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FEMINISTS 4 A PEOPLE'S VACCINE PODCAST EP8 Transcript



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If Not Now, When? The Need to Adopt the TRIPS Waiver *With Sangeeta Shashikant, Clara Alves and Vanita Nayak Mukherjee*

Vanita [00:00:04] Welcome to the Feminists for a People's Vaccine podcast, a space for imaginations, discussion and feminist analysis from the Global South. In this creative journey, we approach the tough questions brought to life by the pandemic. Join us to look at this once in a lifetime event as a passageway to imagine a fair and just world for all.

Clara [00:00:34] I am Clara Alves. I am a Brazilian activist for access to medicines, working in the advocacy unit of the Brazilian Office of Doctors Without Borders, and I'm very glad to have Sangeeta Shashikant, who is a legal and policy adviser for the Third World Network. So it's a pleasure to have you here today. Thank you very much, Sangeeta.

Sangeeta [00:00:55] Thanks, Clara. Thanks for having me on this podcast.

Clara [00:00:58] I'd like to start by saying that I know you have a long experience with access to medicine mobilisation and advocacy at many levels of work, so I believe it would be amazing to know how do you plan and put in practice your activism in the face of such powerful, influential international actors such as the Big Pharmaceutical transnationals facing a space that is also complex and very difficult to access, such as the WTO, the WHO. To illustrate this huge challenge, could you maybe tell us about the civil society mobilisation for the WTO Ministerial in November 202, last year?

Sangeeta [00:01:39] So, one role that TWN, Third World Network place my organisation place is to track, to monitor and to engage where it is possible to engage with international discussions and negotiations that have a development impact. So, for instance, in this case, we very closely follow inter-governmental discussions and negotiations at the World Trade Organisation, the WTO,

and the World Health Organisation, the WHO. And one issue that we have been following very closely since the onset of the COVID-19 pandemic has been around the issue of access to COVID-19 pharmaceutical products and equity. As you know, access to COVID-19 pharmaceutical products is a huge challenge in the global South, in the developing countries. And, in particular, we have been following the issue of the proposal to waive certain obligations from the intellectual property agreement known as the TRIPS Agreement. These are international rules that are set at WTO. So the issue of TRIPS waiver, the proposal, which is now co-sponsored by 65 developing countries and globally supported was a topic of interest ahead of the Ministerial Conference of the WTO. And we were very much engaged. And, as I mentioned, not only do we follow and track these issues, but also engage and where it is possible support governments and civil society from the global South by providing analysis, information on latest development and building capacity. It's basically to support the engagement at the international level so that they are able to address core issues that impact development at the national level.

Clara [00:03:14] And maybe we can continue to speak on the TRIPS waiver proposal, which has been an important demand of the access to medicine movement during the pandemic. Could you tell us a little bit more about this initiative tabled by India and South Africa, how it emerged and how the negotiations have progressed after more than a year it was first presented. I know some moments were quite emblematic, like the shift of the US position. So how was the mobilisation for the waiver received these ups and downs, how is going on today?

Sangeeta [00:03:47] So the TRIPS rule proposal was submitted in October 2020 by India and South Africa, and the proposal is to waive specific provisions of the World Trade Organisation agreement on intellectual property. This is known as Trade Related Aspects of Intellectual Property Rights, the TRIPS agreement, and this agreement sets out the international rules with respect to intellectual property such as patents, trade secrets, copyright and industrial designs. So it really emerged as a recognition of the need to diversify manufacturing and expand supply options. When the COVID-19 broke out, there were limited supply of medical products and the demands of rich countries were prioritised. Production is heavily concentrated and all of this affected access in developing countries. Now, to contain the pandemic, we need equitable access, and this has got two elements to it: availability and affordability. And this requires in turn for there to be scaling up of global manufacturing. We need to diversify suppliers globally and especially in developing countries. So that is the motivation behind the TRIPS waiver proposal that was submitted by India and South Africa, but it has generated a huge, vast support globally. It is now co-sponsored by 65 countries and supported by the majority of the WTO membership and not just WTO members, but it has received extensive global support from civil society, trade unions, academics, parliamentarians, Nobel laureates, world leaders.

Sangeeta [00:05:21] Now what is it proposing? It is really proposing specifically with respect to COVID-19, to waive the obligations that governments have in the WTO with respect to a certain intellectual property that could actually affect the scaling up of production. And I want to stress: it is limited to COVID-19, the prevention, treatment and containment of COVID-19 and would be for a very specific duration. So it is really responding to the emergency that we are facing currently. It is about recognising at the WTO level that countries have the option or freedom to operate by suspending implementation and enforcement of relevant intellectual property obligations for the purpose of containing COVID-19. So, by doing so, we are actually avoiding some of the procedural and administrative delays in addressing intellectual property barriers. There will be greater freedom to collaborate amongst countries with respect to development and production.

It can also facilitate economies of scale. We currently do have flexibilities within the WTO TRIPS agreements, such as compulsory licence, and they are very important for access. But there are limitations because the scale of challenge confronting us is huge, global, and, you know, when we talk of compulsory license, for instance, is more limited in the context of patents. So, what I would say is, you know, if we look at the history of intellectual property in the TRIPS agreement, we have been discussing its impact on access and it's now recognised that it has an effect on access. And the intellectual property rules at the international level came about as a result of lobbying efforts of intellectual property associations and multinational companies such as Pfizer. And it was made at that time, very few developing countries were even aware of the impact of these rules. And, you know, at that point, promises were being made as to what developing countries would gain out of, for instance, agriculture. Of course, we have not gained there, but instead we have woken up to the fact that these rules that are that internationally have huge impact on access, and we see this very clearly in the context of COVID-19. And while there are some policy space, you know, we call them flexibilities, TRIPS flexibilities, but the history of countries trying to use these flexibilities is they often come under pressure not to use them. All right, where countries have tried to use them, they are threatened by developed countries. And so given the scale of emergency we are facing, given the global access needs, the waiver is really about providing an additional tool to empower governments to take action towards equitable access. And, of course, if it's adopted, it has to cover all the health products and technologies that are needed to control the pandemic. And that is why the waiver is limited to COVID and the waiver by its very nature would be for a specific duration. So we do need a waiver that would cover at least vaccines, diagnostics and therapeutics because we really need to bring an end to this pandemic. It has had such huge social and economic consequences. While developed countries have had the resources, financial, fiscal, policy resources to address the impact, developing countries are especially vulnerable. They have less resources to deal with the impact of COVID-19. So I think we all have the task of doing everything we can, ensuring at the international level we adopt all the relevant policies and waivers that are needed so that governments can do what is necessary at the national level.

Clara [00:08:50] Yes, it's time to use everything we have. And you spoke about the compulsory license and how it works for patents. And we know also that some countries have been in favor of just breaking patents, suspend patents. But, as you normally say, and we know, it's not enough, because there are other many IP rights, such as trade secrets, that also must be suspended. So I think it would be very interesting to hear from you how those other rights also act as barriers to accessing COVID-related technologies.

Sangeeta [00:09:25] So, the first point I want to make is, when we talk of using the flexibilities or even in the context of the waiver: this is not about breaking patterns. It is about exercising rights governments have within the WTO agreement. So if you talk of the waiver, there's a very concrete legal basis for a waiver, it is granted by Article 9 of the WTO agreement, which actually allows waivers from WTO obligations for exceptional circumstances. And the COVID-19 would definitely be such an exceptional circumstance. You know, if we don't use it now, when would we actually use it? So in the WTO granting a waiver from WTO obligations is not a new thing. There are many precedents in WTO where waivers have been granted, including in the area of intellectual property. Now, when it comes to scaling up manufacturing, we do need to address the issue of IP because if you look at any product, there are different categories of intellectual property that are involved. And the issue is not just patents, it also extends to trade secrets. Depending on the products, you might have also industrial design issues and as well as copyright. These are all different categories of intellectual property, and they can hinder production, supply and access in

different ways that each of these grants different levels of monopoly rights to the IP holder. So if you take in the case of vaccines, mRNA, the patent landscape is complex. You know, there could be multiple patent holders, holding patents on different aspects of the vaccine technology and then the manufacturing methods, the know-how, protected by trade secrets. So we do need to address IP issues beyond patents. A lot of the focus tends to be on patents, but we do need to have a better understanding of what is the impact of other intellectual property protection, such as trade secrets on excess. And governments need to have the correct policy tools for them to be able to ensure that they are able to do what is necessary to gain access to trade secret, where it is important from a public health perspective and, you know, COVID-19 being a huge global health emergency, we do need to discuss these issues that go beyond patents.

Clara [00:11:38] As you probably know, the Brazilian National Congress approved a bill to temporarily suspend intellectual property rights in the context of public health emergencies. This was a huge result of a big articulation of activists, civil society organisations and Brazilian social movements here. The bill suffered presidential vetoes, and today we are mobilising advocacy efforts to overturn these vetoes. But anyway, I see it as a national example of how to work in favour of other COVID technology as well and maybe spying other initiatives at international level. So maybe the Brazilian example could also help other countries in societies. So could you share with us your thoughts about national mobilisations and gains on access and IP issues on the pandemic?

Sangeeta [00:12:28] Yeah. So like Brazil is trying to equip the government itself with policy tools. I think a lot of other countries as well, there is quite a bit happening. I think there is, in some countries, we see a reform of national laws, including intellectual property laws, either to facilitate and expedite the granting of compulsory license. Some countries have actually issued a compulsory licence, and this is especially the case of therapeutics. The first country was Israel that did it at the very beginning of the pandemic, where it was considered that HIV drug lopinavir/ritonavir could work. They issued a compulsory license to be able to produce as the originator could not supply the product. Since then, the patent on lopinavir/ritonavir has been suspended by the originator company. Russia has issued compulsory license when they wanted access to remdesivir. Indonesia has also done the same, compulsory license as well. You see, civil society activism, but also other manufacturers are still filing patents oppositions against the granting of patents at the national level. As we see, we are likely to face a barrage of patents as new patent applications come through for COVID-19, and I think I would say that this is the time to use whatever tools are available to facilitate access. So this would be the time to make the relevant policy reforms to facilitate access to expand exceptions to intellectual property rules. For instance, if you ask for a concrete example, you can say some U.S. free trade agreements have data and market exclusivity provisions. For instance, in Latin America, a lot of countries have signed a free trade agreement with the United States, right? Now, these provisions then delayed the entry of generic pharmaceutical products. So there should be reform to ensure that there are sufficient exceptions, you know? So that the generic version of the more affordable version can be registered as quickly as to make it available to the population. So that's at the national level where I think this is the time countries need to take a look at what they have in their laws, policies and practices and to reform them accordingly. And where there's opportunity to use these flexibilities, they should use it to facilitate access. Now, when it comes to flexibilities and, again, when we look at the scale of challenge at the international level, for instance, compulsory license. When you show a compulsory license to override the patent, normally it would be subject to the condition that it is predominantly for the supply of the domestic market. Now this will hinder how much can be exported and then when you do a compulsory license, you know you have to follow certain

national proceedings. It takes time. We also need greater clarity on what kind of exceptions they can have for trade secret protection. And I think if we have it at the international level, then it will be even easier for it to be rolled out globally. So at the international level as well, action can be taken and this is the basis for the TRIPS waiver proposal but, of course, where there is opportunity already at the national level, action should already be taken. We should not wait for the TRIPS waiver proposal to be adopted. I think where action is already possible and governments have the tools and need access, they should do whatever is needed to provide that access.

Clara [00:15:36] So MSF and other partners just launched a study listing over more than 100 factories that could produce the mRNA vaccine. So many other studies and documents have also showed the possibility of scaling up the production, so this is notable. [00:15:54]But [0.0s] what would be the challenge for technology transfer beyond the waiver approval?

Sangeeta [00:16:01] So, beyond the TRIPS waiver, there is a call to license technology to potential manufacturers in developing countries. Now, we have heard the argument that developing country manufacturers do not have the capability, capacity, to manufacture mRNA vaccine. And if they manufacture it, there would be quality issues. And the recent study that you mention shows that this is not true. There are capable manufacturers in developing countries, and even before COVID-19, WTO papers have shown developing country manufacturers were major suppliers of vaccines, and many of them are WTO pre-qualified as well. So the supplying of vaccines from developing country manufacturers is not new. Before COVID, they were supplying the majority of the vaccines to the developing world. Now, despite they're being capable manufacturers, the challenge is that the originator manufacturers are not interested in providing licenses. Big Pharma, at the very start, has rejected participation in the WHO Technology Access Pool that was set up in mid-2020. Moderna and Pfizer have refused to license to WHO's mRNA Hubs. The reason is: their business model depends on scarcity of supply because by having an artificial scarcity of supply, this is how they maximise profits. Pfizer is known to make up to thirty six billion dollars in 2021, and we have seen that where licenses have been granted, they are subject to restrictive terms and conditions, for instance, supply only to very few countries, often just one country, especially in the case of vaccines. So, what we have seen is production and supply currently based on business as usual, profit-making industry approaches and basically failing to leverage global production capacity and meet global needs. Developed countries have promised collaboration. What we note is that this collaboration has not materialised, and this has also been the conclusion of WTO Independent Panel on Pandemic Preparedness and Response. They have made it very clear that the promise of collaboration has not materialise and we are almost two years into the pandemic now and voluntary licenses have not been forthcoming. This is again another conclusion they have reached, and they themselves have said "WTO members should now align with the TRIPS waiver". So the challenge here is the reluctance of many of these manufacturers to do licensing and where there have been a few licenses, it does not go far enough. They have got restrictive terms and conditions. So we are in a situation where global manufacturing capacity has not been leveraged, and I think this is the challenge that we are facing with respect to tech transfer and licensing.

Clara [00:18:40] So WHO created the COVID-19 Technology Access Pool, the C-TAP, in the beginning of the pandemic as we know, however, its first closed technology transfer agreement was in November 2020, so two months ago. Do you think it would be possible maybe to take advantage of this whole voluntary mechanism in some way?

Sangeeta [00:19:03] So the challenge of voluntary license, as I mentioned, is really the refusal of the manufacturers to license, to have their license in some cases is subject to restrictive terms and conditions. Some of these terms and conditions can also impact access. So I think we have to tread very carefully when it comes to voluntary license. But if there is opportunity of a good voluntary license that could improve access, I think, of course, we should take a look at that. But at a more broader scale in terms of global health governance, I think what we need is a system where WTO can have more leverage and manufacturers have got legal commitments to provide access. And we think this is possible by creating a framework for access and benefit-sharing, where sharing of biological samples and sequence information, a subject of fair benefit-sharing, such as access to vaccines, diagnostics, therapeutics, licensing of technology. There is also a need to ensure greater transparency and accountability required of manufacturers such as to ensure that any provision of public funding is subject to certain terms and conditions, as we know in the case of COVID-19 R&D. It has been substantially funded by public funding, but there have been no strings attached. So I think this situation has to change and we do need greater transparency with respect to cost of production, you know, supply. Basically, the whole production supply chain has little transparency in it, and I think this has to change as well.

Clara [00:20:36] How do you believe that access to medicines struggle will look like in regards to future generations of COVID technologies, not just vaccines, but also all those kind of health goods that would be necessary to respond the pandemic and maybe the next pandemics? How to maintain the access to medicines struggle alive regarding maybe all those people in authorities who are already flexibilizing sanitary recommendations and refusing to see inequality of access in the global South?

Sangeeta [00:21:08] We have to stress the point that equitable access to affordable pharmaceutical products is, at the core, realising the right to health, and what we need is really greater awareness. We need to educate and expand constituencies that are involved in this discussion, and I think we do need to involve the public in this discussion and to educate them as to what is at stake. A lot of the R&D is publicly funded, and I think it has to be subject to certain terms and conditions, it has to be accountable, it has to be transparent. So, in terms of how we maintain the access to medicines struggle and keep it alive, we really need to expand and create greater public awareness as to what is at stake and how it's going to impact the right to health and what is at stake in our future. I think in developed countries as well as in developing countries, these are huge issues affecting everybody, and I think we need to create much more awareness as to the issues that are involved.

Clara [00:22:09] I would like to hear about the role of civil society in the face of all these issues that we just brought it up. Also, considering the diversity and variety of populations around the world, how can we outrage and mobilise people in order to build a solidarity network that is sensitive to the inequalities of access to medicines, especially in the global South?

Sangeeta [00:22:33] So the civil society has played a central role in highlighting the challenge of IP towards achieving equitable access, and they need to continue playing this role, and I think, as I mentioned, we do need to expand communities that are engaged in the discussion, create greater awareness, build capacity in the global South. And we do need to engage with policymakers, implementers, and relevant stakeholders: share information, provide legal and technical expertise at the national level. We also need to support developing countries governments to engage at international forums such as the World Trade Organisation, the World

Health Organisation, to raise their voices to exercise their rights. And, finally, most importantly, it is to hold national governments in the South accountable to ensure that they're using all possible means and approaches to facilitate access at the national level and to identify opportunities at the international level so that they can create the space for greater facilitation of access to medicines, to address the barriers that are there at the national level, but not just national, also regional level as well. So I think governments, civil society, all have a role to play, and civil society, in particular, has a role to play at the national and international level, you know, in doing research, analysis, advocacy, sharing information, providing technical support and building capacity.

Clara [00:24:01] So it was great, Sangeeta, thank you very much. I was very glad to have you here. I think you just brought many important issues to access to medicines struggle in the global South.

Sangeeta [00:24:12] Thank you very much, Clara. It's my pleasure. And I'm very delighted to share this information and to be involved in this podcast. Thank you very much for inviting me.

Vanita [00:24:25] The Feminist for a People's Vaccine podcast is produced by DAWN, Development Alternatives with Women for a New Era and TWN, the Third World Network. Today's episode was edited by Alice Furtado and engineered by Ernesto Sena. Thank you for joining us today. I'm Vanita Nayak Mukherjee. See you on the next episode!