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TRIPS-plus provisions in plurilateral/regional trade agreements and their impact on access to medicines at the national and global level

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Thank you very much Director Priyadarshi. It is a pleasure to be here in a room with so many old friends. Many of the people in this room go back to the beginning of time in this area. I would particularly like to single out in the first row Director General of South Africa's Department of Health, Precious Matsoso, who played such an important role in standing firm against industry pressures in the late 1990s and early 2000s, and was a leader in assuring that South Africa and the African continent received the access to medicines they need.

1. As Director Priyadarshi noted at the outset, this is not a new subject. In fact, the ink on the Doha Declaration was hardly dry before we began to express concerns about provisions of regional trade agreements, plurilateral trade agreements or preferential trade agreements, I will call them as PTAs, that were being negotiated in the immediate aftermath and which seemed to present potential obstacles to access to medicines.

2. The signed but not yet ratified Transpacific Partnership Agreement, or TPP, is but the most recent manifestation of a trend that has been going on for a long time. Before I turn to some specific specifics about the TPP, I would like to make some general observations.

3. TRIPS-plus provisions such as those incorporated in the TPP are the logical consequence of the way the international framework for research and development, production and supply of medicines and related technologies is organized. Today's predominant R&D mechanism is grounded in a patent-based funding model that depends on high prices to generate capital for investment. Commercially valuable patents are owned by large pharmaceutical corporations that promise high levels of return to investors, which in turn are dependent on large volumes of sales of high-margin products. The countries in which the major pharmaceutical companies are based approach the economics from a national interest perspective in which the objective is to secure the highest returns from overseas sales. Those returns provide a benefit to the national economy in terms of financing R&D infrastructure, employment and increased value of

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domestically-based enterprise. This is not a secret or a new discovery, but it is an important fact that underlies the issues concerning PTAs.

4. It is easy to be critical of the behavior of let us call them “certain governments” where the major multinational corporations are based, but as a thought experiment it is important to ask what a country with a comparable combination of established industry and political/economic power would do in comparable circumstances? Would other governments behave differently than certain governments? My suggestion is that most countries capable of exercising mercantile power to protect their overseas sales will do so. So, this is not a matter of identifying a particular bad actor. But rather, how to address the underlying structural issues. This is a question which the UN Secretary General’s High Level Panel on Access to Medicines has been engaged in for the past several months. I am sure that many of you were at or saw the hearings in London and Johannesburg and the great attention that is being given by the High Level Panel and we hope that they will have a very good result by the end of June.

5. Coming from the United States, you would probably like to hear a few words about the prospects for the TPP and whether or not it will be approved. I do not really have any particular magic insight into this question. As you probably saw on the news this morning, President Obama is in Asia promoting the TPP. The Asian governments and the Asian business community are supporting it. Just recently our International Trade Commission issued a report which actually showed there to be very marginal gains or losses from the TPP. It is a non-event from a US domestic economic standpoint. Of course, Ambassador/USTR Froman was quick to say – ah, but you haven’t taken into account enough the additional returns from strong patents - which raises an interesting question to the people in this room. Is that the added benefit that we are really looking for from the agreement? It is evident that Pres. Obama is certainly going to drive strongly to get the agreement approved before the elections. Both presumptive candidates, presumptive candidate Trump has expressed a general disdain for trade agreements although it is not exactly clear why, but it certainly throws things into some state of uncertainty. Presumptive candidate Clinton has opposed the TPP, but she supported it before she opposed it, and I suspect that after, if she is elected, she will find a way to reverse her position again and support it. So, I do not think we can take any real bets on this, but the US typically at the end of the day approves these kinds of agreements so it would not be entirely surprising.

6. Turning to the specifics of the TPP, it really does not represent a dramatic break from the past 15-year trend of TRIPS-plus provisions in PTAs, but it does raise some new and additionally problematic elements. I am going to run through what I think are the highlights of the potential problem areas.

7. Countries will need to provide patents for new uses of known products, or new methods of use of previously known compounds. The good news on this front is that the provision that would have effectively negated the type of provision that India adopted as section 3(d) was eliminated from the agreement. So, it was not adopted in its worst-case form.

8. Countries must link registered patents with drug regulatory approval, providing at least a notice and opportunity to seek a preliminary injunction, or alternatively simply to block approval based on a patent. Linkage is another issue that everyone in this room is familiar with. Linkage presents the largest scale problem for the countries with the least well developed legal systems. Countries where preliminary injunctions may last for a decade because there is no one that can effectively challenge them.

9. The most widely reported and controversial provision of the TPP is the eight-year period of exclusivity for newly approved biologic products, or the alternatively incomprehensible 5+3 formula. It was not much discussed during the negotiations, but it is certainly an important point, that TRIPS Agreement Article 39.3 - that provides the basis for regulatory exclusivity - probably does not cover biologicals. As you all know, it covers new chemical entities. One of the reasons the Bio industry was so actively pressing for the biologics exclusivity period was to fill this gap in the TRIPS Agreement. Again a major issue, we do not have time to go into all of them in detail.

8. There is a requirement that customs authorities will have *ex officio* power to seize goods in transit based on suspicion of trademark infringement. Again, another well-worn issue here in Geneva. We recall the seizure of goods in transit through Dutch airports based on patents. Patents are not specifically covered in this provision in the TPP.

9. There is a criminal trademark provision, I will call it a “stealth provision”. The criminal trademark provision makes it illegal to repackage and relabel using a registered trademark of a party. This provision, not much mentioned, could wreak havoc with parallel trade worldwide. Because, there is jurisprudence to the effect that reusing an existing “non-original” trademark may, in fact, constitute a trademark infringement.

10. The TPP investment chapter enumerates intellectual property as protected investment, and authorizes investor to state dispute settlement (ISDS), including a problematic compulsory licensing exemption. The Eli Lilly investor claim brought against the government of Canada under the NAFTA represents a very substantial threat to the sovereignty of the Canadian courts and to the Canadian patent laws in general. While I think that Eli Lilly is abusing the ISDS process and will not succeed, it is important to point out that this provision constitutes a major threat. Health ministers certainly have to be sensitive to making sure that ISDS provisions are controlled under any new agreement.

11. There is an artfully named “Transparency and Anti-corruption” chapter of the TPP, which includes an Annex which gives private third parties the right to challenge decisions by national health authorities about the drugs that can be listed on their reimbursement formularies, thus potentially depriving all of the health ministers of the right to make independent determinations regarding what drugs should and should not be on their formularies.

12. I should note that the IP Chapter does recognize the importance of the Doha Declaration and that nothing in the agreement will prevent ministers or governments from addressing public health, but it does not really say how conflicts with Doha will be resolved. There is no specific mechanism to do that. And, conflicts are inevitable.

14. Regional agreements are not inherently bad. We can imagine a lot of good public-health oriented regional agreements. Regional agreements on sharing R&D expenses and results, approximation and establishment of regional drug regulatory authorities to increase efficiencies, regional production and regional purchase pooling. The word "regional agreement" should not be taken as something inherently bad. It is the way that the current ones are being negotiated that may be at least somewhat bad, and something that really needs to be addressed. Everyone in the room knows that the health ministries are not given a major place at the table in these negotiations, so one big question for all the health ministers in the room is how do we get you at the table? How can you be more forceful in the negotiations at the table?

15. But, ultimately, and the problem I mentioned at the outset, is that there is an underlying structural problem regarding the way that medicines research and development is undertaken, that production is undertaken, that marketing is undertaken under exclusivity rights, which tends to lead to very distorted results. And, we will only cure the problem of regional arrangements when we cure the underlying structural issues.

16. There are quite a few other things I could mention, but I will refrain.

17. My final observation and most critically is that states have a core obligation to protect the fundamental human rights of their citizens including the right to health. And, nothing that is negotiated in a PTA can prevent a government from taking the necessary measures to invoke and defend that core obligation. That is just something that every government should recognize and put into practice.

Thank you very much.