**South Africa’s intervention at the Informal TRIPS Council, 20 November 2020**

Thank you, Madame Chair.

Let me join other co-proponents in thanking Members for their very active participation in the last TRIPS Council meeting. As our co-proponent Kenya indicated, the objective of this meeting is to respond to issues that Members raised the last meeting of the TRIPS Council. Those opposing the waiver proposal have repeatedly suggested that voluntary approaches offer the best solution. As would have been emphasized, the TRIPS waiver proposal is supportive of any voluntary licenses issued by companies, however the terms of such licenses are often such that they may restrict access or reserve supply only for wealthy nations. Amidst a global pandemic, Gilead signed secretive bilateral licenses for Remdesivir with a few generic companies of it’s choosing that excludes supply to nearly half of the world’s population including many developed and developing countries.[[1]](#footnote-1)

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 countries representing 14% of the global population[[2]](#footnote-2), 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.[[3]](#footnote-3)

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.[[4]](#footnote-4) Some companies are not offering prices at a not-for profit price, charging anywhere from $20[[5]](#footnote-5) to an estimated $40 per dose[[6]](#footnote-6), which would cost governments billions of dollars. Pfizer and BioNTech are expected to make at least $13 billion from their vaccine next year.[[7]](#footnote-7)

Madam Chair,

Ad hoc, non-transparent and unaccountable bilateral deals that artificially limit supply and competition cannot reliably deliver access during a global pandemic. These bilateral deals do not demonstrate global collaboration but rather reinforces “nationalism”, enlarging chasms of inequity.

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”.[[8]](#footnote-8) 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.

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

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.[[9]](#footnote-9) Some voluntary licenses even exclude the manufacturing countries from supplying their home country markets.[[10]](#footnote-10) Hence, conventional voluntary licenses do not offer a sustainable path to resolving the COVID-19 pandemic.

**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.**

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**

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.[[11]](#footnote-11) 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.

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.[[12]](#footnote-12) 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[[13]](#footnote-13), 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[[14]](#footnote-14) on the drug even though the WHO was about to disclose that through its own trials the drug was not effective.[[15]](#footnote-15)

In therapeutics, monoclonal antibodies (mAbs) holds promise for curbing COVID-19. Many mAbs are currently in development for treatment and prevention of COVID-19.[[16]](#footnote-16) 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.[[17]](#footnote-17) Prices also remain prohibitively expensive.

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.[[18]](#footnote-18)

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 US$450 million deal in July to sell to the US enough doses of its antibody treatment, REGN-COV2, to treat around 300,000 people.[[19]](#footnote-19) Similarly Eli Lily has announced an agreement with the U.S. government for US$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).[[20]](#footnote-20)

**Diagnostics**

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.[[21]](#footnote-21) 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.[[22]](#footnote-22)

Shortages of testing materials in developing countries have also been widely reported as most supplies are destined for the US or Europe.[[23]](#footnote-23) 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”.[[24]](#footnote-24) This situation prevents laboratories from making their own test materials or procuring test materials from sources other than the diagnostic machine’s manufacturer.

MSF in its analysis[[25]](#footnote-25) 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”[[26]](#footnote-26).

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[[27]](#footnote-27) , either at once or on a regular basis[[28]](#footnote-28), as a route out of the pandemic.

And yet, the disparity in testing between developed countries and other countries is vast. As of 11th November, reported tests for every one million population, was approximately 342 000 in developed countries, 81000 in developing countries and 9700 in LDCs.[[29]](#footnote-29) 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[[30]](#footnote-30) 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**

45 vaccine candidates are in human trial, while about 10 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.

The effects of patents in hindering the introduction of affordable vaccines in developing countries have been published by MSF.[[31]](#footnote-31) 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.

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.[[32]](#footnote-32)

**Other Medical Products**

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 $11,000 each), and their regular supplier could not produce them on time.[[33]](#footnote-33) Two local engineers reverse engineered and 3D printed replacement valves for the cost of about $1.[[34]](#footnote-34) It is reported that the original manufacturer declined to share the blueprints and even threatened patent infringement[[35]](#footnote-35) 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”.[[36]](#footnote-36)

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”.[[37]](#footnote-37) 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)”.[[38]](#footnote-38) Notably in In March 2020, WHO noted a shortage of ventilators around the world.[[39]](#footnote-39)

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.[[40]](#footnote-40)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**

Emerging intellectual property disputes already threaten the development and supply of COVID-19 medical products.[[41]](#footnote-41) 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.[[42]](#footnote-42)

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