WORLD TRADE ORGANIZATION

IP/C/W/672

15 January 2021

(21-0501)

Page: 1/30

Council for Trade-Related Aspects of Intellectual Property Rights

Original: English

WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19 – RESPONSES TO QUESTIONS

COMMUNICATION FROM THE PLURINATIONAL STATE OF BOLIVIA, ESWATINI, INDIA, KENYA, MOZAMBIQUE, MONGOLIA, PAKISTAN, SOUTH AFRICA, THE BOLIVARIAN REPUBLIC OF VENEZUELA AND ZIMBABWE

The following communication, dated 14 January 2021, is circulated at the request of the delegations of the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe.

This document contains responses to questions raised on the waiver proposal in the TRIPS Council meetings on 16 October, 20 November, 3 and 10 December 2020.

1 ANSWERS TO QUESTIONS RAISED FROM FLOOR IN THE FORMAL MEETING OF TRIPS COUNCIL ON 16 OCTOBER 2020

1.1 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 notion.

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

2. 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.

3. 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 31*bis* 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.

4. Article 31*bis* 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.

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

- the European Union (EU) IP enforcement report 2020, issued right before the COVID-19 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 licenses if patent holding companies do not fulfil the obligation of supporting production of medicines locally; and
- the United States Trade Representative (USTR) 2020 Special 301 report, issued right in the middle of the COVID-19 pandemic, continue to condemn countries who improve their laws on compulsory license or make use of compulsory licenses – countries specifically pressured for their law or their use of compulsory license include Chile, Indonesia, Colombia, Egypt, India, Malaysia, the Russian Federation, Turkey, Ukraine, El Salvador.

1.2 Voluntary Licenses are somehow touted as the solution for COVID-19! This is not the case.

6. 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.

7. Nine months into the pandemic voluntary approaches have proven to be insufficient. For instance, despite receiving significant public funding of at least USD 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.

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

9. 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.

10. 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.

11. 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.

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

12. 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 taxpayer 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.

13. 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.

14. 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.

1.4 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 co-sponsors 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% of the world's population have already cornered more than half (51%) of the promised doses of leading COVID-19 vaccine candidates[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 COVID-19 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 COVID-19 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 COVID-19 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 COVID-19 medical tools; and
    - COVID-19 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.

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

1.5 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 USD 70 billion mostly from governments including many developing countries governments; it is taxpayers in different countries who have invested the COVID-19 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; and
- 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.

15. 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 co-sponsors 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, that facilitated these collaborations – not IP!

2 ANSWERS TO QUESTIONS RAISED FROM FLOOR IN THE INFORMAL MEETING OF TRIPS COUNCIL ON 20 NOVEMBER 2020

2.1 Some Members argue that the TRIPS Agreement, strikes the right balance and provides for the necessary means and remedies to allow the use of protected products.

16. TRIPS flexibilities, including those confirmed in the Doha Declaration on TRIPS and Public Health, have undoubtedly, played a crucial role in promoting access to medicines. However the present COVID-19 global pandemic presents exceptional circumstances. After all, countries all over the world have had to put in place extraordinary measures to contain COVID-19, ranging from putting in place emergency legislations and lockdowns to seeking military help. But, when it comes to IP, these same countries shy away from even recognizing the evidence that IP is a barrier, let alone mustering the global cooperative effort required to scale up manufacturing by addressing the IP issues for ensuring timely, equitable and affordable access to COVID-related therapeutics, vaccines and other goods for all.

17. In our view, though the TRIPS flexibilities do allow limited policy space for public health, they were never designed to address a health crisis of this magnitude. Invoking them for a range of health products and technologies, required for treatment and prevention of COVID-19, is not a feasible option, because:

18. Understanding of TRIPS flexibilities is usually in the context of patents. However, as explained before, various types of intellectual property rights i.e. patents, copyrights, industrial designs and trade secrets pose a barrier towards an effective response to the COVID-19 as the pandemic requires access to various commodities, involving multiple IP rights. Flexibilities in other categories of IPRs than patents, are less understood and rarely implemented before. Therefore, options available to Members through existing TRIPS flexibilities are limited.

19. Many countries lack the institutional capacities to utilize such flexibilities.

20. Moreover, compulsory licenses are issued on a country by country, case by case and product by product basis, where every jurisdiction with IPs would have to issue compulsory license, practically making collaboration among countries for the development and manufacturing of medical products (where different components are sourced from different countries) extremely onerous.

21. Further Article 31*bis* mechanism established to support countries with insufficient or no pharmaceutical manufacturing capacity has even in normal times been widely criticised for its cumbersome procedures. The mechanism includes procedures such as specific labelling or marking of products; special packaging and/or special colouring/shaping of products, making it practically meaningless. The procedure being used only once, since its inception in 2006, itself testifies difficulties associated with its use.

22. Finally, very often the implementation and use of flexibilities is accompanied by pressures from trading partners as well as other stakeholders.

23. We encourage the use of TRIPS flexibilities by Members. Members that have the capacity to implement flexibilities in a timely manner should continue to do so. Furthermore, those Members who think that TRIPS flexibilities are enough for COVID-19 response and they do not need the waiver, can choose to not implement the waiver in their domestic legislations, but they should not come in the way of international collaboration with respect to development, production and supply of needed healthcare products for COVID-19 that we seek to achieve through the TRIPS Waiver. The waiver is more than just a legal mechanism, it is a statement of intent by all countries that they accord highest value to protecting human lives rather than protecting private profits.

2.2 Some Members argue that initiatives such as ACT-Accelerator (ACT-A) and COVAX Advance Market Commitment (AMC) including donations to these initiatives are sufficient to address global need for vaccines and therapeutics.

24. We welcome the global cooperation initiatives, including ACT-A and COVAX AMC and encourage funding by Members to these initiatives. Every effort towards achieving an equitable access for COVID-19 products should be supported. However, in our view, these would not be sufficient to ensure timely and equitable access to COVID-19 products and technologies. The aim of ACT-A including the COVAX AMC is to provide two billion vaccine doses (for one billion people if we consider two-dose vaccine regimen) to the world by the end of 2021. It is designed to address only the initial, acute phase of the pandemic to forestall health service collapse and thus to deliver only 20% or less of LMICs' need. Even these acute, minimal goals of the ACT-Accelerator may not be met because it has currently raised only about 15% of its funding needs[2]. These initiatives are obviously inadequate to meet the medium and long term needs of the 7.8 billion people of this world.

25. In the immediate term, even with these initiatives, there is visible disparity in access between the developed country Members and the rest of the world. Developed country Members have been able to leverage their financial position and enter into increasing number of bilateral deals securing preferential access creating uncertainty for universal timely and affordable access. As Kenya has pointed out, majority of the doses of recently announced effective vaccine, based on initial data, have reportedly been reserved by high-income countries. On one hand, these countries are buying up as much of the limited supply as they can, leaving no vaccines in the pie for developing and least developed countries. On the other hand, and very strangely, these are the same countries who are arguing against the need for the waiver that can help increase the global manufacturing and supply to achieve not just equitable, but also timely and affordable access to such vaccines for all countries.

26. The global needs are massive and can only be addressed with global sharing of technology, knowledge and related IP, which is what our waiver proposal seeks to achieve. We believe it would be naïve for any country to think that it can win over a virus, which knows no boundaries, by simply vaccinating their own population. We would like to conclude by saying that we all need to rise up to the demands of this crisis and show to the world that WTO is still relevant and very much capable of responding to the global need of saving lives and livelihoods, at least during a health crisis like COVID. We are open to the suggestions from Members on the text of the Proposal, including its scope and coverage, duration or any other aspects and look forward to a constructive discussion.

[2] https://www.who.int/news/item/13-11-2020-access-to-covid-19-tools-accelerator-commitments-reach-us-5.1billion-following-new-contributions-including-at-paris-peace-forum

2.3 Some Members that are of the view that they will not benefit from the waiver or do not need the waiver.

27. It is important to note that the adoption of a waiver at the international level does not obligate implementation of the waiver at the national level.

28. In addition, 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. For instance emergency, disaster management legislations or any other relevant legislation may be relied upon for executive action to operationalise the waiver at the national level. We want to 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.

29. 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. 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. As already indicated, our proposal demonstrates the existence of exceptional circumstance that justifies our request for a waiver decision and clear terms and conditions governing the application of the waiver.

2.4 Those opposing the waiver proposal have repeatedly suggested that voluntary approaches offer the best solution.

30. 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. Amidst a global pandemic, Gilead signed secretive bilateral licenses for Remdesivir with a few generic companies of its choosing that excludes supply to nearly half of the world's population including many developed and developing countries.

31. 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. Many companies have not signed any agreements to expand manufacturing and supply, meaning that during the time of vaccine development when such supply bottlenecks could have been addressed, companies are refusing to share intellectual property in a responsible fashion. This turns countries against each other to compete for supply in lieu of working together to defeat the pandemic. For instance, 82% of the recent Pfizer/BioNtech vaccine that is claimed to be 90% effective has been pre-booked by developed country Members representing 14% of the global population , and no public commitment has been made in support of sharing its COVID-19 vaccine knowledge, technology and related intellectual property to boost supply, reduce price and enhance equity.

32. Some argue that pharmaceutical companies have made a "no-profit pledge" during the pandemic. But even this pledge is suspect given the absence of transparency on actual costs of research and development and that pharmaceutical companies may unilaterally declare an end to the pandemic, as early as July 2021, according to at least one agreement with a manufacturer. Some companies are not offering prices at a not-for profit price, charging anywhere from USD 20 to an estimated USD 40 per dose , which would cost governments billions of dollars. Pfizer and BioNTech are expected to make at least USD 13 billion from their vaccine the following year.

33. Some point to the unilateral non-enforcement announcement of Moderna as an example of the success of voluntary approaches. In October, Moderna announced that "while the pandemic continues, Moderna will not enforce our COVID-19-related patents against those making vaccines intended to combat the pandemic" adding that "we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period". This announcement does not provide other manufacturers much legal certainty as to freedom to operate and does not include other forms of intellectual property protected information and technology needed to produce the vaccine such as cell lines and know-how. Furthermore, with respect to future intentions, it is unclear what period is

intended by "while the pandemic continues" and what licensing arrangements will be applicable post-pandemic, which territories will be covered etc.

34. In sum, the global pandemic response cannot be dependent on the possibility of such ineffectual, *ad hoc* announcements.

35. Voluntary licenses offered by patent-holding pharmaceutical corporations also tend to exclude millions of people from access to more affordable treatments. For instance, the Medicines Patent Pool licenses normally exclude many developing countries and all high-income countries from being supplied under the licenses. There are also several other restrictions attached to voluntary license. Some voluntary licenses even exclude the manufacturing countries from supplying their home country markets. Hence, conventional voluntary licenses do not offer a sustainable path to resolving the COVID-19 pandemic.

2.5 Some have suggested that there is no evidence that intellectual property is a barrier to accessing vaccines, treatments, or technologies in the global response to COVID-19.

36. Cases involving potential intellectual property infringements emerged early on in the pandemic revealing the complex legal implications of producing copies of life-saving medical products or parts thereof as well as impact on access.

Therapeutics

37. A number of therapeutics are under investigation. Some of the therapeutics are presently off-patent but as its use is explored for COVID-19 treatment, the filing of new patent applications extending to secondary uses of these therapeutics can be expected. Several other therapeutics under examination are patented in multiple jurisdictions. Attached please refer to a selected patent landscape of priority therapeutics. Some of the candidate have patents filed and/or granted in nearly 50 developing and least developed countries.

38. The case of Remdesivir best sums up the how patents can block access to therapeutics. The primary patent on the base compound of Remdesivir has been granted to Gilead in more than 70 low-and middle-income countries, hence potentially blocking access to generic alternatives until 2031. Civil society called for non-enforcement of Gilead's patents, but this call went unheeded. Instead Gilead signed secretive voluntary licenses with a few generic manufacturers of its choosing to supply countries as determined by Gilead. As a result, other manufacturers in countries with patents were excluded from manufacturing and nearly half of the world's population were prevented from being supplied by the licensee and hence denied from accessing more affordable generics. While more recently WHO has declared Remdesivir to be ineffective in the treatment of COVID-19 , this case study is a striking example of inequities that will replay should the international community fail to take steps to address intellectual property barriers. Such inadequacy of supply also allowed Gilead to bid up the price of the treatment for those countries that were excluded from a voluntary license agreement, and to use the lack of supply to persuade some countries, such as the 27 Member States of the European Union, to spend more than one billion euros on the drug even though the WHO was about to disclose that through its own trials the drug was not effective.

39. In therapeutics, monoclonal antibodies (mAbs) holds promise for curbing COVID-19. Many mAbs are currently in development for treatment and prevention of COVID-19. Even prior to the spread of COVID-19, access to mAbs was highly unbalanced, with Europe, US and Canada accounting for 80% of global sales. Prices also remain prohibitively expensive.

40. Many of the monoclonal antibody candidate therapeutics such as tocilizumab, sarilumab, bevacizumab are under patent protection in many developing countries. Secondary patents on new uses or formulations of an existing mAb product could further strengthen the patent holder's market monopoly, also the primary reason for delayed introduction of biosimilars in some markets including in the US.

41. Disparity in access is certain unless concrete steps are taken to address intellectual property barriers. Competition to lock up existing capacity is already intense. For instance, it is reported that Regeneron signed a USD 450 million deal in July to sell to the US enough doses of its antibody treatment, REGN-COV2, to treat around 300,000 people. Similarly Eli Lily has announced an

agreement with the U.S. government for USD 375 million to supply 300,000 vials of bamlanivimab (LY-CoV555) 700 mg, an investigational neutralizing antibody, granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA).

Diagnostics

42. In March 2020, it came to light that Netherlands was not able to do mass testing for COVID-19 as most Dutch testing laboratories work with Roche equipment and depend on Roche for supplies of the liquid buffer needed to run the tests, and there was a shortage of this buffer. Initially, Roche refused to provide the recipe for the buffer. With the recipe, labs would be able to quickly make their own solution and ramp up their testing capability. Eventually however as public pressure mounted and the European Commission considered investigating Roche for possible abuse of its market position, Roche agreed to release the recipe to the Dutch authorities.

43. Shortages of testing materials in developing countries have also been widely reported as most supplies are destined for the US or Europe. In May 2020, South Africa, my home country, faced similar challenges as its diagnostic infrastructure also depends on the use of proprietary test materials – including reagents, consumables and cartridges. A virologist with the South African National Health Laboratory Service explained "that commercial diagnostic manufacturers develop their own tests, containing proprietary reagents and unique consumables and packing. As a result, the tests cannot be interchanged between different diagnostic systems" adding that "even we don't know what is in the proprietary reagents", as the specific formulations are protected as trade secrets". This situation prevents laboratories from making their own test materials or procuring test materials from sources other than the diagnostic machine's manufacturer.

44. MSF in its analysis has found that "major diagnostics companies hold a considerable number of patents, often bundled into thickets for various instrumentation, assays, methods and software, related to different aspects of the technologies, methodologies and devices", concluding that "the overall business model for diagnostics results in multiple dominant closed diagnostics systems (since each major diagnostics company develops both the device and the consumable parts – for example the reagent kits or reagent-loaded integrated cartridges – specifically tailored to that device), making competition extremely difficult. The high cost and burden of switching between systems results in a "locked-in" effect for end users since they have no choice but to buy both the device and the assays from the same company".

45. Testing is a crucial aspect of containing the spread of COVID-19 especially in the absence of effective therapeutics and vaccines, and some countries are now moving to a model of mass testing of the entire population, either at once or on a regular basis, as a route out of the pandemic.

46. And yet, the disparity in testing between developed country Members and other countries is vast. As of 11th November, reported tests for everyone million population, was approximately 342000 in developed countries, 81000 in developing countries and 9700 in LDCs. In other words, high income countries are testing its population at nearly 35 times the rate of the world's poorest countries. When new tests come onto the market, only a few countries rapidly purchase all of the existing supply or put forward large sums of capital to claim all supply. More supply is needed, and such supply requires multiple manufacturers unhindered by any barriers to production. Intellectual property has proven to be a barrier in the scaling up of testing for COVID-19. Existing manufacturers are unable to keep up the needed global supply, hence negatively impacting a country's ability to screen samples for COVID-19 – an essential part of controlling the pandemic.

Vaccines

47. 45 vaccine candidates are in human trial, while about ten are in or entering phase III trials. The candidate vaccines are of various types – virus vaccines using live attenuated virus, viral vector vaccines, protein- based vaccines, and nucleic acid or RNA and DNA vaccines, which are completely new platforms.

48. The effects of patents in hindering the introduction of affordable vaccines in developing countries have been published by MSF. While the focus is on pneumococcal conjugate vaccines (PCV) and the human papillomavirus (HPV) vaccine, the paper reveals the expansive patent claims applied for or granted across the entire spectrum of vaccine development, production and use including on

vaccine-production materials such as chemical reagents, host cells, vectors, and DNA/RNA sequences; vaccine compositions; process technologies; vaccination age groups; methods of using vaccines; and vaccine schedules and presentations. These patents increased uncertainty, costs, delayed competition, leading to high prices in developing countries and hindering access. In 2016-2017, MSF filed a patent opposition and later a writ petition to challenge Pfizer's vaccine composition patent that blocked development of alternative versions of Pfizer's PCV13 vaccine. Equivalent patent granted in South Korea, compelled a Korean vaccine developer to close their production of PCV13. The patent invalidation proceeding launched by MSF towards Pfizer remains open in India concerning PCV13.

49. A similar situation will materialise with COVID-19 vaccines unless concrete steps are taken to address the intellectual property barriers. Research already discloses many patent filings and grants such as more than 100 patents on mRNA platform technologies that are used for COVID-19 vaccines.

Other Medical Products

50. In March 2020 in the Lombardy region in Northern Italy, one of the areas which was hit hardest by the pandemic an Italian hospital ran out of ventilator valves (which cost USD 11,000 each), and their regular supplier could not produce them on time. Two local engineers reverse engineered and 3D printed replacement valves for the cost of about USD 1. It is reported that the original manufacturer declined to share the blueprints and even threatened patent infringement and that potential legal implications stopped the engineers from distributing the digital design file more widely, despite receiving hundreds of requests for the 3D-printed valves".

51. Following this case, a law firm warned "[m]anufacturers should be aware of the complex intellectual property issues concerned with this 3D printing technology. Parts such as valves or other medical devices and equipment are capable of protection by patent and/or registered design. Unregistered design rights and copyright will also apply to the part itself and/or the digital model or CAD file. Some or all of these rights might apply in respect of a single component". The firm cautioned "In scanning a component such as a valve, and manufacturing a part using 3D printing equipment, there is a risk that this action will infringe an existing patent, design or copyright which protects the component, leading to an injunction or claim from the rights holder for damages or other remedies (such as delivery up of infringing parts)". Notably in In March 2020, WHO noted a shortage of ventilators around the world.

52. In another case, the Governor of Kentucky has called on multinational company 3M to release its patent for the N95 respirator — a desperately needed type of protective gear that's difficult to get during the coronavirus pandemic — so that more manufacturers can start making it. The N95 is considered top-of-the-line face protection for the professionals on the front lines of this pandemic. The Governor is reported as saying "The procurement is incredibly difficult, as is the manufacture because it's under patent. I'd like to see the people with that patent, which is 3M, provide that to the nation under a license for this period of time," adding that "I believe it's their patriotic duty, and they should put it out there so everybody else can manufacture it," he said of 3M. "That hasn't happened."

Intellectual Property Disputes

53. Emerging intellectual property disputes already threaten the development and supply of COVID-19 medical products. In one dispute Regeneron and vaccine developers Pfizer and BioNTech are facing a lawsuit from Allele Biotechnology and Pharmaceuticals alleging that their coronavirus products were developed using Allele's mNeonGreen fluorescent protein without the company's permission.

2.6 Considerations, in connection to EU's emphasis on the TRIPS flexibilities.

54. We welcome EU's emphasis on the TRIPS flexibilities. However, in the E. Commission Report on the protection and enforcement of intellectual property rights in third countries of 2020, developing countries are criticized for improving the criteria for granting compulsory licenses on the basis it undermines "effective patent protection" although the 2001 Doha Declaration on TRIPS and Public Health states in paragraph 5(b) that "Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted". For instance it states

"stakeholders report that very broad, vague and arbitrary criteria are applied for granting compulsory licenses, which undermine the effective patent protection in Ecuador, India, Indonesia and Turkey, notably for pharmaceuticals and chemicals" and in relation to India criticizes its use of TRIPS flexibilities including compulsory license.

2.7 United States of America: How do proponents envision that Members would return to compliance with their TRIPS obligations after the waiver expires?

2.8 United States of America: What effect do the proponents think that the waiver will have on innovation related to products that address the prevention containment and treatment of COVID-19? What would be the long-term implications for innovators willingness to participate in future pandemic response efforts?

55. Some Members have queried what would happen when the waiver ends and what would be the impact on future innovations. After the waiver ends, WTO Members will revert to the application of the relevant TRIPS provisions.

56. With respect to the impact of the waiver on innovations and innovators' willingness to participate in future pandemic response efforts, we reiterate that most of the R&D is driven by public investments. In addition, should we not be more concerned about how our failure to take prompt action will prolong this pandemic and consequently the suffering of people all over the world? Moreover, in a global pandemic, innovation must be open and accessible to the global community, and not be the monopoly of one or a few companies or countries.

2.9 United States of America: If the waiver were to be implemented, how long do the proponents think it will take for there to be an impact in the prevention containment or treatment of COVID? What data are proponents relying on to reach this conclusion?

57. The proponents have also been asked, if the waiver were granted, how long it will take for there to be an impact on the prevention, containment or treatment of COVID-19, and what data has been relied on to reach such a conclusion.

58. The impact of the waiver will depend on many factors. Presently there are many unknowns, as we are dealing with a completely novel pathogen. The science of COVID-19 is constantly evolving, and we are learning new things about this virus on a daily basis. Even with the therapeutics and vaccines that are showing promise, there are many unknowns including their immediate and long-term impact. We also do not know how long the vaccines will remain effective, how much immunity will be conferred, and how logistical issues will be overcome, among others. We see many measures being taken in the absence of any concrete data. Even the approvals of the current vaccines are based on interim data.

59. Hence the impact depends on a variety of factors such as the kind of technology that is involved, and information available about the technology. What is clear however is that if WTO Members decide to work together to share knowledge, technology and related IP with the aim to diversify and expand supply options, the journey to the end of the pandemic will be faster as we do know that removing IP monopoly and improving freedom to operate for manufacturers can introduce competition, expand supply and reduce prices. This is the experience we have had in handling the HIV/AIDS epidemic.

60. I hope that these responses provide more clarity to some of the specific questions posed by the Members.

61. If there is anything that COVID-19 has taught us, it is that the only way to urgently contain this threat to humanity is for the world to come together in new ways to defeat it. COVID-19 is a test of our global solidarity, and we can pass this test only if we work together for the sake of humanity. The co-sponsors, once again, call upon the WTO Members to rise to the collective call of defeating the pandemic and saving lives by supporting this proposal for temporary waiver. This will help in truly achieving equitable, timely and affordable access for COVID-19 products by removing the IP barriers to scale up the global production and supply.

2.10 United States of America: What are the expected impacts on Members' commercial and economic interests as a result of the waiver? (Japan & the European Union also claim there would be a negative impact on investment and cooperation on future R&D).

2.11 United States of America: Could the proponents explain how the waiver is a proportionate response to COVID-19?

2.12 Brazil: What are the expected impacts on authors, inventors and other creators?

2.13 Brazil: We would like to ask the proponents to share their views on possible effects of a waiver on small and medium enterprises.

62. Several questions were posed to the proponents as to how the waiver will affect WTO Members' commercial and economic interests as well as its impact on authors, inventors and other creators and SMEs.

63. COVID has wreaked havoc on national and global economies. As per WTO data, global trade is expected to drop by about 9% in 2020.[3] While trade is expected to rebound in 2021, there is a lot of uncertainty as it depends on the evolution of the pandemic.[4]

64. The COVID-19 pandemic has hit hardest the informal economy and hundreds of millions of enterprises worldwide. As per the ILO estimates global labour income has declined nearly 11% or USD 3.5 trillion in the first three quarters of 2020 and as a result, the World Bank estimates that as many as 150 million people could be pushed into extreme poverty by 2021.[5]

65. MSMEs are particularly exposed to COVID-19 pandemic's economic impact because of their size and their prevalence in the economic sectors most affected by the pandemic, such as accommodation and food services, cultural and creative sectors, and wholesale and retail services. MSMEs in almost all countries have been and continued to be most severely hit by the pandemic. In developing countries, as per the World Bank estimates, sales fell for about 84% of firms relative to the same period in 2019. The average decline was 49% and has been strikingly persistent.[6]

66. Even in the pharma sector, many MSMEs have manufacturing capacity but hindered by IP barriers they are not able to manufacture and supply COVID-19 medical products.

67. With regards to the question on expected impacts on authors, inventors and other creators**,** it depends on what the creation or invention is being talked about. If it is not related to COVID-19, then they will not be anyway impacted by this waiver, as the copyright being waived under the proposal is only in the context of rights hindering the response to COVID-19.

68. Evidently the longer the pandemic continues, with governments having to continue with measures such as lockdowns and quarantine, national and global economies will continue to suffer, with many more millions pushed into poverty. Every country is trying to reduce the impact of pandemic and come out of it. Our proposal for waiver from certain provisions of TRIPS Agreement, is one part of this effort. It is, therefore, in our mutual interest to collaborate, to help diversify and expand the supply of vaccines, therapeutics and other COVID-19 health products to curb this pandemic as soon as possible.

69. Some of the opponents of the waiver proposal may consider that they will be safe, since they have large quantities of vaccines pre-booked. But, if COVID remains unaddressed in any one country, it will affect all other countries, with serious consequences for society and the economy.

70. Some Members have argued that recent announcements from industry of the success of some vaccines, showed that the intellectual property system as a framework that provides incentives to invest and innovate has delivered. We disagree with this claim. We believe that without the huge

[3] https://www.wto.org/english/news_e/pres20_e/pr862_e.htm
[4] https://www.wto.org/english/news_e/pres20_e/pr862_e.htm
[5] https://blogs.worldbank.org/psd/firms-struggle-stay-afloat-after-losing-half-sales-still-keep-workers
[6] https://blogs.worldbank.org/psd/firms-struggle-stay-afloat-after-losing-half-sales-still-keep-workers

state funding, these vaccines would probably not have been developed so speedily. Therefore, it is not the IP system that has delivered, but the public funding and institutional support in terms of research contributions by public universities and the global sharing of sequence and public health information that has led to the development of successful vaccines in record time.

71. We need to respond to COVID with cooperation, solidarity, and equity. The aim of the waiver is to restrain the spread of COVID-19, and in the context of the current scale of devastation, the impact of the waiver would be positive. The current "business as usual" approach which is narrowly focused on supplying a few rich countries artificially limiting global supplies and competition is a greater threat to WTO Members' social, economic and commercial interests.

72. The proponents have been asked how the waiver is a proportionate response to COVID-19. 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[7], mandating wearing of masks, seeking military help etc. So, waiver is definitely a proportionate demand.

73. If we work together to waive relevant IP and enable access to knowledge and technology, we will swiftly bring the pandemic under control and save the world economy from further avoidable damage.

2.14 Brazil: How Members facing legal and institutional difficulties when using flexibilities would automatically and expeditiously overcome legislative and institutional barriers for the successful implementation of a waiver?

2.15 Whether a waiver could reveal instead to be cumbersome and difficult to implement considering that most Members would have to submit it to their national parliaments and delve into the specific rights in each of the IP domains that would fall into the scope of the measure.

2.16 Brazil: A waiver would hardly be a global solution if we consider that several Members may not implement it either because they choose not to or are unable to due to the already mentioned legislative and institutional difficulties or because they are also bound by bilateral or regional agreements.

2.17 United Kingdom (UK): How would such a waiver even operate; how would it be implemented into national legislation?

74. Proponents have been asked how the waiver can be a global solution if some countries do not implement it. If a waiver is adopted, all WTO Members would be encouraged to utilise it. The proposal we have made follows what is allowed within the parameters of Article IX of the WTO Agreement.

75. As to national implementation, we have addressed this issue at the last informal TRIPS Council. 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. Many governments are already using executive action to put in place lockdowns, quarantine and other measures to curb the spread.

76. With respect to institutional and legal difficulties when using flexibilities, this is a real challenge facing many countries. For instance, countries that have never utilised compulsory license or the Article 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 Article 31*bis*, can an importing country that has not implemented Article 31*bis* in its national law utilise the provision,

[7] https://publicservices.international/resources/news/spain-nationalises-all-private-hospitals-uk-rents-hospital-beds?id=10645&lang=en

what are the Article 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 countries and from pharmaceutical companies while dealing with such issues. Moreover, compulsory licenses are to be issued on product by product and country by country basis, making collaboration between countries near impossible. 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 COVID-19 pandemic does not present an expedited solution. In any case, it cannot be any body's case that such flexibilities were even designed keeping in view a crisis of this magnitude.

77. All of this can be avoided and millions of lives can be saved, if Members here agree to a temporary waiver from certain provisions, which can then be made use of by Member countries using emergency legislative provisions at their disposal to address the challenges posed by once in a millennium pandemic like COVID.

2.18 United States of America: How do proponents plan to suspend rights that exist without formal government registration such as copyrights?

78. We have been asked repeatedly about how the waiver will be implemented including how proponents plan to suspend rights that exist without formal government registration such as copyrights.

79. As we have mentioned, national implementation should be left to national governments as each operates within its own legal system. One size does not fit all. We also think that in many cases implementation may be done through executive action, relying on existing national legislation or through use of emergency legislative provisions.

80. More specifically, if a IP right exists such as a patent has been granted or a person is entitled to copyright protection (with or without registration) which is related to prevention, containment and treatment of COVID-19, a country may take executive action suspending enforcement of the protection conferred by the patent or copyright law to it for the duration of the waiver.

81. To the countries who have argued against the need of the Waiver, we would like to pose the following questions:

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 World Health Organization (WHO) COVID-19 Technology Access Pool (C-TAP), an initiative that encourages voluntary contribution of IP, technology and data to support global sharing and scale-up of manufacturing and supply of COVID- 19 medical and pharmaceutical products?

82. We hope that our intervention addresses the concerns raised by Members. Moreover, the proponents are ready to engage with the Members, should there be any further questions. But the objective, as stated earlier, is to reach to a common ground as early as possible, so that a large proportion of world population is not left behind in the quest for a timely, equitable and affordable access to successful vaccines and therapeutics. WTO Membership needs to act now to ensure that the pandemic should not be needlessly prolonged, only because we fail to act collectively at this juncture.

2.19 United States of America: Could the proponents provide data that establishes that the identified TRIPS obligations have systematically hindered or blocked the prevention, containment or treatment of COVID-19?

2.20 United States of America: No explanation why compliance with each of the identified TRIPS obligation creates an identifiable and undue hardship such that waiver is necessary.

2.21 Brazil: Further elaborate the rationale for including industrial designs in the proposal.

2.22 Brazil: Further specify the cases in which waiver in copyright could be pertinent for preventing containing or treating COVID-19.

83. 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.

84. In formulating the proposal, the starting point was to consider what products are needed to curb COVID-19 and what are the barriers to diversifying suppliers and scaling up manufacturing. Several key medical products crucial for curbing COVID-19 include ventilators, N95 masks and other personal protective equipment, diagnostics, therapeutics and vaccines. Global shortages of these medical products have been widely reported. Shortages are also expected as vaccines are rolled out. Due to the limited voluntary license issued by Gilead, the world also witnessed shortages of remdesivir a therapeutic once thought to hasten recovery. As new therapeutics are approved, shortages are further expected. For instance, antibody treatments by Regeneron and Eli Lilly have recently been approved by the US Food and Drug Authority for COVID-19 treatment, shortages are already expected in the US[8], while how the rest of the world will get sufficient access to these treatments remains unclear.

85. Disparity in access is the ugly reality of this pandemic that we cannot and must not ignore. The challenges of access are visible in developed country Members, but disproportionately affects least developed countries. We have provided concrete evidence of the staggering inequality in access to essential products between developed countries and least developed countries.

86. According to UNCTAD, "since the onset of the pandemic, each resident of high-income countries has benefited, on average, from an additional USD 10 per month of imports of COVID-19-related products. This number is much lower for middle income countries- at about USD 1, and lower still for low-income countries – a mere USD 0.10. In other words, per capita imports of the medical goods essential to mitigate the COVID-19 pandemic have been about 100 times larger in high income countries in comparison to low-income countries. While it should be expected that the increase of per capita imports of COVID-19 products would be larger for wealthier countries, the sheer difference is staggering."[9]

87. A solution to this challenge is to diversify and increase production and supply. This requires addressing the legal barrier of IP that prevents diversification and production. Not all categories of IP are implicated. To prevent, contain, and treat COVID-19, and more specifically for the medical technologies required, the relevant categories of IP are patents, trade secrets, industrial designs and copyright.

88. Several delegations have queried why the proposal includes industrial designs and copyright within the scope of the waiver.

[8] https://uk.reuters.com/article/us-health-coronavirus-lilly/u-s-hospitals-to-restrict-lilly-covid-19-antibody-treatment-due-to-limited-supply-idUKKBN27X1EU; https://www.bostonherald.com/2020/11/22/fda-allows-emergency-use-of-antibody-drug-trump-received/

[9] https://unctad.org/system/files/official-document/ditcinf2020d4_en.pdf

89. We would like to clarify. As mentioned, the starting point of the proposal is what tools are important to curb COVID-19. This question is what led us to investigate which categories of IP would be relevant? Industrial design and copyright protection can become barriers to reproduction of the products. We have highlighted the case in Italy where two local engineers 3D printed ventilator valves to supply a local hospital as the regular supplier could not supply the valves, and faced IP barriers.

90. Following the case a legal firm cautioned "In scanning a component such as a valve, and manufacturing a part using 3D printing equipment, there is a risk that this action will infringe an existing patent, design or copyright which protects the component, leading to an injunction or claim from the rights holder for damages or other remedies (such as delivery up of infringing parts)".[10]

91. For medical products such as ventilators, personal protective equipment and other technologies that may be relevant to curbing the spread of COVID-19, copyright and/or industrial design can be a barrier, in addition to patents and trade secrets.

92. At the last informal TRIPS Council meeting, the co-sponsors provided examples of IP barriers hindering development, production and supply of COVID-19 products.

93. The TRIPS Agreement sets minimum standards for patents, trade secrets, copyright and industrial design, that WTO Members except for LDCs have to comply with or be subject to WTO's dispute settlement mechanism. And these standards do limit the policy space available for countries to take the measures necessary to collaborate, manufacture and supply addressing the shortages mentioned. Where flexibility exists, in some cases there is also uncertainty as to its scope, while in other cases, the use of flexibility is subject to conditions and procedures. As mentioned before, since the entry into force of the TRIPS Agreement, developing countries have faced constant pressures from their trading partners to limit the use of flexibilities, often criticising actions that may be taken to simplify the use of flexibilities.

2.23 United States of America: How the waiver would directly resolve issues related to COVID-19 prevention, containment or treatment in a Member.

2.24 United States of America: Do the proponents have any data that would show how a waiver would demonstrable reduce COVID-19 prevalence or impact during the acute phase of the pandemic. We note that new pharmaceutical manufacturing capacity typically cannot be established quickly.

2.25 United States of America: If the waiver were to be implemented how long do the proponents think it will take for there to be an impact in the prevention containment or treatment of COVID? What data are proponents relying on to reach this conclusion?

2.26 United Kingdom: How would this help countries like in manufacturing capacities and even if limited in time the waiver creates long-term uncertainty and undermines the system for the future including future pandemics.

94. Several questions were posed as to how the waiver would resolve issues related to COVID-19 prevention, containment and treatment and what is the evidence?

95. It is important to note that neither the waiver alone nor any other mechanisms or policy intervention on its own, can resolve all challenges we face. Different legal and policy measures are needed to respond to different problems. The waiver by offering policy space can help leverage the full capacity globally for production and supply. We have clearly demonstrated the limitations of voluntary measures by companies. Some companies only choose to work with one or two other multinational corporation despite manufacturing capacity being available in different countries. With such an approach of course there will still be severe supply shortages.

[10] https://www.shoosmiths.co.uk/insights/articles/3d-printing-social-responsibility-vs-legal-risks

96. Some delegates may argue that in those circumstances, compulsory license can be used, including Art31*bis* license. However, as we articulated earlier, TRIPS rules today do not facilitate a collective use of compulsory license by multiple countries on all components needed to produce a medical product. Both Article 31 and Article 31*bis* licenses are territorial and used on a case-by-case basis raising difficulty of using them to leverage all untended capacity in different countries together. The waiver provides a practical alternative in the context of the pandemic so that countries can be better coordinated.

97. In addition, manufacturing capacity in this pandemic need to be discussed at the global level. Not all countries can produce everything by themselves and no single country can sustainably supply the whole world with their existing manufacturing capacity. The proposal on the table suggests that we look at a global picture of manufacturing and supply capacity and consider ways to coordinate and enable access to knowledge and technology. For countries that do not have manufacturing capacity at all at this moment in time on certain medical technologies, the waiver could open up more supply options while they do not have to stick with one or two perceived solutions and avoid being held hostage by any individual companies.

98. The challenges we face in this pandemic are novel as we are dealing with an unknown pathogen. We are constantly learning what works and does not work. Nationally as well governments are experimenting with different measures, to see what works and what does not, adapting and modifying as lessons are learned and new information becomes available. Most measures have been put in place without demonstrable evidence as to the efficacy of the measures. For instance, early on in the pandemic, many experts thought face coverings were not effective.[11] Now the guidance has changed, with most countries recommending or mandating the wearing of masks.

99. Similarly, early on in the pandemic several WTO Members such as Canada[12], Germany,[13] Hungary[14] took pre-emptive steps to amend their law to simplify the procedures for issuing CL, should they need to use it to override the patent barrier. Several other countries such as Chile[15], Colombia[16] and Ecuador[17] have issued resolutions or decree to set the stage for the issuance of compulsory licenses.

[11] https://www.independent.co.uk/life-style/health-and-families/face-masks-coverings-coronavirus-do-they-work-shops-transport-a9617666.html

[12] Canada has passed emergency legislation entitled An Act Respecting Certain Measures in Response to COVID-19. Part 12 of Bill C-13 amends the Patent Act so that, among other things, upon the application of the Minister of Health the Commissioner must authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern. Source: https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access

[13] With the Act for the Protection of the Population in the Event of an Epidemic Situation of National Significance of 27 March 2020, the Federal Ministry of Health was authorized to issue orders under Section 13, subsection 1 of the Patent Act. Section 13 was already contained in the Patent Act before the COVID-19 pandemic. The Section stipulates that a patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare (Section 13, subsection 1, sentence 1). Source: https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access

[14] According to Government Decree 212/2020 (May 16, 2020), compulsory licensing is available for patented medicinal products, active substances and medical devices, exclusively for meeting domestic demand. This regulation will remain in force until the state of danger declared by way of Government Decree 40/2020 (March 11, 2020) is lifted. However, draft legislation is already in front of Parliament that will modify Act No. XXXIII of 1995 on the Protection of Inventions by Patents to allow for the continued issuing of compulsory licenses for products and technologies used for pandemic relief. Source: https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access

[15] On March 17, the Chilean parliament approved a resolution (896/2020) declaring that the COVID-19 pandemic justifies the use of compulsory licenses for COVID-19 technologies, which can facilitate the procedure for compulsory licenses to be issued in the country. Unofficial English

[16] On March 25, Colombia approved a decree allowing the Ministry of Health to declare of public interest all medicines, medical devices, vaccines and other health technologies related to COVID-19. The declaration of public interest is a necessary step prior to the grant of a compulsory license. The decree also the flexibilization of the rules regarding registration and importation of health technologies in the country.

[17] On March 20, the Committee of Education, Culture and Science and Technology of the National Assembly of Ecuador approved a resolution asking the Minister of Health to issue compulsory licenses on all patents related to COVID-19 technologies, as well as access to test data.17 Unofficial English.

100. The waiver opens up policy space for WTO Members to take steps required to initiate manufacturing of pharmaceutical products. It is well-proven that when IP such as patents are not a barrier and a country has manufacturing capacity, generic manufacturing can and does take place. We have seen this for many products even before the pandemic. Hence the freedom to operate offered by a waiver will prove to be invaluable in expanding supply options and capacity.

2.27 United States of America: Waiver is broad. Unclear what measures would fall within or outside the scope of the waiver. With respect to scope that the proponents explain how Members would determine whether a measure is "related to the prevention containment or treatment of COVID-19 and this falls within the scope of the proposed waiver". For example, if a measure waives an intellectual property right covering a given product or book or work with the product or work have to be directly related to the prevention containment or treatment of COVID-19 in order to fall within the scope of this waiver proposal. Could the product or work be indirectly related, how indirectly related and who would make this determination.

2.28 United States of America: How is the waiver proposal targeted considering it implicates the suspension of at least 34 provisions of the TRIPS Agreement?

101. 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.

102. 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.

103. Each country will need to decide what is needed nationally to curb COVID-19 and the parameters of implementation of the waiver. The needs and conditions of each country varies, hence prescribing a one size fits all approach will not be beneficial. We should recall that the WTO Agreements including the TRIPS Agreement already provides governments discretion on how to implement their commitments and implementation of the waiver is no different. If a country decides that the waiver is inappropriately implemented in another country, it may pursue its case under the WTO dispute settlement mechanism that would continue to be available to the WTO Members.

104. In addition, it has been suggested by an opposing country, that the waiver proposal implicates suspension of at least 34 provisions of the TRIPS Agreement. We are of the view that this misrepresents the waiver proposal.

105. 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 COVID-19. 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.

106. In short, the waiver is very narrow and specific to the circumstance of COVID-19 and the key aspects of the TRIPS Agreement that can affect a country's ability to prevent, contain and treat COVID-19.

107. I am sure we all agree that COVID-19 presents an extraordinary, unprecedented challenge for the world, and no one is safe until everyone is safe, hence the call for a waiver from certain TRIPS obligations with respect to COVID-19.

2.29 Mexico, the Republic of Korea, Ecuador, and Israel: Waiver proposal is not clear enough as regards its scope and implementation and its possible implications. Additional information why current provisions are not sufficient to address concerns. ACT-A & COVAX exists.

2.30 Canada remains the only Member to have used this special compulsory licensing system under Article 31*bis* and can thus observe on the basis of concrete experience that this system has worked as intended. Article 31*bis* only used once does not suggest that the system is inadequate rather Canada believes that this suggests that the overall TRIPS regime works as part of the broader international framework that provides Members with sufficient latitude and flexibility such as there has been limited or no need to issue compulsory licenses under Article 31*bis*.

108. 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 previous TRIPS Council. We reiterate that the targets set by Act-A including the COVAX is to provide two billion vaccine doses (for one 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. At best, these initiatives offer short-term and very limited access to diagnostics, therapeutics and vaccines. The insufficiency of ACT-A and COVAX is apparent with the current wide disparity in access between the developed countries and the developing countries. For vaccines, it only aims to provide up to 20% of the needs of developing countries, which is insufficient to build global immunity. In addition, to date only 15% of the needed funding has been raised. ACT-A and COVAX also do not extend to other tools needed during a pandemic such as masks, ventilators etc.

109. 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. As explained an effective response to the COVID-19 pandemic requires access to various commodities and various types of intellectual property that is patents, copyrights, industrial designs and trade secrets may pose a barrier to the manufacturing and supply of these commodities.

110. At the informal TRIPS Council meeting of 20th November, the co-sponsors circulated patent status of several priority therapeutics for COVID-19. These therapeutics are likely to be patent protected in many jurisdictions. Let me explain how cumbersome the process will be to diversify and scale-up manufacturing simply relying on the issuance of CLs by way of Article 31 and Article 31*bis* of the TRIPS Agreement.

111. Assuming country X with manufacturing capacity decides to override the patent barriers to expand supply. It will have to issue a compulsory license based on national procedures, a process that can take weeks if lucky, but perhaps even months or years, if national laws have additional requirements or if trading partners and pharmaceutical industry interfere to dissuade its use. Some countries have special CL procedure for government use, which can help to accelerate the process but not all countries have such a fast-track procedure.

112. If this country X requires to source patented ingredients from multiple jurisdictions, each of these jurisdictions will also need to issue a CL. Each of these CLs will be limited by the condition of Article 31(f) that it has to be predominantly for the supply of the domestic market. At this juncture, country X with manufacturing capacity, although able to supply, is likely to be hindered due to the number of CLs required, and the conditions imposed. Even if country X overcomes this challenge and manufactures the product under a CL, country X will not be able to export widely to supply even neighbouring countries due to the limitation in Article 31(f) that a CL has to be predominantly for the supply of the domestic market. Instead, the manufacturing country X and each and every importing country will have to issue a CL if there is a patent and utilise the procedures of Article 31*bis* that includes among others specific notification to the WTO by importing and exporting countries specifying the quantities to be imported and exported. As more quantities are imported and exported, more notifications may be needed, in addition to other requirements such as specific labelling or marking of products; special packaging and/or special colouring/shaping of products.

113. It is also worth noting that whether or not a manufacturing takes place is very much dependent on whether economies of scale exist. Countries may have capacity to manufacture but lack economies of scale hence making manufacturing an unattractive option.

114. The country by country, case by case approach offered by CLs hinders north-south, south-south, regional and international collaboration to achieve economies of scale and ramp-up global manufacturing and supply. The waiver will remove the legal barriers and facilitate collaboration at the regional and global level, allow economies of scale to be achieved, motivating further manufacturing, and consequently lower prices. With a waiver, the administrative and procedural delays and conditions linked to Article 31 and 31*bis* will be avoided, meaning that countries will have full freedom to collaborate, manufacture and supply the required products.

115. Canada asserts that its experience shows that the Article 31*bis* mechanism has worked as intended and that it shows that the overall TRIPS regime works and that there has been limited or no need to issue compulsory licenses under Article 31*bis*.

116. We believe this assessment does not reveal the depth and complexity of the access to medicines problem facing the international community including in developed country Members even before the COVID-19 pandemic. To date the CLs issued have generally been by countries with manufacturing capacity for their own use or to import from countries that have manufacturing capacity but where patent was not a barrier. India for instance did not put in place pharmaceutical product patent protection until 2005, meaning that many pharmaceutical products were not patented in India, allowing other countries to import available generics for many years post 2005 without any concern. Several of the patent applications have also been opposed and challenged in India, and where this has been successful, generics have managed to enter the market after some years. These scenarios do not create a conducive environment to address the challenges of this pandemic, as the COVID-19 products are likely to be widely patented in countries with manufacturing capacity.

117. For many patented medicines, generic alternatives are still not available, and the originator products simply unaffordable to patients. In addition, trading partners and pharmaceutical companies have placed immense pressure on countries with manufacturing capacity, discouraging the issuance of CL. Hence even before the pandemic, many medicines that can save lives, remains out of reach of the patients that needed them. This reveals the limitations of the options provided by the TRIPS Agreement including Article 31*bis*, more so in this current pandemic.

118. In the case of Canada's implementation of the 30th August 2003 decision, we note that MSF was involved in the Jean Chrétien Pledge to Africa (JCPA) passed in May 2004, which implements the August 2003 decision which is now translated into Article 31*bis*. MSF notes in a paper on its experience with respect to the Act that it "contains over 19 sections and over 100 clauses and sub-clauses".[18] If this is indeed the case, we fail to see how such a mechanism delivers expeditious access.

119. MSF goes on to say that "Simply understanding the legislation requires legal training or support. Significant financial and human resources are necessary for a government to analyse and use this legislation – resources which are limited in many developing and least developed countries". The MSF paper also quotes Tanzania's High Commissioner to Canada, His Excellency Ombeni Sefue, which noted "It's not that we don't want to do it. It's just that we haven't because... all the bureaucratic, administrative, and legal requirements take a lot of time...The system is too complicated..."

120. We fail to see how such a mechanism can be a reliable to deliver access in this pandemic. Canada can insist it works, despite evidence to the contrary, but the failure of Canada and other WTO Members to take action will cost many lives especially in the developing world.

[18] https://msfaccess.org/neither-expeditious-nor-solution-wto-august-30th-decision-unworkable

2.31 United States of America: How would the waiver of each of the identified TRIPS obligations be implemented by a Member? For example, how would the waiver of obligations related to undisclosed information be implemented, does proponent intend to implement legislation that would release undisclosed information submitted for regulatory purposes for undisclosed information such as Trade Secrets. Will the proponents suspend their laws on trade secret theft? Have the proponents considered whether this would result in an increase in trade secret theft?

121. US posed questions on trade secret, how would it be implemented, would suspension of laws give rise to trade secret theft

122. In several common law countries, there is no dedicated legislation for trade secret protection, instead trade secrets are enforced through contract or tort law.[19] Hence the issue of suspending trade secret protection does not arise. What is relevant in the context of facilitating access to COVID medical products is to diversify and expand the production of medical products. In this context, a waiver of Article 39 of the TRIPS Agreement can be enabling.

123. We understand that the trade secret regime in US and EU recognize disclosure to advance public interest. The Re-Statement (Third) Of Unfair Competition, §40, Comment C recognized a limited privilege to disclose trade secrets, stating:

> Depends upon the circumstances of the particular case, including the nature of the information, the purpose of the disclosure, and the means by which the actor acquired the information. A privilege is likely to be recognized, for example, in connection with the disclosure of information that is relevant to public health or safety, or to the commission of a crime or tort, or to other matters of substantial public concern.[20]

124. Subsequent legislations explicitly recognizes the exception. For instance, the Economic Espionage Act of 1996 provides two such exceptions. Section 1833 of the Act states:

> Exceptions to prohibitions ''this chapter does not prohibit—''(1) any otherwise lawful activity conducted by a governmental entity of the United States, a State, or a political subdivision of a State"; or
>
> "(2) the reporting of a suspected violation of law to any governmental entity of the United States, a State, or a political subdivision of a State, if such entity has lawful authority with respect to that violation"

125. The Defend Trade Secret Act which amends the Economic Espionage Act adds the following important exceptions along with other exceptions:

> ''(i) IMMUNITY.—An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that— ''(A) is made— ''(i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and ''
>
> (ii) solely for the purpose of reporting or investigating a suspected violation of law;

126. Further, Court remedying anticompetitive aspects of a merger in *U.S. v. Bazaarvoice*, Inc, had an agreement not to enforce n its trade secret restrictions on current and past employees who were hired by the divestiture acquirer.[21]

---

[19] https://www.dlapiperintelligence.com/goingglobal/intellectual-property/index.html?t=trade-secrets&s=legal-framework

[20] Peter S Mennel Et all, Intellectual Property in the New Technological Age: 2016, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2780190, p.128.

[21] https://www.ftc.gov/system/files/attachments/us-submissions-oecd-2010-present-other-international-competition-fora/ip_licensing_us-oecd.pdf

127. Similarly, Article 5 of the EU Directive on Trade Secret[22] provides exceptions to trade secret protection:

> Member States shall ensure that an application for the measures, procedures and remedies provided for in this Directive is dismissed where the alleged acquisition, use or disclosure of the trade secret was carried out in any of the following cases:
>
> a. for exercising the right to freedom of expression and information as set out in the Charter, including respect for the freedom and pluralism of the media;
>
> b. for revealing misconduct, wrongdoing or illegal activity, provided that the respondent acted for the purpose of protecting the general public interest;
>
> c. disclosure by workers to their representatives as part of the legitimate exercise by those representatives of their functions in accordance with Union or national law, provided that such disclosure was necessary for that exercise; and
>
> d. for the purpose of protecting a legitimate interest recognized by Union or national law.

128. This clearly shows that disclosure to public authorities or disclosure to advance a public policy goal is well permitted under the laws of the US and EU. However, in many countries including the US the scope of public policy exception is determined by the court taking into account the facts and circumstances. This is time consuming and can delay the required result in pandemic time. In the present circumstances the waiver will bring the legal clarity with regard to the scope of exception to trade secret.

129. We would also quote an Associate Professor of Law David Levine from the US who has said "not all secrets deserve unwavering protection, and not all alleged "trade secrets" are actual trade secrets. As difficult, time-consuming, and expensive as it may be, because information may not qualify as a trade secret upon closer inspection and because public needs may need to trump private, profit-maximizing interests, we should always question, interrogate, and weigh any designations of untrammeled trade secret protection over valuable information. If it turns out that an alleged "trade secret" is actually a trade secret, then a harder question must be asked: Should the trade secret be shared anyway? In the COVID context, certain trade secrets might serve society more thoroughly through wider access, allowing full technology transfer that would foster rapid expansion of needed manufacturing capacity and reduced pricing".[23]

2.32 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.

130. 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 COVID-19. 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.

[22] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L0943&from=EN
[23] http://infojustice.org/archives/42493

2.33 Further clarification about safety, quality counterfeit medicines.

131. 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.

132. The grant of IP or being an 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.

133. 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 mechanism that also looks at substandard and falsified medical products.

134. 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.

2.34 Some Members have queried why TRIPS flexibilities and COVAX are insufficient to address the challenge of access posed by COVID.

135. 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 two billion vaccine doses (for one 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.

136. 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.

2.35 Some delegations (Brazil, the European Union, and Switzerland) have referred to document 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. The European Union mentioned that it would be interested to know more about these medicines.

137. 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.

138. 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.

139. 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.

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

141. 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.

142. The patent landscape in document 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 World Intellectual Property Organization (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.

2.36 The European Union 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?

143. 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 Article 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 Article 31(f) that it has to be predominantly for the supply of the domestic market, meaning only very limited export is allowed.

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

145. 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 countries, 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 31*bis* of this Agreement and the provisions of the Annex to the TRIPS Agreement.

146. 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).

147. 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.

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

149. 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.

150. Also worth recalling that Article 31 and 31*bis* only addresses patent barriers while there are also challenges with respect to protection of undisclosed information, a barrier which remains unaddressed. On this, especially Article 39.3, the European Union, US and other developed country Members 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.

151. 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.

152. Strangely, developed country Members 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 European Union's annual IP enforcement report and US' annual "Special 301 Report", released in the midst of a raging COVID-19 pandemic.

2.37 Some delegates (e.g., US) asked for data regarding how certain obligations have systematically hindered prevention, treatment, and containment of COVID-19 so that a waiver is needed.

153. 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.]

154. 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 the European Union's annual IP enforcement report and the annual "Special 301 Report", which was released even amidst the COVID-19 pandemic!

155. Several delegations highlight TRIPS flexibilities, particularly compulsory license under Article 31 and Article 31*bis*, 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 European Union and Switzerland both highlight the flexibilities as the key measures for Members to use, does it mean the European Union 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 United States Trade Representative (USTR) do the same to its Special 301 report?

156. We notice the recent IP action plan and pharmaceutical strategy published by the European Commission which urges European Union Members to use fast track compulsory license and explore coordinated compulsory license in the European Union. 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.[24] 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."

157. 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"?

158. The European Union 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 European Union 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 European Union 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."

159. Following on from President Ursula von der Leyen's State of the Union call for the establishment of an European Union BARDA, the European Union'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?

160. We would counter the European Union'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 European Union IP Action Plan's recommendation that European Union Member "establish fast-track procedures to issue compulsory licenses in emergency situations"?

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

2.38 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?

162. As the European Union has opted out of Article 31*bis* of the TRIPS Agreement, how would the European Union Members 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"?

[24] https://ec.europa.eu/commission/presscorner/detail/en/speech_20_2212.

2.39 Brazil: International collaboration and voluntary licensing could and should be used for the purposes of scaling up production of medical products and guaranteeing sufficient and affordable supply.

2.40 United Kingdom: Voluntary licensing is supporting the availability of medical equipment and existing mechanisms that facilitate the sharing of Ip and know how are being geared to address COVID-19.

163. Several countries have repeatedly suggested that voluntary licensing should be used or is being used to scale-up production suggesting that such voluntary licensing (VLs) are providing sufficient affordable supply and facilitating the sharing of IP to address COVID-19.

164. We find these assertions to be completely divorced from reality. Nine months into the pandemic, VLs have proven to be either non-existent or insufficient.

165. For instance, in the case of Remdesivir, despite receiving significant public funding, Gilead signed secretive bilateral licenses with a few generic companies of its choosing that excludes supply to nearly half of the world's population including many developed and developing countries such as Brazil and Mexico.[25]Its limited supply has also been reserved mainly for wealthy nations.[26] WHO has recently delisted the medicine from COVID-19 treatment, but this shows a typical negative example of VL.

166. VLs where they exist are shrouded in secrecy. Usually, their scope is limited to specific amounts or for a particular country or for a limited subset of countries, thereby encouraging nationalism rather than international collaboration. Notably some companies have not signed any agreements to expand manufacturing and supply. Each country is in race with others to secure supply. This is the antithesis of international collaboration. For example, at least 82% of the recent Pfizer/BioNtech vaccine that is claimed to be 90% effective has been pre-booked by developed country Members representing 14% of the global population[27]. To date, there is no public commitment to share its vaccine knowledge, technology and related intellectual property, so that affordable supply may be expanded.[28]

167. Moderna announced that "while the pandemic continues, it will not enforce our COVID-19-related patents against those making vaccines intended to combat the pandemic" adding that "we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period".[29] While this announcement is a step forward, manufacturers will need a firmer commitment for the sake of legal certainty. Some other companies also hold mRNA technology patents, and Moderna's non-enforcement announcement alone is not sufficient to provide legal certainty.[30] There is also no commitment to share know-how that would also be protected. Uncertainty also prevails over what is meant by "while the pandemic continues" and what licensing arrangements will be applicable post-pandemic etc.

168. We are extremely concerned that these *ad hoc*, non-transparent and unaccountable initiatives only lead to artificially limit supply and competition. In a global pandemic, these "business as usual" approaches will surely cost more lives.

169. Earlier this year, WHO launched a solidarity call to action that calls on holders of knowledge, intellectual property or data to existing or new therapeutics, diagnostics and vaccines to voluntarily license such rights on a non-exclusive and global basis or voluntary non-enforcement of intellectual property rights, to facilitate the wide scale production, distribution, sale and use of such health

[25] https://www.citizen.org/news/remdesivir-should-be-in-the-public-domain-gileads-licensing-deal-picks-winners-and-losers/

[26] https://edition.cnn.com/2020/07/01/health/remdesivir-drug-supply-us-intl/index.html

[27] https://www.independent.co.uk/news/health/covid-pfizer-vaccine-doses-latest-uk-supplies-b1721162.html

[28] A shot at recovery Measuring corporate commitments towards a free, fair, and accessible COVID-19 vaccine, https://www.oxfamamerica.org/explore/research-publications/shot-recovery/

[29] https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19

[30] https://www.nature.com/articles/d41573-020-00119-8

technologies throughout the world. About 41 governments and several international agencies have supported this initiative, but such collaboration has been spurned by the pharmaceutical industry. [31]

170. We have to ask ourselves, how we can sincerely say that this current situation amounts to international collaboration.

2.41 United Kingdom (UK): On test data and other undisclosed information or to Article 39.3 of the TRIPS Agreement sets out that undisclosed test for other data shall be protected against disclosure unless necessary to protect the public.

2.42 United Kingdom: It is also important to note that the way the regulatory framework is inextricably linked to the IP framework and has an integral role to play in ensuring the efficacy and safety of COVID-19 treatments as they are developed. How would a waiver be able to ensure that these standards particularly safety and quality standards or maintain an essential question relevant to another pressing challenge vaccine hesitancy.

171. The UK mentioned that the regulatory framework is linked to the IP framework and plays a role in ensuring efficacy and safety of COVID-19 treatment and queried how a waiver would ensure standards of safety and efficacy and address vaccine hesitancy.

172. We would like to clarify that the objective of the regulatory system is to ensure quality, safety, and efficacy of medical products. But IP has nothing to do with quality, safety and efficacy of a product. For instance, the grant of a patent does not guarantee quality, safety or efficacy. The primary purpose of IP is to prevent third parties from using the protected subject matter without the permission of the IP holder.

173. The waiver would greatly contribute in ensuring transparency in COVID clinical trial data which in turn will increase confidence in the use of COVID therapeutics and vaccines especially vaccines hesitancy. Article 39.3 of the TRIPS Agreement states "Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.". While disclosure is allowed to protect the public, there is constant pressure from trading partners and the pharmaceutical industry to limit the flexibility allowed under TRIPS Article 39.3.

174. The 2020 EU Report on the protection and enforcement of intellectual property rights in third countries, finds that "[a]nother area of continued concern reported by right holders is the absence of an effective system for protecting undisclosed test and other data generated to obtain a marketing approval for pharmaceuticals [……] This problem affects the European industry mainly in Argentina, Brazil, China, India, Indonesia, Malaysia, the Russian Federation, the Kingdom of Saudi Arabia, Ukraine and the United Arab Emirates."[32]

175. Similar pressures have been seen from the US as well.

176. In view of this, from the perspective of public health, the waiver would be a very positive development. It would give regulatory agencies the confidence to disclose clinical trial and other relevant data in the public interest which in turn generates confidence in using the relevant diagnostics, therapeutics and vaccines. This is especially important given the rapid processes involved in the development and approval of therapeutics and vaccines that may give rise to vaccine hesitancy and other uncertainty over the safety and efficacy of a product.

2.43 Some delegations have argued that the IP system provides the necessary incentives for development and commercialization of the products.

177. We have addressed this point in significant detail during the informal discussions.

178. It is a fact that R&D for emerging infectious diseases has typically depended on public funding and not the IP system. And COVID-19 is not different. Billions of public money has been spent on

[31] https://www.ft.com/content/9ed5ca5e-9360-11ea-899a-f62a20d54625
[32] https://trade.ec.europa.eu/doclib/docs/2020/january/tradoc_158561.pdf

R&D and manufacture of the vaccines. For instance, in the case of Pfizer/BioNtech vaccine, there has been USD 546 million of public investment[33], and more than USD 6 billion has been spent on supply deals. It is also reported that Moderna's R&D is mostly publicly funded and it has received commitments of over USD 1 billion for purchase of the vaccine.[34] AstraZeneca has gone so far as to state that the development of the vaccine will have no financial implications for the company since "expenses to progress the vaccine are anticipated to be offset by funding by governments and international organisations."[35]

179. Given this reality, in a global pandemic, we fail to see the logic of maintaining IP monopolies that limit global supply and competition, and require taxpayers to repeatedly bear the cost of these IP monopolies.

2.44 Some delegations 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.

180. In the situation of unprecedented social, health and economic crisis that we are facing today, insufficient supply and inequitable access to COVID-19 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 COVID-19 pandemic. We had explained the rationale behind this argument in significant detail over the previous meetings. However, I would like to reiterate some points raised earlier in our intervention.

181. Article 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 31*bis*. Countries that have never utilised compulsory license or the Article 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 Article 31*bis*, can an importing country that has not implemented Article31*bis* in its national law utilise the provision, what are the Article 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 COVID-19 pandemic does not present a viable solution.

182. 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.

183. 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. Waiver being sought for a limited period and that too only from some specific TRIPS provisions in the context of COVID does

[33] https://assets.oxfamamerica.org/media/documents/A_Shot_at_Recovery.pdf; https://www.reuters.com/article/us-health-coronavirus-eu-pfizer-exclusiv-idUSKBN2800IC; https://www.thesun.co.uk/news/13169692/pfizer-covid-vaccine-cost-uk-600million-ten-oxford-jab/

[34] https://assets.oxfamamerica.org/media/documents/A_Shot_at_Recovery.pdf

[35] https://www.astrazeneca.com/media-centre/press-releases/2020/covid-19-vaccine-azd1222-showed-robust-immune-responses-in-all-participants-in-phase-i-ii-trial.html

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.

2.45 The European Union 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.

184. 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 itself. 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.

185. 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 Article 39 of the TRIPS Agreement.

186. 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.

187. 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 COVID-19 Technology Access Pool. Existing licenses are non-transparent, restricted and limited. We have addressed this matter extensively in the informal consultations.

188. 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.

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

190. 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, which we all need to reflect upon, and that can be answered only through true solidarity and global 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 COVID-19 and Beyond: Trade and Health initiative by the European Union, Switzerland, Canada and few others, which talks about enhanced preparedness to fight against current and future pandemics. 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 prove 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.

2.46 It was mentioned during informal consultations and today that advance purchase agreements contributed to expanding production calling on companies to use licensing mechanisms to maximise production. Reference was made to Astra Zeneca's license with Serum Institute. We would like to take this opportunity to address some of the points raised by a delegation in the last meeting. Do such agreements actually expand global production; and do they enable equitable and timely access?

191. In our view, the race to secure vaccine supplies through advance purchase agreements is in fact, reinforcing inequitable access to vaccines. Even if production is being expanded, it seems to be for the benefit of a few wealthy nations. As reported openly, all of Moderna's vaccine and 96% of Pfizer/BioNTech's has been acquired by rich countries. It has also been reported that wealthy nations representing just 14% of the world's population have bought up fifty-three (53%) of all the most promising vaccines so far. According to several reports, some countries have already made arrangements to acquire up to nine doses per person, while among 70 developing or poor countries, only one out of every ten people will be vaccinated by the end of 2021 given the limitations of the COVAX facility. It is also estimated that many lower income countries could have to wait until 2023 or 2024 for vaccination.

192. This situation reveals a lack of global cooperation and solidarity to ensure equitable access and allocation. More specifically, IP monopolies are limiting vaccine production and equitable access. Regarding Astra Zeneca's license, it must be emphasised that the license is limited, and insufficient to meet global need. Their pledge to provide doses to developing nations, can only reach 18% of the world's population next year at most. Besides, Astra Zeneca's CEO has reportedly opposed any public sharing of technology and IP.

193. While we appreciate the idea of asking companies to voluntarily license and maximise production, the strategy does not deliver access. A recent study on the lessons learned from voluntary licensing also demonstrates that IP-holding corporations tend to apply restrictive licensing terms such as limited geographic coverage of supply and other conditions that limit the benefits of competition and global supply. We have already seen this happening during the pandemic. The global pharma industry has also objected to participation in WHO's COVID Technology Access Pool.

_____