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Mustaqeem De Gama Q&A: Philanthropy Will Not Fix Lack of Vaccine Access

South Africa is campaigning for the World Trade Organization (WTO) to waiver intellectual property rights on all products related to COVID-19 for the duration of the pandemic. Mustaqeem De Gama, Counsellor at South African Permanent Mission in Geneva, is leading the campaign. Kerry Cullinan and Elaine Fletcher spoke to him about the reasons why he sees the WTO initiative as central to efforts to get COVID treatments and vaccines to people worldwide.

Health Policy Watch: What kind of support do you have for the waiver proposal, which was discussed at WTO TRIPS Council on Friday? Other than India, it seems that mostly smaller countries support it.

Mustaqeem De Gama: From our consultations, we have a feeling that we have majority support for this proposal. You can actually see it from what happened in the first meeting of the TRIPS Council where we had introduced the proposal on 16 October. There were about 40 interventions. At least 30 to 31 were positive, while 9 said they could not support this. About 12 or 13 countries have no condition on their support, 15 or 16 countries support the waiver but have a few questions, and then the third group said that they could not support our idea.

We also had statements from the African Group, the Least Developed Countries group, and from the Africa-Caribbean-Pacific Group, all favourably disposed to the proposal. I haven't done a headcount, but I think a big proportion of the 164 member countries would be in support of this proposal.

HPW: The ball game seems to flip back and forth between the WTO and the COVAX initiative: between the WTO, and big philanthropy, donor-driven models like Bill Gates - which funds a lot of vaccines at accessible prices and pharma agreements for the creation of voluntary licenses for vaccines with generic manufacturers - which gives countries the option to act at national level.

MDG: We are happy to work within the confines of multilateral approaches with, for instance, the ACT Accelerator [Access to COVID-19 Tools (ACT) Accelerator], its vaccine access arm, COVAX, and the COVID-19 Technology Access Pool (C-TAP).

What our waiver proposal says is: let's make available any drug, vaccine or technology that will help everyone to deal with COVID-19. So from that perspective, the COVAX initiative that could make available vaccines to low and middle-income countries, is welcomed. COVAX is a good start however it is not a long-term solution.

We are also able to work with voluntary licenses given by companies such as AstraZeneca.

Every little bit helps us to achieve the quickest possible access, but these approaches do not result in ramping up the production capacity. They are limited to only a handful of producers.

Look at the volume projections of the Pfizer vaccine for example: 50 million doses before the end of this year and 1.5 billion by the end of next year, with pre-order purchases that have already been put in by rich countries. Even if countries such as South Africa, which self-fund under COVAX, were to try to purchase this vaccine in the open market, there's no guarantee we could get access to enough within the timelines required to establish effective access.

We are confronted with a situation where, even if COVAX could procure large volumes, there would not be enough vaccines to cover a substantial part of the population. It is projected that, for low- and middle-income countries, only 20% of the population will be covered. But this is not even feasible now, given various issues that have arisen, such as a two-dose regimen. This is now becoming the standard and it effectively halves the number of people who can be vaccinated. There will be limited benefits for the developing world that has limited ability to pre-purchase vaccines.

By the end of 2021, COVAX could possibly come to an end. From that point of view, we think that's the shortcoming of institutions that are run on the basis of gifting or philanthropy. They are not effective long-term mechanisms because these only have a short-term time horizon. It's a good idea in principle but is hampered by funding problems and issues around transparency.

Our waiver proposal is supportive of these processes, but we don't think that they go far enough. Every country should be in a position to take control of the public health challenges that it faces.

HPW: What emerged from the meeting last Friday in the TRIPS Council and what are the next steps? Are South Africa and its allies going to ask for a vote on the issue?

MDG: There has been a lot of focus on a vote. But the WTO works on consensus. We don't have to go to a vote to get an outcome. We feel that this process could benefit from greater political oversight in the WTO General Council, as opposed to the TRIPS Council. We are working on a report to take to the General Council next month for further consideration and discussion. Then we will rely on the General Council to give further direction, including possible recommendations.

We are also trying to demystify the proposal and build further support. At last Friday's meeting, there was a good discussion on core issues, but we ran out of time. So we want to use the next few weeks to reach out to both like-minded and opposing delegations to explain our position, and also build a coalition and consensus among like-minded groups.

We want the WTO to show that it is part of the solution to COVID-19, and not part of the problem. This is an organisation that has competence in trade-related matters: this is where intellectual property rights come in. There is a powerful role for the WTO to play to ensure that everyone has access to what they need to try and address the epidemic, whether it is in prevention, diagnosis or treatment.

HPW: Are you open to fine-tuning this waiver, and possibly confining it to vaccines, tests treatments, ventilators and PPE – a more defined set of the public goods?

MDG: There are four broad categories of intellectual property rights that we suggest could be suspended for the duration of the pandemic: copyright, industrial designs, patents and undisclosed information.

We think that there are good reasons to suspend them. First, COVID constitutes an international emergency, which is part of the requirements to invoke the waiver in the first place. Secondly, the waiver has a specific scope of application. And thirdly, It should be in place until a vaccination or COVID is largely defeated, that is it applies only for a limited time period.

HPW: Are you saying that the problems go beyond patents to also include "trade secrets", copyright and industrial designs? Can you explain why these are important right now?

MDG: Currently, a lot of patents require disclosure of information when they are filed. Companies get a monopoly if they disclose the 'new thing' that they did, and for that they get the right to a 20-year patent, for example.

But many companies are not doing that anymore or rely on other modes of protection. They are going the "trade secret" route - [which is a separate category under the TRIPS agreement]. In the last four or five years, we've seen most industrialised countries upgrade these aspects of their laws that are not necessarily included in the patent application. For example, what doses and combinations work could be considered trade secrets and hence protected. The same applies to test data, medical formulas, in the case of vaccines and other biological medicines: cell lines and genomic information can be held as trade secrets.

There is very limited experience in dealing with trade secrets, I cannot think of any publicly available information where a national authority would have issued a compulsory licence to [enable a local manufacturer to produce a product that is covered by a "trade secret"], and the same could be said for industrial designs or copyright. We have to remember that copyright also protects databases, compilations, algorithms and mobile data that can be leveraged for the detection and control of COVID-19. These are novel issues. South Africa requested the TRIPS Council to discuss these issues previously when it submitted a communication entitled: "Beyond Access to Medicines and Medical Technologies Towards a More Holistic Approach to the TRIPS Flexibilities." [dated 17 July 2020, contained in IP/C/W/666.]

We have very little experience in how we could apply government measures to force disclosure on some of these if the rules are not clear. So, we thought we should give a little bit of flexibility for things to happen in the interim which would also give governments the ability to access certain types of information in order to scale up production or the address aspects such as detection, prevention and control of the coronavirus.

HPW: How will the waiver happen in an orderly and legal fashion?

MDG: The proposal has caused a lot of anxiety for many countries. They ask if we are saying that we need to invalidate half of the TRIPS agreement. Our answer is a very simple ‘no’. The waiver will be agreed at the level of international commitment and every country will decide on how it wants to benefit from the waiver.

We don't believe that countries will suspend all the IP rights that are mentioned, nor are they required to do so. They may do it selectively. Some don't have production capacity but may want to import generic versions of medicines that could be effective, not only for COVID but also for the comorbidities that are associated with COVID. They may import a very narrow range of pharmaceuticals, or they may want to import a vaccine if it is being produced. Other countries may have needs on the diagnostic side. Some countries may have needs in terms of testing, access to buffers, and so forth. The waiver presents a bespoke solution to all countries that need it. If a country decides that it does not need to invoke the waiver, it is free to do so as well.

Countries will have to decide what their greatest needs are and implement the waiver from that perspective. The waiver is not a blank cheque to waive all legitimate IP obligations. That's why we've limited the scope of application to cover on COVID and related products and processes, and left it to the discretion of individual members to invoke aspects that they require.

HPW: But if each country can invoke that part of the waiver that it wants to use, wouldn’t that create a real hodgepodge that undermines an international agreement?

MDG: We have the 2003 waiver decision that creates an exception for countries that don't have manufacturing capacity, now embedded in Article 31bis of the TRIPS agreement. Countries may invoke this system, known as the paragraph 6 system, however the procedure is fraught with both procedural and substantive hurdles which makes it difficult to use. It has only been used once.

Nonetheless, when this waiver was implemented, certain industrialized countries indicated that they would not use this waiver in any way while other countries said they will only use it in emergency situations. It is no different with this waiver proposal, countries may choose they want to use the waiver and - for transparency purposes - may notify the WTO just as would have been envisaged under the 2003 waiver.

When countries invoke the waiver, the “law of the jungle” will not apply. At a national level, when you issue a compulsory license, there are specific processes that are followed in which the rights of all parties are protected, including the licensor and the licensee. The principle of good faith also applies in this situation.

HPW: You are saying this won’t be the “law of the jungle”. How will that be ensured?

MDG: People are creating this Frankenstein monster about the waiver but this should not be the case. This is an opportunity to have collaborations that will strengthen our ability to deal with future pandemics. The waiver is a short-term solution, it is opening up the possibility for longer-term, more sustainable solutions. We have to build a better system after COVID to ensure resilience in the face of future challenges.

In a pandemic of this nature, it's unlikely that states will act in bad faith and do things that they are not allowed to do. Once the period for which the license has been granted is over, those rights are fully recovered by the rights holder. But we also believe in the process we could create other avenues for collaboration. It is in our common interest to protect IP, but only to the extent that it respects the balance between rights of holders and the public interest. Thus when such rights are 'limited' it is done under conditions of the rule of law and national legal parameters that will ensure that such information is nonetheless protected.

I can't imagine that my grandmother and her friends will now request the 'recipe' for a vaccine, to make it in a kitchen sink. There are only a handful of countries and producers that can do that. The fear of abuse is totally irrational and unfounded.

HPW: AstraZeneca has come out with news that their vaccine is 90% effective, and as well as not requiring freezer storage, that vaccine can be sold at US$3 a dose - isn't that good news still for low and middle-income countries like South Africa?

MDG: We have AstraZeneca saying their vaccine is 90% effective, Moderna saying theirs is 95%, and then you have a restatement from Pfizer. There's no peer review on the exact figures so who is to say that these companies are correct. There is still a way to go with most of these vaccines. We cannot go on the companies' words. They will have to submit vaccines for regulatory approval. Let's see whether authorities share the same views as the companies as to the efficacy claim around their vaccines.

We ought also to observe how companies will share data about their vaccines. Will vaccines make less people infectious or will they only prevent severe illness? This is not yet clear from information that companies have made available. Since the SARS-CoV-2 virus accumulates in the upper respiratory tract before causing symptoms, there is the possibility that vaccines will not necessarily prevent people from spreading the virus even if they may be largely immune to the virus. I think there is still a long way to go with COVID-19.

While pricing may be cessional for as long as the pandemic lasts, companies have ultimate discretion on how they will apply these in a highly lucrative market which is estimated to be worth in excess of US$40 billion worldwide. Who will make the decision when the pandemic is over? I think without intervention, profit will prevail over lives.

HPW: What about global production capacity to make a vaccine?

MDG: Many pharmaceutical companies have sold or outsourced their production capacity, including companies such as Moderna and AstraZeneca. This is a problem because they have very little in-house production and are reliant on third-party producers.

This is why they are now licensing to third parties in the developing world, not because they are magnanimous but because they just don't have the capacity to produce at the rate that is required.

You'll see more and more of these voluntary licenses, but it's a throwback to the model that pharmaceutical companies and biotechnology companies would have chosen to advance their agendas. The fact that they entered into these licensing agreements does not indicate it is because they like us: it shows they need us.

HPW: You indicated in your address to the TRIPS Council on Friday that some pharmaceutical companies that had declared that they would operate on a "no profit principle", but some of these companies have retained the legal power in their licensing agreements to suspend this principle as early as July 2021. What's the implication of that?

MDG: Allowing companies to say when the pandemic is over is certainly problematic. The signals of the 'home country' is likely to be decisive in such a decision. But as soon as that country declares the pandemic is over in its own territory, companies will invoke provision in the licensing conditions entitling them to move from no profit to exorbitant profit.

Part of the transparency requirements that we put on the table, asks companies to make available the licensing agreements in full so that we can know what it costs for them to produce their vaccine, as well as disclosing any funding received from governments, whether directly through subsidies or indirect through collaboration with publicly funded institutions. The same logic would apply to disclosure of information regarding the effect of vaccines: how long immunity lasts, whether boosters will be required outside a two dose regimen that frontrunners are signaling. If so, how long? Six months, a year or longer? It's just too early to tell. COVID-19 seems likely to become endemic.

At present, we don't even know what the collaboration agreements might mean. Information has emerged of a collaboration agreement with Aspen [a generic manufacturer] in South Africa but we don't know what the full extent of their license agreement is except to say that 300 million doses will be produced. We are not certain whether some doses will go to South Africa. If so, how many, and what will go to the African continent?

HPW: Why is South Africa one of the countries leading this campaign?

MDG: South Africa's stance is not new. The country took pharmaceutical manufacturers to court [for medicine pricing] under President Nelson Mandela's government, while Dr. Nkosazana Dlamini-Zuma stood accused of trying to steal IP rights because of amendments to health legislation. The positions that we have taken are consistent with the mandates that we have in our Constitution on access to health and the right to life.

Our delegation has raised these issues for at least the last 4 years in the TRIPS Council, but was met with deafening silence. When confronted with issues of access, high pricing, and

the unfair competitive practices of pharmaceutical companies, developed countries merely respond that these are not matters for the TRIPS Council and that they should be dealt with somewhere else. But if these matters are raised in the World Health Assemblies, then they say these are IP matters that should not be raised in the World Health Organisation so where should we raise these issues?