**Indian intervention for TRIPS Council meeting on 10 Dec 2020**

Thank you Chair for re-convening TRIPS Council meeting in formal mode to continue discussions on the issue of TRIPS Waiver. We would also like to thank you for your efforts in engaging Members over the Chair’s status report to the General Council. We look forward to the discussions in General Council on the report. We welcome Bolivia as the latest co-sponsor to our Waiver Proposal. We also acknowledge the tremendous support by Civil Society Organisations for the Waiver. Rarely has an issue being dealt in WTO, united so many disparate aspects of society from developed, developing and Least Developed Countries alike in delivering a clear message: to put health first and save lives.

Chair, at the outset, we would like to emphasize that this is not a proposal only for India but for the global community at large. India may be having the required manufacturing capacity, the national legislations to cater to its needs but we believe that in a global pandemic, where every country is affected, we need a global solution**.** Global community should not be looking inward at this juncture. Though we have repeatedly heard that no one is safe until everyone is safe, yet even the most optimistic scenarios today cannot assure access to vaccines and therapeutics for all, even by the end of 2021.

All of us witnessed the shortages of essential Covid items, like PPE kits, gloves, sanitizers etc. during the initial phases of the pandemic. But the world was able to upscale the manufacturing of these items by pooling resources and production capacities and thereby overcome the shortages. At present, we need the same pooling of IP rights and know-how for scaling up the manufacturing of vaccines and treatments, which unfortunately has not been forthcoming, necessitating the need for waiver.

Today, we have heard about concrete evidences regarding IP barriers experienced by Indonesia. We would like to thank Indonesia for coming forward and explaining such evidences to Members and we encourage other Members to also share similar experiences that they would have faced.

Chair, our waiver proposal represents an open and expedited global solution to allow uninterrupted collaboration in development, production and supply of health products and technologies required for an effective Covid19 response. The Proposal in targeted and proportionate as it seeks waiver for a limited period from four specific sections of TRIPS Agreement, namely patents, copyrights, industrial designs and undisclosed information, in so far as they hinder the production of health products and technologies, for prevention, treatment and control of COVID pandemic. Every country has been taking extraordinary and unprecedented measures, unheard of before. This includes requiring weeks and months of lockdowns, imposing quarantine, nationalising private hospitals, mandating wearing of masks, seeking military help etc. Viewed against that, the waiver is definitely a proportionate response to the problem we are trying to address.

Chair, it is important that the interventions by co-sponsors at the previous two informal sessions are reflected on record of today’s formal TRIPS Council meeting or are circulated as an IP series document as written answers by co-sponsors to the questions raised. We have submitted our statements of the informal meetings on 20th Nov and 3rd Dec for this purpose.

We thank Malaysia, Oman, NZ and Vietnam, who have intervened for the first time on waiver proposal. We also thank Sri Lanka, Chad, Egypt, Indonesia, Mauritius, Venezuela, Jamaica & the ACP Group and China for their support. We appreciate the constructive engagement by Turkey, Singapore, Ukraine, El-Salvador, Norway, Canada, UK, EU, Japan, Ecuador, Korea, Brazil and US. We would like to address some of the additional questions that have been raised by some Members at the last informal meeting, in today’s meeting and also some of the overlapping issues raised in the submission IP/C/W/671, though we would be submitting written answers to all the questions raised in the submission, at a later stage.

**Q1: Some delegations have argued that a waiver will bring great uncertainty to the IP system and will impact the incentives, while some others have argued that existing flexibilities under TRIPS Agreement are sufficient to address the pandemic and the waiver is not necessary. Also, there have been questions as to what the national implementation of the waiver will entail.**

**Response:**

In the situation of unprecedented social, health and economic crisis that we are facing today, insufficient supply and inequitable access to Covid19 health products, heightens the sense of insecurity and uncertainty. The existing flexibilities under the TRIPS Agreement were never designed keeping in view a crisis of this magnitude and are woefully inadequate in context of Covid19 pandemic. We had explained the rationale behind this argument in significant detail over the past meetings.

Art. 31 compulsory licenses are issued on a case by case, country by country basis according to national patent law procedures and practices. It is an impractical option, if one takes into consideration the need for regional and international collaboration to scale up supply, the need to source materials from various countries and the need for economies of scale to make manufacturing viable. We have already highlighted the limitations associated with the use of Article 31bis. Countries that have never utilised compulsory license or the Art. 31*bis* mechanism will have to consider what are the national procedures for doing so, what to do if procedures do not exists, who should request this license, who should issue the license, what would be the adequate remuneration to be paid, what are the requirements of Art. 31*bis*, can an importing country that has not implemented Art.31*bis* in its national law utilise the provision, what are the Art. 31*bis* requirements for the exporting country, what are the national law requirements in the exporting country. Many a times, countries also have to deal with pressures from other trading partners and from pharmaceutical companies while dealing with such issues. Given the urgency to save lives and the time it takes to get a compulsory license implemented on ground in most of developing countries, use of this flexibility in context of Covid19 pandemic does not present a viable option.

With regard to the question on national implementation, we have addressed this issue at the last informal meetings. National implementation of the waiver depends on a country’s political and/or constitutional arrangement. There is no one size fits all approach to national implementation. However, once the waiver proposal is approved, emergency, disaster management legislations or any other relevant legislative methodology may be relied upon to provide for executive action to operationalise the waiver at the national level. Implementation of Waiver at the National level can also be done in the same way as the unprecedented steps, like lockdowns, quarantine and other measures, put in place to curb the COVID spread.

In contrast to the waiver bringing uncertainty to the IP system, we are of the view that a waiver once implemented will provide greater certainty to manufacturers by providing them freedom to operate, and for governments to collaborate to increase supply options. Waive being sought for a limited period and that too only from some specific TRIPS provisions in the context of covid does not increase uncertainty for the IP system. Instead it shows that in exceptional circumstances, the IP system can be flexible and accommodating. On the contrary, a rigid IP system that prioritizes IP monopolies and profits over peoples’ lives, would present a greater uncertainty to the world today in addressing the Covid crisis.

**Q2: EU has sought an explanation as to how the waiver could operate with regard to the vaccine production, including the transfer of the required technology and know-how and how it would affect the existing licensing mechanisms and Covax in general.**

Response: In the area of vaccines, there are two primary barriers, patents and protection of undisclosed information. Patents are used to protect various aspects of the underlying technology as well as the product. Document IP/C/W/670 presented by South Africa, presents a preliminary non-exhaustive snapshot of the patent filing and granting status on selected therapeutics candidates. As the new vaccines emerge, we are likely to see many more patent applications concerning all aspects of vaccines in the coming months.

In addition, manufacturing know-how, test data, and cell lines are needed to facilitate diversification of vaccine production. Hence the importance of addressing protection of undisclosed information under Art. 39 of TRIPS.

The wide range of patents and patent applications as well as exclusivity related to undisclosed information creates a complex and uncertain legal environment for scaling up vaccine development, production and supply. The waiver, if granted, would provide potential manufacturers the freedom to operate and achieve economies of scale, thereby incentivizing production and supply of therapeutics and vaccines

We also need to recognize that to date most multinational corporations holding COVID-19 vaccine IP have not shown any willingness to openly license or transfer technologies to all competent vaccine developers globally. The pharma industry has objected to participation in WHO’s Covid19 Technology Access Pool. Existing licenses are non-transparent, restricted and limited. We have addressed this matter extensively in the informal consultations.

The waiver is about lifting the legal barrier, it does not preclude the possibility of companies agreeing to voluntary licenses. Covax will also benefit from the Waiver as production will expand with more manufacturers engaged in manufacturing. With robust competition, prices can also be expected to be substantially reduced.

Today, EU has reiterated that transfer of technology and know-how should be encouraged through licensing. We would like to know how EU plans to persuade pharma companies to enter into transparent, non-exclusive global open licenses, where all manufacturers can be engaged without any restrictions, and what steps EU is taking to ensure full transparency and accountability in the cost of R&D and in licensing agreements.

Chair, we also look forward to hearing from the Members who have argued against the need of the Waiver, on the four questions that we had raised at the 3rd Dec meeting, namely:

1. Do the opponents have any data regarding how the waiver would demonstrably have negative impact on Members’ economies, if any?
2. Public funding has been driving COVID-R&D. In addition, billions of dollars are spent on purchasing the vaccine. Given the demand volumes, pharma companies will anyway make profits. So why is there a need for IP as an incentive, in a global pandemic situation?
3. Can the opponents provide data as to how voluntary licensing approaches and existing global cooperation mechanisms, including ACT Accelerator, the Covax facility and Covax AMC, would be sufficient to address the vaccine requirements of 7.8 billion people in the world?
4. If voluntary mechanisms work, why has the pharmaceutical industry collectively rejected participation in the WHO COVID-19 Technology Access Pool (C-TAP)?

Like the proponents have provided substantive answers to the questions from other Members, in the same way evidence-based specific responses to these questions will enable constructive engagement and take us closer to our objective.

**Chair,** according to the WHO, nearly one third (32%) of vaccines have fewer than four suppliers. We would like to ask the WTO Membership how these limited suppliers will be able to cater to the needs of 7.8 billion global population and if at all, they can, then after how many months and years, after how many more deaths, will everyone get access to vaccines and treatments. These are some pertinent questions, Chair, which we all need to reflect upon, and that can be answered only through true solidarity and cooperation. Our Waiver is the only possible solution to scaling up global production to address the pandemic, and considering the urgency of the crisis, we need to take time-bound action now rather than limiting ourselves to indefinite debate. We also note the Covid19 and Beyond: Trade and Health initiative by EU, Switzerland, Canada and few others, which talks about enhanced preparedness to fight against current and future pandemics. Madam Chair, history will not judge us kindly if we fail to find an expeditious solution to the current pandemic while claiming to prepare for the future ones. We hope the Membership can rise to the demand of this crisis and demonstrate that WTO can actually deliver on timely, equitable and affordable access for all, by agreeing to the waiver. World will remember the contribution of WTO during the pandemic for generations to come. We now have the opportunity to show that when the situation demands, WTO can indeed deliver. Certainly the pace of other ongoing negotiations at WTO that have continued for more than 20 years, should not be a benchmark for this proposal.