members must explore international collaborations and binding commitments to facilitate the open sharing and right to use technologies, know-how, data and global non-exclusive rights to use and produce COVID-19 medical products.

Members must take policy and legislative measures to ensure that patents and other intellectual property do not erect barriers to access to medicines, diagnostics, vaccines and medical supplies and devices. This includes addressing evergreening of patents by restricting the grant of secondary patents on known medicines and excluding from patentability second medical uses as being mere methods of treatment

in terms of Article 27 of the TRIPs Agreement. Members are encouraged to take measures to facilitate the local manufacturing or import of essential medical supplies, devices or technologies including diagnostics, medicines and vaccines.

ITEMS 5, 6 & 7

Madam Chair,

It has become a practice to address the three agenda items together under the rubric of the 'Triplets'. However, in this discussion we often lose the relative importance of the individual components making up the 'Triplets'. The Doha Ministerial Declaration instructed the TRIPS Council as part of its work programme to review Article 27.3(b) as well as examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity and the protection of traditional knowledge and folklore. These are legitimate outstanding implementation issues which remain an integral part of the Doha round single undertaking. In recent times paragraph 31of the Nairobi Ministerial Declaration (WT/MIN(15)/DEC) reaffirmed the strong commitment of all Members to advance the negotiating on TRIPS issues under the work programme of the Doha Ministerial Declaration.

South Africa believes that the debate in respect of the Article 27.3(b) is not a static one. South Africa requires disclosure of the use traditional knowledge or biological resources in patent application. Sections 30 (3A) of the *Patents Act No. 37 of 1952* as amended by *Act No. 20 of 2005*. Despite this requirement and various legislative approaches to curb biopiracy, the problem continues to grow. In the absence of an internationally agreed and enforcement system, as applicable under the TRIPS Agreement, national disclosure requirements are of limited effect due to the territorial application of intellectual property rights.

South Africa is a non-examining patent country; any complete patent application that is led and meets with the formal requirements (fees and correct forms) of the Patents Act will therefore be granted. The practice of non-examination gives rise to the potential of abuse, as patentees aunt their 'rights', safe in the knowledge that the general public does not understand the concept of non-examination and that IP litigation is expensive and time consuming. Between January 2005 and July 2015 40,131 patents originating from all over the world which were registered in South Africa, only 4064 of those patents has a South African origin. We are now attempting to fix this by introducing formal examination as envisage in our IP Policy. The IP Policy sets out a range of proposals relating to key aspects of patent law that have an impact not only on public health but more broadly. In addition to substantive search and examination, IP Policy addresses the following issues (amongst others) - patent oppositions, patentability criteria, parallel importation, exceptions and compulsory licences. The South African patent landscape is characterized by the easy grant of patents of dubious quality and value, as well as the enforcement of a legal framework that appears to be heavily skewed in favour of patentees. What this means in practice is that in exchange for very little, market exclusivity is easily granted, and maintained, ordinarily at a high cost to society.

In respect of the relationship between the TRIPS Agreement and the Convention on Biological Diversity and the protection of traditional knowledge, a large group of WTO members have sought to introduce a mandatory disclosure requirement in patent applications. The best way to ensure the proper use of genetic resources and associated traditional knowledge is through an amendment to the TRIPS Agreement as set out in document TN/C/W/59.

In line with our previous statements, it would be useful for the CBD Secretariat to brief the TRIPS Council on the CBD and other implementation issues under the Nagoya Protocol as well as any new developments.

We wish to raise once more the issue of the update of the three technical notes contained in documents IP/C/W/368/Rve.1, IP/C/W/369/Rev.1 and IP/C/W/370/Rev.1. It would be appropriate for the Secretariat to update the information contained in these notes in a neutral manner to further facilitate discussions among Members.

ITEM 8

NON-VIOLATION AND SITUATION COMPLAINTS

Note: Due to my late arrival I could not read the statement but hereby request our written statement to be included.

The possibility of bringing complaints on otherwise GATT-consistent measures was introduced into the GATT 1947 to address situations where the concessions or benefits obtained in a tariff negotiation could be easily frustrated by non-tariff measures, such as domestic subsidies, that the GATT 1947 did not regulate. As the original GATT did not require Contracting Parties to make substantive commitments on many such non-tariff measures, non-violation complaints were introduced as a remedy that could address any impairment of the benefits of tariff concessions as a result of such measures.

Thus, the basic function of Article XXIII:1(b) was to protect expectations that arose out of tariff concessions negotiated by parties to the GATT. It was to ensure that a GATT Contracting Party could obtain compensation, or a right to the compensatory or retaliatory withdrawal of concessions, where another Contracting Party introduced a measure subsequent to the negotiation of a tariff concession that frustrated the achievement of those concessions. In effect, non-violation complaints are a fall-back remedy designed to prevent circumvention of GATT obligations through measures that are not themselves GATT-inconsistent. We should however note that the non-violation remedy is an "exceptional" remedy. There has been no successful recourse to the non-violation remedy in any of the WTO disputes in which Article XXIII:1(b) has been invoked. In over 70 years of the existence of multilateral trading system, reports were adopted by the GATT Contracting Parties in only the remaining three out of the eight cases.[9] Even in those disputes in which non-violation complaints have been successful, there was agreement by the parties involved that it was an exceptional remedy to which "a cautious approach" should be taken.[10]

This experience with non-violation complaints in GATT/WTO jurisprudence suggests that the evolution of the multilateral trading system, and the expansion in the provisions of WTO Agreements regulating non-tariff measures, may have had the effect of making non-violation complaints largely redundant as a remedy. Nonetheless, my delegation is not a proponent of the application of NV&Cs and if the proponents of the application of NV&Cs complaints under the TRIPS Agreement have not provided concrete examples of the kind of scenarios under which an otherwise TRIPS-consistent measure would impair or nullify benefits beyond those arising from the obligations set out in the Agreement. Thus, as we previously suggested, it may be useful to clarify what situations proponent Members wish to avoid by having a non-violation remedy available under the TRIPS Agreement and, on the other hand, to ensure that a non-violation remedy in the TRIPS context would not be so broad as to have the effect of expanding the existing TRIPS obligations.

[9] See Report of the Working Party on Australia - Ammonium Sulphate, Panel Report on Germany - Sardines and Panel Report on EEC - Oilseeds I.
[10] See, for instance, EEC- Oilseeds I, where both the US and the European Community made statements to this effect.

ITEM 11

TECHNICAL COOPERATION AND CAPACITY BUILDING

We wish to thank the Secretariat for its ongoing commitment to assist developing make maximum use of the multilateral system. Due to COVID-19 the cooperation and capacity building activities may have been affected as reported ITTC in its briefing to the CBFA. Face-to-face training in most cases have been postponed until the next financial year while some online activities have taken place. South Africa attaches importance to the use of online mode during this time to continue technical cooperation and capacity building. Technical assistance and capacity-building must always respond to members' needs, at this time many members may have a need for technical assistance and capacity building to respond to the COVID-19 pandemic. In the context of the Biennial Technical Assistance and Training Plan 2020 – 2021 (WT/COMTD/W/248/Rev.1)**,** emphasis has been placed on improving eLearning programme. Expanding access to materials is also envisaged under the plan, this would be valuable for the public at large.

ITEM 12

LDC GROUP PROPOSAL ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT

Thank you to LDC group and the African Group. Transparency is an important aspect of the mandate of this organisation. The simplified template will go a long way in facilitating the work of this Council and comply with the Doha Declaration. The appendix is an important addition in this paper and will enable a more accurate reflection of the recipients of incentives. We would also agree that the definition of 'incentives' should be agreed so as to enable a better understanding of what types of measures will constitute such incentives.

ITEM 13

Read as per the submission

ITEM 14

Read as per the submission