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Council for Trade-Related Aspects of Intellectual Property Rights

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RESPONSE TO QUESTIONS ON INTELLECTUAL-PROPERTY CHALLENGES EXPERIENCED BY MEMBERS IN RELATION TO COVID-19 IN DOCUMENT IP/C/W/671

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

1 INTRODUCTION

1. In document IP/C/W/671, Australia, Canada, Chile and Mexico raised eight questions for the consideration of the Council for TRIPS. These questions follow communication in document IP/C/W/669 on Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, now co-sponsored by the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe. This waiver proposal has received global support from civil society, intergovernmental organizations, human rights and other experts and most importantly from many WTO Members.

2. Shortcomings in ramping up the manufacturing of specific COVID-19 diagnostics, equipment, therapeutics or vaccines are well-recognized by all the Members. And it is surprising that even after the experience of last ten months, certain Members are asking these questions. Whereas the same Members are applying a sequencing or prioritising criteria for administering preventive or curative treatment for COVID-19 in their respective jurisdictions. So, this is beyond our comprehension that Members are recognizing the issue of shortage in supply and at the same time asking question whether we are facing any challenges in ramping up production**.**

3. The Waiver proposal is to ensure that complications arising from intellectual property rights protection do not delay response or lead to suboptimal response from the countries around the world affecting lives of all people. Management of a pandemic needs a swift response and it is in the interest of all countries that every country has the capacity to fight this through vaccines, therapeutics and devices. IP had proved to be a substantive barrier during the HIV crisis and continues to affect access to medicines in the treatment of many diseases. The pandemic has a huge social cost and if unaddressed through swift and appropriate action by each country, will create negative externality for every country.

4. TRIPS Article 31 and 31*bis* do not address the situation created by a pandemic where every country in the world is affected and the numbers impacted continue to rise. Article 31 mainly addresses country specific measures such as in situations of a national emergency, extreme urgency or when the medicine is required for public non- commercial use. Article 31 does not address a situation where the world as such is impacted.

5. Waiver is therefore required because a disease like the COVID 19 needs collaborative action in social interest while IP protected products promote private interests only. Exercise of relief limiting the rights of the right holder will be time consuming and considering the extent of the crisis will have considerable human cost.

6. In this communication, the co-sponsors respond to questions raised in document IP/C/W/671. The responses should be read together with communication titled Examples of IP issues and barriers in COVID-19 pandemic (document IP/C/W/670), and interventions made at the formal and informal

sessions of the Council for TRIPS clarifying and responding to issues and concerns raised with respect to the waiver proposal.

2 RESPONSES

2.1 Question 1: Have Members, or organizations acting on their behalf, experienced IP challenges that have impeded or prevented the timely procurement of COVID-19 diagnostics, equipment, therapeutics or vaccines? If so, can Members describe these challenges, including in relation to the TRIPS Agreement.

7. To revisit IP challenges experienced by countries in the COVID-19 pandemic, it is critical to first clarify that the understanding of IP challenges needs to consider at least five aspects:

(1) the immediate blocking effects on production and supply, such as those arising from patents on medicines and other IP;
(2) the effects of restrictive IP management that limits the production, supply and procurement options, such as those associated with selective and exclusive voluntary licensing practices;
(3) the effects of legal uncertainty and delay on alternative and independent development and production, such as those associated with patent thickets and IP disputes;
(4) the emerging and anticipated barriers that arise alongside the evolving product development pipelines, concerning both background IP and foreground IP-related to COVID-19 health technologies, for instance the unpublished patents on pipeline medicines, vaccines and diagnostics; and
(5) the effects of different types of IP on different aspects of COVID-19 health technologies and their combined effect on availability and affordability, for instance, the combined effect of patents and undisclosed information on medicines, vaccines and diagnostics.

8. Addressing each of these IP challenges requires either removing existing barriers or anticipating emerging barriers and adopting legal measures to enable quicker and easier actions when needed. The need to address IP challenges with a global outlook also challenges WTO Members to look beyond existing legal options under the TRIPS Agreement which adopts a product-by-product and country-by-country scenario.

9. Early in the pandemic, some developed country Members (e.g., Canada, Australia, Germany, Hungary etc.) amended laws to enable quicker and easier procedures for the grant of compulsory licenses to overcome possible IP barriers to COVID-19 technologies, without any specific instance of IP barriers necessitating the actual use of such a measure. These law revisions were done to enable and prepare the governments to act rapidly to address IP barriers, if they were to arise.

10. As explained below, in the context of a pandemic, compulsory licenses offer imperfect solutions. But these examples clearly show the importance of measures to address any possible IP barriers to ensure timely procurement and supply of needed medical products. The revisions also demonstrate shortcomings in existing laws on compulsory licensing and the need for additional measures in responding to the new challenges of COVID-19.

11. We therefore stress in the TRIPS Council that the waiver proposal provides a legal option under the WTO framework for countries to use in addressing IP challenges (that are either present or that might arise) to expand global supply and facilitate access. An individual country's legal preparation is insufficient to address global needs. When a country prepares its law for quicker issuance of compulsory licenses, and some countries have issued compulsory licenses in this pandemic, the measure only benefits the concerned individual country.

12. In addition, the waiver proposal also goes beyond the product-by-product scenario that is currently embedded in the TRIPS Agreement.

IP challenges: IP landscape and restrictive voluntary licensing

13. Examples of IP challenges are detailed in document IP/C/W/670, in which both the emerging IP landscape of pipeline medical products and exclusive and limited voluntary licensing practices have presented ongoing challenges for the prediction, preparation and management of procurement options for countries.

14. For therapeutics, in addition to examples provided in document IP/C/W/670, recent news reports[1] suggest that two anti-inflammatory medicines have shown positive results in treatment. The two medicines – tocilizumab and sarilumab – have both been repurposed for COVID-19 treatment but are not widely available especially in developing countries. As mentioned in document IP/C/W/670, the primary patent on tocilizumab expired in 2017, but multiple secondary patents remain granted in many countries. While for sarilumab, the primary patent on the drug and secondary patents on its formulation have been granted or filed in at least 55 developing countries.[2] This situation poses a challenge for alternative supply of these medicines.

15. On vaccines, as mentioned in document IP/C/W/670, the emerging landscape of both background and foreground IP on key vaccine technologies, and the IP disputes that have already occurred during the pandemic underline evident IP challenges in ensuring legal certainty for vaccine development and supply, especially when some of the main vaccine producers continue to pursue monopolistic approaches in their IP management.

16. **In addition to the patent landscape, exclusive and limited restrictive voluntary licensing practices continue to pose challenges for procurement options for countries.**

17. As mentioned in document IP/C/W/670, Gilead signed limited voluntary licenses on Remdesivir with a few generic companies and excluded many developing countries, including most South American countries, from being supplied under the licenses and benefiting from alternative generic sources. A number of countries that are excluded from the voluntary licensing have generic production capacities.

18. Regeneron also holds patent on a monoclonal antibody pipeline candidate – REGN10933+REGN10987, as mentioned in document IP/C/W/670. However, the company has chosen only one partner for the production and supply, although there are many biologics producers in different countries, including in developing countries, which have the capacity to produce and supply. Such practices artificially limit competition and supply, reducing the prospect of procurement for countries globally.

19. Presently, high-income countries have bought up the majority of the existing vaccine supply capacity, which poses a significant challenge for COVAX, and consequently for supply to low- and middle-income countries (LMICs) and other developing countries. Obviously, this is not a sustainable situation. One of the key reasons underlying insufficient supply and impacting procurement is the way major vaccine developers are managing their IP and technologies. If we allow ramping up of manufacturing, and diversifying of supply options there will be more timely and equitable distribution.

20. For instance, Oxford/AstraZeneca's vaccine candidate is one of the vaccines included in COVAX for supply. Reportedly the company has signed limited, restrictive and selective licenses, and even their terms and conditions are not fully available publicly. A few other vaccine developers, such as Pfizer/BioNtech, have not even indicated any plan for out-licensing their IP-protected technologies for production and supply.

21. Some Members opposing the waiver proposal argue that the issuance of voluntary licenses is a matter of contract law and not related to the TRIPS Agreement. However, it is imperative for the TRIPS Council to recall the objectives of the TRIPS Agreement under Article 7 on promoting the dissemination of technologies and the protection of mutual advantage of producers and users, as well as its principles under Article 8.1 and 8.2 empowering Members to take necessary measures to protect public health and to **prevent** the abuse of intellectual property. In light of Articles 7 and 8 of the TRIPS Agreement, the non-intervention of Members with respect to restrictive voluntary licensing practices, and the lack of sharing technology, knowledge and related IP in this pandemic is clearly detrimental to public health and is undoubtedly an issue of concern related to the TRIPS Agreement.

[1] https://www.bbc.com/news/health-55574662

[2] https://www.medspal.org/?product_standardized_name%5B%5D=Sarilumab+131.6+mg%2Fml&product_standardized_name%5B%5D=Sarilumab+175+mg%2Fml&disease_areas%5B%5D=COVID-19+(drug+candidate)&page=5

2.2 Question 2: With respect to the local production or manufacture of specific COVID-19 diagnostics, equipment, therapeutics or vaccines, have Members, or organizations acting on their behalf experienced IP challenges that have impeded or prevented local production or manufacturing? If so, can Members describe these challenges, including in relation to the TRIPS Agreement?

22. Document IP/C/W/670 already provides multiple examples concerning IP challenges impeding production and supply. Recalling the interconnection between procurement, production and supply as mentioned under question 1, it is important to bear in mind that IP challenges concerning local production involve the immediate blocking effects, the restrictive licensing practices of IP holders and other anticipated challenges associated with the emerging pipelines.

23. During the TRIPS Council meeting on 10 December 2020, Indonesia shared information on challenges it faced with respect to local production of Remdesivir, i.e., it failed to convince Gilead to expand its production in Indonesia through voluntary licensing to address shortages and affordability of the medicine. Indonesia added that importing the medicine was more costly and difficult due to limited supply and higher price in the region.

24. In respect to vaccines, past experience has shown that under conventional IP practice, patents could be applied for on nearly every single step and aspect of vaccine development, production and use,[3] ranging from starting materials, composition process and the final products to methods of filling and packaging, methods of vaccination and vaccine schedules. In addition to patents, trade secrets also are a challenge. Given the conventional trade secret and patenting practice on vaccines, the huge legal uncertainty it brings to leveraging production capacities, and augmenting supply and use during this pandemic cannot be overlooked.

25. Some Members opposing the waiver proposal mentioned the example of mRNA technology as an important innovation. Yet, the IP situation around mRNA technology raises clear challenges for leveraging the full potential of this technology in COVID-19 vaccine development and production although this technology is considered by the scientific community as having potential for the rapid development and scale-up of manufacturing at a lower cost.[4]

26. As mentioned in document IP/C/W/670, the literature has identified more than 100 background patents on mRNA platform technology used for COVID-19 vaccine development that are owned by different entities. Several patent disputes have arisen between different COVID-19 mRNA vaccine developers. Thus, even if one patent-holding company has announced its decision to not enforce its mRNA patents during the pandemic, such an announcement has no effect on other holders of mRNA patents and provides no clarity and legal certainty for other vaccine developers using the platform. As mentioned above, one patent holder has indicated no plan to license-out their IP on their vaccine candidate, and the other has not shared openly manufacturing know-how after its patent non-enforcement announcement. The remaining patent thickets, the insufficient voluntary actions also effectively limit the potential of scaling up manufacturing and supply of mRNA vaccines globally.

27. Some Members opposing the waiver proposal hold the view that the waiver could affect ongoing technology transfer under voluntary licenses when it comes to ramping up production. We consider this premise as lacking any basis. Do such Members have any evidence to prove this? On the contrary, it is evident that limited and restrictive voluntary licenses have resulted in shortage of essential COVID supplies. As mentioned, existing voluntary licenses have not been transparent and only very limited information is available in the public domain for scrutiny. In any case, the proposed waiver does not affect terms and conditions of agreed voluntary licensing agreements; those terms and conditions continue to be effective and can be implemented without interruption.

[3] https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf

[4] https://www.nature.com/articles/nrd.2017.243

2.3 Question 3: Have Members formally initiated processes toward the issuance of compulsory licenses under Article 31 of the TRIPS Agreement in relation to any COVID-19 diagnostics, equipment, therapeutics or vaccines, but were unable to complete these processes and issue any corresponding compulsory licence due to circumstances other than those attributable to domestic legislation, procedures, or litigation? If so, can Members identify what prevented the issuance of any such compulsory licence?

28. It is important to look at the merits and challenges of using compulsory licenses under Article 31 of the TRIPS Agreement from historical contexts and from the perspective of the public health needs in the present ongoing pandemic.

Challenge in relying on Article 31 to contain COVID-19 globally

29. In the context of COVID-19, we recognize that Israel and the Russian Federation have issued compulsory licenses for domestic use of certain medicines used for treatment of COVID. However, Article 31 was never designed to address the global access challenge of a pandemic as its primary focus is to empower individual countries to solve domestic problems with production and supply. In this pandemic, as we have collectively experienced and witnessed to date, supply of essential medicines, vaccines and diagnostics requires actions beyond national borders. Using compulsory licensing under Article 31 will not leverage uninterrupted collaboration for countries to share production and supply capacity and to walk out of this pandemic together.

30. To ensure access, the supply of needed medical products needs to be expanded and diversified to the maximum level at the international level. This in turn requires countries and manufacturers to have full freedom to operate and to not be hindered by intellectual property where such issues exist or are emerging. In document IP/C/W/670, the preliminary patent landscape of several priority therapeutic candidates and vaccine candidates for COVID-19 has been provided.

31. In the current situation where every country is suffering and in desperate need of adequate supplies, relying mainly on Article 31 to address IP challenges in ensuring global access is seriously ill-advised. Article 31 offers a country-by-country, case-by-case and product-by-product solution. This means that for every product, wherever there is a patent barrier, each country will need to issue compulsory licenses either to manufacture, import or export the product or its components.

32. In addition, the use of Article 31 is also subject to certain conditions, in particular that the use is predominantly for the supply of the domestic market of the Member authorizing the use, meaning its use is mainly for the purpose of supplying domestic needs. Hence country by country compulsory license remains unsuitable to facilitate regional and global collaboration, and the ability of governments and manufacturers to freely manufacture, import and export needed products and their components to curb the spread of COVID-19. Under Article 31, the legal validity of the authorized compulsory licence may also be challenged, hindering expeditious supply.

33. Further Article 31 only pertains to patents. The proposed waiver will also address other needed IP on COVID-19 medical technologies i.e. industrial designs, copyright and trade secrets.

34. WTO Members, including countries opposing the waiver proposal, have repeated in various forums that "no one is safe until everyone is safe". In December, we saw this come true, with the spread of new variants of the coronavirus that are even more transmissible, resulting in many more infections and deaths globally. The sooner all countries around the world receive the needed medical products including diagnostics, vaccines and therapeutics, the better the world, including countries that are opposed to the waiver proposal, will be for it.

35. In times of a global pandemic, what we need is to maximize sharing of knowledge, technology and exploiting available manufacturing capacity. And this aim cannot be met by merely relying on Article 31 of the TRIPS Agreement. There should be full freedom to operate by waiving relevant TRIPS provisions.

Pressure tactics from trading partners and patent holding corporations

36. It is also important to note that the history of use of Article 31 is fraught with pressures from developed country Members and patent-holding pharmaceutical corporations. In document

IP/C/W/670, some examples of pressure tactics on developing countries with respect to use of compulsory licensing and other flexibilities have been provided.

37. In 2020 in the midst of a raging pandemic, the Office of the United States Trade Representative (USTR) issued its Special 301 Report citing "actions by trading partners to unfairly issue, threaten to issue, or encourage others to issue compulsory licenses," and specifically highlighting Chile, Colombia, Egypt, El Salvador, India, Indonesia, Malaysia, the Russian Federation, Turkey, and Ukraine.[5] The report "urges Chile to ensure transparency and due process in any actions related to compulsory licenses" although ironically transparency and due process are mostly absent in voluntary licensing. It further adds that "Chile should use compulsory licenses only in extremely limited circumstances and after making every effort to obtain authorization from the patent owner on reasonable commercial terms and conditions".

38. The European Commission in its 2020 "Report on the protection and enforcement of intellectual property rights in third countries" complains 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…." [6]

39. These assertions contradict the provisions of Article 31 and the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which reaffirms that "Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted". Further, Article 31 is also clear that the requirement to have first sought prior authorization from the right holder is waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, and in cases of anticompetitive practices.

40. Similarly, patent-holding pharmaceutical industry has consistently undermined the use of Article 31 of the TRIPS Agreement. The Pharmaceutical Research and Manufacturers of America (PhRMA) in their Special 301 Submission 2020 states: "In its 2019 Special 301 Report, USTR rightly highlighted concerning actions by 'trading partners to unfairly issue, threaten to issue, or encourage others to issue, compulsory licenses' and committed to 'engage, as appropriate, with trading partners'. PhRMA members welcomed these statements and urge USTR and other federal agencies to engage to address serious and growing compulsory licensing threats across Latin America, Southeast Asia and elsewhere."[7]

41. These are just a few examples of the immense pressure that has been placed on developing countries in the last 25 years, deliberately introducing legal uncertainty and limiting the scope of available flexibilities and discouraging efforts to improve national legislation implementing TRIPS flexibilities as well as to use compulsory licensing.

42. In this context, it is rather surprising to expect all WTO Members to have expedited provisions for using compulsory licenses and to be ready and able to use such licenses efficiently. In 2020, Australia, Germany, Canada and Hungary amended their national laws to simplify and/or facilitate the use of compulsory licensing for public health purposes (without any specific instance of IP barriers necessitating the actual use of such a measure) demonstrating that even developed country Members found shortcomings in their national legislations to address pandemic-related challenges.

43. Generally we recognize the need for all WTO Members to have optimal public-health-sensitive provisions that maximize the flexibilities provided by Article 31. We condemn efforts to undermine and limit the use of Article 31 and support the use of compulsory licenses not as a "last resort" but based on national needs including public health needs as envisaged by Article 7, Article 8 and Article 31 of the TRIPS Agreement and the 2001 Doha Declaration on the TRIPS Agreement and Public Health. While a number of delegates opposing the waiver proposal have explicitly acknowledged the importance of using TRIPS flexibilities and compulsory licensing, they however have not acknowledged the historical suppression nor committed to ensuring that in future developing countries will no longer be put under such pressures.

[5] https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf
[6] https://trade.ec.europa.eu/doclib/docs/2020/january/tradoc_158561.pdf
[7] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/PhRMA-2020-Special-301-Submission.pdf;

2.4 Question 4: Have Members formally initiated processes toward the issuance of compulsory licenses under Article 31*bis* in relation to COVID-19 pharmaceutical products, but were unable to complete these processes and issue any corresponding compulsory licence due to circumstances other than those attributable to domestic legislation, procedures, or litigation? If so, can Members identify what prevented the issuance of any such compulsory licence?

44. The question posed sidesteps issues with respect to the complexity of Article 31*bis*. For more than a decade, experts, civil society and even generic manufacturers have viewed the mechanism as unworkable, as evidenced by the fact it has only ever been used once and even this experience is reported to have been difficult.

45. Citing its experience, Canada has repeatedly asserted that the Article 31*bis* mechanism works. However, the generic supplier involved has pointed out that the system is "unnecessarily complex and does not adequately represent the interests of those who require treatment".[8]

46. In addition, Médecins Sans Frontières (MSF), which was also involved in Canada's implementation of the 30th August 2003 decision, i.e. in the Jean Chrétien Pledge to Africa (JCPA), has noted in a paper on its experience with respect to the Act that it "contains over 19 sections and over 100 clauses and sub-clauses",[9] adding that "[s]imply 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".

47. We fail to see how such a mechanism can be a reliable means to deliver access in a pandemic of this magnitude. The requirements of Article 31*bis* are cumbersome (see table below). In addition to these procedures, the national laws/regulations of the exporting and importing countries may have additional extensive requirements, which vary from country to country.

48. The need for compulsory licensing in the exporting and importing countries, the requirements for specifying quantity in each notification and the requirements of differentiating packaging and other characteristics in each supply are simply impractical in a global pandemic, the biggest global health crisis facing nearly all countries. As we have collectively experienced, the transmission and spread of the virus have outpaced interventions in many countries. Hence the requirements of Article 31*bis* are not fit for the purpose of dealing with the pandemic challenge facing the international community where timely intervention is the essence.

[8] https://www.biospace.com/article/releases/apotex-inc-life-saving-aids-drug-for-africa-gets-final-clearance-/

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

Table

The requirements of Article 31*bis* include: (1) notification to Council for TRIPS by eligible importing Member: (i) specifies the names and expected quantities of the product(s) needed; (ii) confirms 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 Article 31*bis*; and (iii) confirms 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 the TRIPS Agreement and the provisions of the Annex. Least developed countries are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector. For other eligible importing Members, insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways: (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply. In addition, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion, to prevent re-exportation of the products that have actually been imported into their territories under the system. (2) compulsory licence by importing Member (if patent exists) (3) compulsory license by exporting country with the following conditions: (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS; (ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and (iii) before shipment begins, the licensee shall post on a website the following information: - the quantities being supplied to each destination as referred to in indent (i) above; and - the distinguishing features of the product(s) referred to in indent (ii) above. (4) notification to Council for TRIPS by exporting Member: 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 referred to above.

Scenario analysis with respect to Article 31 and 31*bis* of the TRIPS Agreement

49. Assume country X with manufacturing capacity decides to override the patent barriers to expand supply. It will have to issue a compulsory licence based on national procedures on a product-by-product basis, a process that can take weeks at best, but perhaps even months or years, especially if national laws have additional requirements or if trading partners and/or the pharmaceutical industry interferes to dissuade its use. Some countries have compulsory licensing procedure for government use, which can help to accelerate the process, but not all countries have such a fast-track procedure. If this country X is required to source patented ingredients from multiple jurisdictions, each of these jurisdictions will also need to issue a compulsory licence.

50. Each of these compulsory licenses 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

compulsory licenses required, and the conditions imposed. Even if country X overcomes this challenge and manufactures the product under a compulsory licence, it will not be able to export widely to supply even neighbouring countries due to the limitation in Article 31(f) that a compulsory licence 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 utilize the procedures of Article 31*bis* outlined in the table above. 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.

51. It is also worth noting that whether or not 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.

52. The country-by-country, case-by-case approach offered by compulsory licenses hinders North-South, South-South, regional and international collaboration to achieve economies of scale and ramp up global manufacturing and supply.

53. On the other hand, the proposed waiver requires only a one-time implementation and, for the duration of the waiver, will remove legal barriers and facilitate collaboration at the regional and global levels, allow the inclusion of multiple technologies in its scope, 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.

2.5 Question 5: Have Members experienced copyright-related challenges in specific instances of procurement or of seeking local manufacture or production of COVID-19 diagnostics, equipment, therapeutics or vaccines? Specifically, have Members experienced any such challenges that could not be addressed through the implementation of the flexibilities contemplated in the TRIPS Agreement? If so, can Members describe these challenges, including in relation to the TRIPS Agreement?

2.6 Question 6: Have Members experienced industrial-designs-related challenges in specific instances of procurement or of seeking local manufacture or production of COVID-19 diagnostics, equipment, therapeutics or vaccines protected by industrial-design rights? Specifically, have Members experienced any such challenges that could not be addressed through the implementation of the flexibilities contemplated in the TRIPS Agreement? If so, can Members describe these challenges, including in relation to the TRIPS Agreement?

54. The responses to question 5 and 6 have been combined as they cover overlapping issues and designs may also be protected under copyright law.

55. It is surprising that the questions seek information about specific instances wherein copyright-related and industrial designs-related challenges have been faced, which could not be addressed through the implementation of the flexibilities contemplated in the TRIPS Agreement. For instance, there has been no denial regarding the instance given below, which has been widely reported in the media. We would be happy to receive any information from Members if such incidences did not handicap the global COVID response.

56. In March 2020 in the Lombardy region in Northern Italy, one of the areas which was hit hardest by the pandemic, a hospital ran out of ventilator valves (which cost USD 11,000 each), and their regular supplier could not produce them on time.[10] Two local engineers reverse-engineered and 3D-printed replacement valves at a cost of about USD 1.[11] It is reported that the original

[10] https://metro.co.uk/2020/03/16/firm-refuses-give-blueprint-coronavirus-equipment-save-lives-12403815/ and https://www.techtimes.com/articles/248121/20200317/maker-ventilator-valves-threatens-sue-volunteers-using-3d-printed-coronavirus.htm

[11] https://www.techtimes.com/articles/248121/20200317/maker-ventilator-valves-threatens-sue-volunteers-using-3d-printed-coronavirus.htm

manufacturer declined to share the blueprints and even threatened patent infringement[12] 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.[13]

57. Following this case, a law firm warned that "[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".[14] 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)."[15]

58. This case reveals complex intellectual property issues involved in the manufacture and procurement of needed medical technologies and their parts. Industrial design and/or copyright issues arise not only in the context of 3D printing (which has played a crucial role globally in addressing scarcity of supplies) but also with respect to other health technologies such as product information documents or product labelling, diagnostic kits, software for medical devices and digital technologies.

59. With regard to industrial designs, Article 26.2 of the TRIPS Agreement allows exceptions to the rights conferred on the owner of industrial designs if these are limited, do not unreasonably conflict with the normal exploitation of protected industrial designs, and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties. According to an information note by the WTO Secretariat, some Members' laws provide for exceptions such as private use, use for experimental or teaching purposes or prior use of a protected design. These exceptions are inadequate, and they also provide less clarity on the use for public interests, hence additional legal measures are needed to protect the use for public interests.

60. Copyright limitations and exceptions involve a three-step test under Article 13 of the TRIPS Agreement: limitations or exceptions be confined to (i) special cases; (ii) which do not conflict with a normal exploitation of the work, and (iii) do not unreasonably prejudice the legitimate interests of the right holder. The scope of these limitations and exceptions is vague and there is uncertainty with regard to their application for public health purposes and in situations of emergency.

61. In January 2020, South Africa submitted a communication (document IP/C/W/663) highlighting that there is disagreement over the interpretation of the three-step test among academic scholars and as is reflected in state practice, adding that it would be useful to address the relationship between the TRIPS Agreement and the three-step test for limitations and exceptions to copyright in order to further clarify the flexibilities afforded to Members to fulfil their obligations in implementing the objectives and principles of the TRIPS Agreement. The lack of clarity poses a risk for WTO Members.

62. In addition, identifying the various IP claims involved with respect to a particular product or technology, the IP holders, and negotiating the terms of use involve a costly, time-consuming, and complex process as products and technologies involve multiple IP holders. IP holders may also simply refuse to license their IP. In times of an emergency, such legal issues should not hinder an urgent public health response.

63. Hence the call for a waiver from relevant provisions of the TRIPS Agreement for the prevention, treatment and containment of COVID-19. In any case, waiver is only an enabling provision that the Members can choose whether to implement.

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[12] https://www.techtimes.com/articles/248121/20200317/maker-ventilator-valves-threatens-sue-volunteers-using-3d-printed-coronavirus.htm

[13] https://www.forbes.com/sites/amyfeldman/2020/03/19/talking-with-the-italian-engineers-who-3d-printed-respirator-parts-for-hospitals-with-coronavirus-patients-for-free/#1529841378f1

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

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

2.7 Question 7: Have Members experienced challenges in specific instances of procurement or of seeking local manufacture or production of COVID-19 diagnostics, equipment, therapeutics or vaccines with underlying undisclosed information? In any such instances, have Members experienced challenges with the application of the flexibilities outlined the TRIPS Agreement, due to circumstances other than those attributable to domestic legislation, procedures, or litigation? If so, can Members describe these challenges, including in relation to the TRIPS Agreement?

64. A widely publicized instance[16] is the case where a pharmaceutical company initially refused to release the recipe for a solution, a lysis buffer, needed for the COVID-19 diagnosis tests that would have helped laboratories to quickly produce their own solution and to increase their testing capabilities. However, following public pressure and threat of investigation for possible abuse of market position, the company agreed to release the recipe for others.

65. As in the above case, access to proprietary test materials has been a challenge in other countries as manufacturers could not meet global demand. In April 2020, *The New York Times* reported that "Scientists in Africa and Latin America have been told by manufacturers that orders for vital testing kits cannot be filled for months, because the supply chain is in upheaval and almost everything they produce is going to America or Europe".[17] In South Africa as well, similar challenges have been reported as testing materials are protected as trade secrets.[18] Most of South Africa's diagnostic infrastructure requires the use of proprietary test materials, including reagents, consumables and cartridges, hence preventing laboratories from making their own test materials or procuring test materials from sources other than the diagnostic machine's manufacturer.

66. Article 39 of the TRIPS Agreement deals with the protection of undisclosed information. Article 39.2 sets out the criteria for information that qualifies for protection. Article 39.3 outlines obligations to protect against unfair commercial use of undisclosed test or other data the origination of which involves considerable effort submitted to the regulatory authorities as a condition of approving the marketing of pharmaceutical products which utilize new chemical entities. In addition, under Article 39.3, 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.

67. There is significant controversy around the interpretation of protection against "unfair commercial use". Generally some developed country Members have argued that this involves granting the originator of data exclusive rights with the effect that national authorities would not be permitted during the exclusivity period to rely on data they have received in order to assess subsequent applications for the registration of similar products. On the other hand, developing countries have generally been against this position. It is against this background that developing countries have faced constant pressure, from developed country Members, advocating restrictive interpretations of Article 39 and hampering use of flexibilities.

68. For instance, 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."[19]

69. In addition, except in the case of data submitted to regulatory authorities, Article 39 is generally silent about flexibilities available in other circumstances. The lack of clarity with regard to available flexibility creates a chilling effect on its use. As such, a waiver will support countries to take appropriate actions with respect to COVID-19.

[16] https://www.statnews.com/pharmalot/2020/03/27/roche-covid19-coronavirus-netherlands/ ; https://www.ftm.nl/artikelen/roche-releases-recipe-after-public-pressure-while-european-commission-considers-intervention-due-to-coronavirus-test

[17] https://www.nytimes.com/2020/04/09/world/coronavirus-equipment-rich-poor.html

[18] https://www.spotlightnsp.co.za/2020/05/05/covid-19-behind-sas-shortages-of-test-materials/

[19] https://trade.ec.europa.eu/doclib/docs/2020/january/tradoc_158561.pdf

70. It will also support disclosure of all data and documents submitted to regulatory agencies, and strengthen public trust in therapeutics and vaccines developed for COVID-19.

2.8 Question 8: In relation to the above questions, as the TRIPS Agreement is a minimum-standards agreement that is given effect via the applicable domestic laws of its Members (per Article 1.1), how would the proponents envisage giving effect to such a waiver under Members' domestic IP legal regimes? Put another way, what specific legal amendments or actions would the proponents seek to enact for the prevention, containment, and treatment of COVID-19 that are not – or may not be – consistent with the TRIPS Agreement and its flexibilities?

71. 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 and disaster management legislations or any other relevant legislative methodology may be relied upon to provide for executive action to operationalize the waiver at the national level. Implementation of the waiver at the national level can also be done in the same way as for the unprecedented steps, like lockdowns, quarantine and other measures, put in place to curb the COVID spread.

72. Each WTO Member can decide on the modality of implementing the waiver in a speedy and appropriate manner. It could be implemented through the enactment of statutory laws, amendments to existing laws, or administrative measures, as suitable to a country in the context of its particular circumstances.