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Big support for UN Access to Medicines High Level Panel's Report

There is an urgent need not only to support but to undertake follow up activities relating to the recently released report of the UN Secretary General's high level panel on access to medicines.

This was the conclusion at a briefing session on the report organised by the South Centre, in cooperation with the Secretariat of the panel.

The main speaker was Ms. Ruth Dreifuss, Co-Chair of the High Level Panel, and former President of Switzerland. She gave a detailed presentation of the report, with emphasis on its recommendations.

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South Centre meeting calls for action to follow up on report of UN High Level Panel on Access to Medicines

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The main speaker was Ms. Ruth Dreifuss, Co-Chair of the High Level Panel, and former President of Switzerland. She gave a detailed presentation of the report, with emphasis on its recommendations.

Also speaking were South Centre Executive Director Martin Khor and coordinator of the Secretariat of the high level panel Dr. Mandeep Dhaliwal of UNDP. Dr. German Velasquez of South Centre chaired the meeting.

There were also several questions and comments from the participants.

The briefing for developing country delegations and civil society representatives was held in the Palais des Nations in Geneva on 11 October 2016.

Below is a report of the session by Dr. Viviana Muñoz Tellez of the South Centre.

By Viviana Muñoz Tellez

A South Centre briefing session on the UN Secretary-General's High –Level Panel on Access to Medicines was held at the Palais des Nations, Geneva on 11 October 2016 to enable diplomats and civil society representatives to hear first-hand from Ms. Ruth Dreifuss, Co-Chair of the panel, on the main points of the report. She gave a detailed overview, especially of the recommendations.

The UN Secretary-General, Mr. Ban Ki-moon, convened the high-level panel in November 2015. The objective was "to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies". The Final Report was released on 14 September 2016.

The High-Level Panel was co-chaired by Ms. Ruth Dreifuss, former President of Switzerland, and Mr. Festus Gontebanye Mogae, former President of Botswana, and was comprised of 15 eminent individuals. Their work was supported by a 25-member Expert Advisory Group constituted from academia, the private sector, civil society and relevant United Nations and international organizations.

Introductory Presentations

The briefing was moderated by **Dr. German Velasquez, Special Adviser for Health and Development of the South Centre**. He recalled that the South Centre had submitted inputs to the UN HLP on Access to Medicines and endorsed in a public statement its final report.

Introductory remarks were made by **Mr. Martin Khor, Executive Director of the South Centre**. He pledged the support of the South Centre to continue its work in line with the goals of the UN HLP on Access to Medicines report and to support countries to implement the report's recommendations.

Dr. Mandeep Dhaliwal of the United Nations Development Program (UNDP) and who coordinated the Secretariat of the UN HLP on Access to Medicines, gave a detailed background of the HLP and its operations.

(See next article for more details of these two presentations.)

The panel of the South Centre briefing session on the High-Level Panel on Access to Medicines' report (L-R): Martin Khor, South Centre; Ruth Dreifuss, Co-Chair of the HLP; German Velasquez, South Centre; Mandeep Dhaliwal, coordinator of the UNHLP Secretariat.

Ms. Ruth Dreifuss, Co-chair of the High Level Panel on Access to Medicines and a former President of Switzerland.

Presentation of the Report by Ms. Ruth Dreifuss

Ms. Ruth Dreifuss, Co-chair of the High Level Panel, presented the highlights of the report. She said that the scope of the HLP mandate was to address policy incoherences, which means to make a priority scale in the different goals decision-takers have to make, in order to achieve human rights and public health.

In access to medicines, there are old and new challenges. The old ones remain, including the lack of research for diseases of the poor and the diseases of the few -- until the threat of so called emerging diseases are recognized, such as Zika and Ebola; bad adaptability of treatments to the local settings and conditions of poorer countries; and unaffordable prices for those who pay out of pocket. There is also the question of the sustainability of the progress made through product private partnerships, patent pooling and voluntary licenses.

Some of the new challenges include the growing burden of non-communicable diseases, increasing antimicrobial resistance, high price of new treatments leading to rationalization even in developed country health systems, the need for de-linkage between the cost of R&D and the price of treatments, and the lack of use of the TRIPS flexibilities.

Ten years ago the WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH, which Ms. Dreifuss chaired) was full of hope for an increase in the use of intellectual property flexibilities, following the adoption of the WTO Doha Declaration on TRIPS and Public Health. But now there are great obstacles in the use of these flexibilities, said Ms. Dreifuss.

There is a need for a new approach for biomedical innovation. One of the SDG 3 targets is to support R&D of vaccines and medicines for communicable and non-communicable diseases. The lack of biomedical innovation is no longer limited to neglected tropical diseases. It has become a global challenge. There is a need for public health responses as well as medicines, vaccines, diagnostics and all kind of medical devices.

There is a need for a new approach to guarantee access to medical technologies. SDG 3 refers to the goal of universal health coverage, including access to safe, effective, quality and affordable essential medicines and vaccines for all. The availability at an affordable price for all in need depends largely on patent laws (including the criteria for patentability) and on decisions taken by regulatory and procurement authorities. There are other factors, but the scope of the panel was on these issues.

Ms. Dreifuss said the report of the of the high-level panel makes recommendations in the field of intellectual property, publicly funded research, new incentives for R&D, and transparency, governance and accountability. She then elaborated on these recommendations.

Recommendations on intellectual property:

- **Make full use of the TRIPS flexibilities.** Governments should adopt and implement legislation that facilitates the quick, fair and predictable issuance of compulsory licenses. Many countries don't have enabling legislation. The WTO members should make full use of policy space available in the TRIPS Agreement to curtain evergreening and reward only genuine innovation. WTO members must revise the Paragraph 6 system under the WTO Doha Declaration on TRIPS and Public Health to find a solution that enables swift and expedient export of biomedical products from countries with production capacity to countries without production capacity.

- **Balancing priorities in free trade agreements**. Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the use of TRIPS flexibilities. Instances of undue political and economic pressure should be reported to the WTO Secretariat during the Trade Policy Review of WTO Members. Members should register complaints of political and economic pressure, and take punitive measures against offenders. Governments involved in bilateral and regional trade and investment negotiations should ensure that they do not interfere with the right to health. Governments should undertake public health impact assessments before entering into these agreements.

Recommendations on publicly funded research:

- **Publicly funded research serving public health**. Public funders of research must require that knowledge generated from such research be made freely and widely available in peer-reviewed literature. Universities and research institutions that receive public funding should adopt policies that promote biomedical research and knowledge that benefits the public health objectives over financial returns in patenting and licensing practices, for example non-exclusive licensing, participation in public sector pools, and donation of intellectual property.

Recommendations on new incentives for R&D:

- **Need for new incentives for R&D**. It is imperative that governments increase their levels of biomedical investment to address unmet health needs. Governments, the biomedical industry, funders of health care and civil society should establish and implement new and additional models for financing and rewarding public health R&D. The UN Secretary General should initiate negotiations among governments on the coordination, financing and development of health technologies for a binding R&D convention that delinks the costs of R&D from end prices. As a preliminary step, Governments should establish a Working Group to begin negotiating a Code of Principles for Biomedical R&D.

Recommendations for governments on accountability and coordination:

- **Government accountability and coordination is needed**. Governments

View of the audience during the South Centre briefing on the High Level Panel on Access to Medicines' report.

must review the situation of access to health technologies in their countries in light of human rights principles and States obligations to fulfil them, with assistance from the Office of the UN High Commissioner on Human Rights. These should be made publicly available. Civil society should be supported to submit shadow reports. Governments should establish national level inter-ministerial bodies to co-ordinate laws, policies and practices that may impact on health technology innovation and access.

Recommendations for the UN system on accountability and coordination:

- UN system governance for assessment and increased coherence. The UN Secretary General should establish an independent review body (with broad membership from various constituencies) tasked with assessing progress on health technology innovation and access. The UN SG should establish an inter-agency taskforce to increase coherence between multilateral organizations working on health technology innovation and access. The UN SG should convene a UN General Assembly Special Session on health technology innovation and access by 2018.

Recommendations on transparency in the biomedical sector:

- There is need for greater transparency in the biomedical sector. Governments should require all manufacturers and distributors to disclose the cost of R&D, production marketing and distribution of their products, with each category separated. Governments should require disclosure of public funding received in the development of health technologies such as tax credits, subsidies and grants. The WHO should establish and maintain a database of prices of patented, generic and biosimilar medicines in countries where they are registered.

Recommendations on transparency in clinical trials:

- There is need for greater transparency of clinical trials. Governments should require that data on all completed and discontinued clinical trials be made publicly available regardless of positive outcome. Governments should require that study designs, protocols, data sets and anonymity protected patient data be made publicly available in order to facilitate open collaboration.

Recommendations on facilitation of access to patent information:

- Access to patent information should be facilitated. Governments should establish and maintain publicly accessible databases with patent information status on medicines and vaccines with support of the World Intellectual Property Organization (WIPO) including standard names for biological products, international non -proprietary names, dates of patent grant and expiry.

Recommendations for biomedical companies on transparency and accountability:

- **There is need for biomedical companies to increase transparency and accountability.** Private biomedical companies involved in innovation should report annually on steps taken that promote access to health technologies. They should implement a direct board level of accountability to improve access to health technologies. They should also implement a publicly available policy of contribution to improve access to health technologies with specific objectives, timelines and lines of accountability.

In closing her presentation, Ms. Dreifuss said that the ambition of the Panel with the recommendations was to give tools to the various stakeholders including UN agencies, government authorities, patients and private companies, to give answer to the needs of people. Ms. Dreifuss made a call to the stakeholders and the public to make full use of this tool.

Open Discussion

During the debate several delegations took the floor to endorse and comment on the importance and outcomes of the report.

The Ambassador of Cuba expressed full support to the HLP recommendations. Governments have the responsibility to implement and define what is the best way forward. The HLP on Access to Medicines can play a useful role in supporting these policies. What is needed is good will and political will to implement them. There is unfortunately a divergence of views on this issue in the international arena. She recommended to governments to support the report and its approach to do so in the UN General Assembly, the WHO and other fora.

She added that Cuba being a small country with limited resources and subject to an international blockade has nonetheless managed to have a universal and equitable access to health technologies, and demonstrated that it is possible. Some of the key elements of success are its health policies, a legal framework that supports access to health, education and literacy, biotechnology development and a robust national intellectual property system that protects results obtained and takes into account flexibilities in the TRIPS agreement to take actions to protect public health and access to medicines, a close relationship between biotechnology centers and government, State supervision and support, creation of infrastructure, intellectual capital – human and

scientific, and the integration of biotechnology and pharmaceutical industries and a focus on strengthening regulatory agencies. All health, education, industrial, technology and intellectual property policies have converged and enhanced each other.

The Ambassador of Brazil noted that his delegation had nothing but praise for the report, that raises all relevant issues in a very streamlined fashion with interesting recommendations. The report has helped to put the issues back on the table. These issues have been discussed for over two decades and efforts are still being made to move forward. There is need to mainstream the recommendations of the report in formal bodies in the UN. The obstacle is the refusal and denial by influential countries that do not wish to accept this report as a basis for moving forward. India, Brazil and others made a proposal to include discussion on the HLP report as an agenda item in the WHO Executive Board. The proposal was not accepted by some members of the Board. Hence, there is no entry point in the WHO right now to discuss the report. Follow up actions are necessary.

Representatives from Venezuela, Pakistan, Tanzania, among others, also expressed support for the report.

A representative from the UNCTAD secretariat expressed willingness to assist in implementing a number of recommendations, and noted that a key point of the report is the need to allow countries to decide how best to find a balance among trade, intellectual property, human rights and public health. There is a need to find new spaces and multilateral bodies that can take ownership of the recommendations, and to foster collaboration among different UN agencies.

Conclusion by the South Centre

In his concluding remarks, Mr. Khor said that the report enjoyed high public legitimacy and strong praise and support from many governments, civil society organisations, which have been able to counter the few negative reactions. He said that the main action points that Ms. Dreifuss had highlighted and that the session had endorsed included the need for health concerns to be given top priority over other objectives, the need for countries to be aware of and make full use of TRIPS flexibilities, the need to beware of dangers of trade agreements that seek to curtail the governments' policy space to use TRIPS flexibilities, a proposal that the WTO be used to discipline those members that put pressure on others to not make use of TRIPS flexibilities, and the need to increase R and D for neglected diseases while urgently seeking new R and D models that delink the cost of innovation from the price of medicines and that link them instead to affordable access to medicines.

Mr. Khor said it is now important for all governments, international organisations, UN agencies, health groups and civil society and medical professionals to seriously consider the panel's recommendations and move into action to make them a reality. He affirmed the commitment of the South Centre in promoting the report and in taking forward the recommendations of the report. He thanked Ms. Dreifuss, the other Co Chair and the members of the panel and the expert groups, as well as the Secretariat for producing a very good and remarkable report.

South Centre contributions to the High-Level Panel

The South Centre contributed three submissions to the HLP on Access to Medicines. Dr. Carlos Correa, Special Advisor on Trade and Intellectual Property to the South Centre, was also a member of the Expert Advisory Group which provided overall technical support to the Panel during its work.

Recommended links:

The Report of the High Level Panel and other related information are available at: www.unsgaccessmeds.org/final-report/, www.UNSGAccessMeds.org.

The South Centre submissions to the High Level Panel are available at: www.southcentre.int/south-bulletin-91-18-june-2016/.

The South Centre statement endorsing the report is available at: www.southcentre.int/wp-content/uploads/2016/09/160916_SC-statement-on-the-report-of-the-UN-SG-HLP-on-Access-to-Medicines_EN.pdf.

Viviana Muñoz-Tellez is the Programme Coordinator of the Development, Innovation and Intellectual Property Programme (DIIP) of the South Centre.

Martin Khor, Executive Director of the South Centre (left) with Ruth Dreifuss, Co-Chair of the High Level Panel on Access to Medicines (right).

Background to the UN High-Level Panel Report

At the briefing session on the report of the UN Secretary General's High Level Panel on Access to Medicines, organized by the South Centre and the panel's Secretariat, there were two presentations made before the main speech by the Panel Co-Chair Ms. Ruth Dreifuss. These were made by the South Centre's Executive Director Mr. Martin Khor and by Dr. Mandeep Dhaliwal of the United Nations Development Program (UNDP) and the Secretariat of the High Level Panel. Below is a report by Viviana Muñoz Tellez on these presentations.

The South Centre organised a briefing session on the UNSG's High Level Panel on Access to Medicines' report, in cooperation with the Secretariat of the panel.

By Viviana Muñoz Tellez

In his introductory remarks, **Martin Khor** highlighted the importance of the human right to health and the important role that governments are obliged to play in ensuring this right is realised, including by working to provide universal access to medical technologies. This has been recognized in a recent landmark resolution on access to medicines that was adopted by the Human Rights Council and which had been put forward mainly by the developing countries.

He also emphasized the relevance of the discussion on the UN High Level Panel on Access to Medicines report in the context of achieving the Sustainable Development Goals (SDGs). It is a great challenge for governments, especially from developing countries, to provide universal access to health care. Scarcity of resources is a key factor. High prices of medicines are a major impediment to affordable access, and it is now recognized as a problem not only in developing countries but also in developed countries. It is also a challenge for governments to implement rules and policies on trade, intellectual property, health and human rights in a coherent manner. The South Centre had welcomed the establishment of the High Level Panel that was set up to examine how this can best be done.

When the report was issued, the South Centre also made a statement welcoming it and its recommendations, including the need for the full use of the flexibilities under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), its denunciation of political pressures put on countries not to use these flexibilities, its criticism of provisions in trade and investment treaties that reduce the scope for countries to protect public health, and the need for a research and development (R&D) system that delinks costs of innovation with the price of medical technologies and that links innovation with affordable access.

Mr. Khor reaffirmed the commitment of the South Centre to broaden awareness of the report, promote its use among public health ministries and other government institutions, health organizations and civil society, and to make the report come to life in policies at the national level.

Dr. Mandeep Dhaliwal said that the UNDP was priviledged to have worked with UNAIDS to service the Secretariat for the UN HLP on Access to Medicines. The panel looked more broadly at the relationship between innovation and access to health technologies. Dr. Dhaliwal noted the high global burden of infectious diseases, including HIV/AIDS, TB, malaria and hepatitis B and C. Together these account for over 4 million deaths a year. Neglected tropical diseases as defined by WHO are endemic in 149 countries and account for 12% of global disease burden. Adding to this is the global burden of non-communicable diseases (NCDs), responsible for 38 million deaths a year of which almost 75 percent or 28 million, occurred in low and middle-income countries (LMICs) in 2013.

In addition, there is the challenge of insufficient innovation for many diseases. Many products don't add new therapeutic advantage over existing ones. Of 850 new therapeutic products registered in 2000-2011, 70% of newly registered medicines show no therapeutic advantage. Moreover, only 4%

Festus Gontebanye Mogae is Co-Chair of the High Level Panel on Access to Medicines and a former President of Botswana.

of new products were for neglected diseases. There is also insufficient innovation into new antimicrobials, including antibiotics, which constitutes a major public health threat. Multi-drug resistant TB is a leading killer. Treatment can take 2 years with toxic side effects and at a cost of 4000 USD per patient per year in the United States.

The UN HLP on Access to Medicines follows the Report of the Global Commission on HIV and the Law in 2012. This report requested the UN SG to convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceuticals consistent with international human rights law. The panel also follows the adoption of the 2030 Agenda in September 2015. The Sustainable Development Goal (SDG) 3 is to "ensure healthy lives and promote well-being for all".

One of the targets under SDG 3 is to achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all. Another target is to support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on TRIPS and Public Health. In the Agenda 2030, health and development are linked. Health is an enabler of many SDGs.

The mandate for the high-level panel came out of the report on HIV and the Law and from the SDGs. The UN SG Ban Ki-moon announced the establishment of the HLP on 19 November 2015. The HLP was to address the policy incoherences that are leaving millions of people behind. The 15 Member panel was asked to "review and assess proposals and recommend solutions to remedying the incoherence between international human rights, trade rules and public health that is leaving millions behind when it comes to accessing medicines and health technologies."

The Panel had three mutually- reinforcing axes. These were a high level panel, global dialogue hearings – held in Johannesburg and London -- with calls for multi-stakeholder contributions including civil society, governments and industry to offer ideas on potential solutions which were discussed at the dialogues, and an expert advisory group. Informed by the three axes, the Panel was mandated to make evidence-informed actionable recommendations. The Panel received 182 contributions: from civil society/ patient groups, private sector, academia and think tanks, government and related orgs, international organizations , independent.

The Panel was also informed by developments at the Human Rights Council. The 32nd session of HRC in June 2016 adopted a resolution on access to medicines (A/HRC/32/L.23/ Rev). It was co-sponsored by Brazil, China, Egypt, Haiti, India, Indonesia, Paraguay, Peru, Senegal, Sri Lanka, South Africa, Thailand and Turkey. The resolution referenced the Panel: "Noting with appreciation also the Secretary-General's decision to establish a High-level Panel on Access to Medicines".

The resolution "calls upon States to promote access to medicines for all, including through the use, to the full, of the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights recognizing that the protection of intellectual property is important for the development of new medicines, as well as the concerns about its effects on prices". The resolution also "reiterates the call upon States to continue to collaborate, as appropriate, on models and approaches that support the delinkage of the cost of new research and development from the prices of medicines. The resolution also "invites Member States and all stakeholders, including relevant United Nations bodies, national human rights institutions, civil society, and the private sector, to promote policy coherence in the areas of human rights, intellectual property and international trade and investment when considering access to medicines".

EPHA

The High Level Panel held a well attended public dialogue in London in March 2016.

The South Centre Endorses the Report of the UN High Level Panel on Access to Medicines

Below is the statement by the South Centre on the Report of the UN Secretary-General's High Level Panel on Access to Medicines released on 14 September 2016.

The South Centre endorses the report of the United Nations Secretary General's High Level Panel on Access to Medicines(1) and its call on governments, the United Nations entities and others including the World Trade Organization, to take action on the report's recommendations.

The report signals that significant progress can be made by the global health community on access to medicines by taking concerted action. As the report notes, access to medicines, vaccines, diagnostics and medical devices is a matter of concern for all countries.

The South Centre encourages the UN General Assembly meeting to welcome the report of the United Nations Secretary General's High Level Panel on Access to Medicines and to agree to a mechanism for overseeing the implementation of the recommendations.

Under the able leadership of the co-chairs Ruth Dreifuss and Festus Gotebanye Mogae, the panel was able to build consensus across a wide range of opinions. While the debates of the panel were not public, its composition and commentaries by some members suggest that agreement could not be reached on some proposals that would entail significant changes in the current model of pharmaceutical innovation. Yet the panel managed to produce significant recommendations.

Some of the key recommendations of the high level panel report are the following:

- WTO Members should make full use of the policy space available in Article 27 of the TRIPS Agreement by adapting and applying rigorous definitions of invention and patentability that are in the best interest of the public health of the country and its inhabitants. This includes amending laws to curtail the evergreening of patents and awarding patents only when genuine innovation has occurred.

- Governments should adopt and implement legislations that facilitate the issuance of compulsory licenses.

- WTO Members should revise the paragraph 6 decision in order to find a solution that enables swift and expedient export of pharmaceutical products produced under compulsory license.

- Governments and private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities.

- Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health.

- Universities and research institutions that receive public funding must prioritize public health objectives over financial returns in their patenting and licensing practices.

- Stakeholders, including governments, the biomedical industry, institutional funders of healthcare and civil society should test and implement new and additional models for financing and rewarding public health research and development (R&D).

- The UN Secretary-General should initiate a process for governments to negotiate global agreements on the coordination, financing and development of health technologies, including negotiations for a binding R&D Convention that delinks the costs of research and development from end prices to promote access to good health for all.

- Governments should establish a Working Group to begin negotiating a Code of Principles for Biomedical R&D.

- Governments must review the situation of access to health technologies in their countries in the light of human rights principles and States' obligations to fulfil them, with assistance from the Office of the UN High Commissioner for Human Rights.

- Governments should require the disclosure to drug regulatory and procurement authorities of information pertaining to the cost of R&D, production, marketing and distribution of health technology, and any public funding received in the development of health technology, including tax credits, subsidies and grants.

- Governments should make publicly available all data on clinical trials, as well as the information and databases on patent information status and data on medicines and vaccines.

The South Centre will step up its support to its Member States and all G77 countries in the implementation of the recommendations. Many are already in line with its current work and reflect the proposals submitted to the High Level Panel. The South Centre also stands ready to collaborate with the independent review body tasked with assessing progress on health technology innovation and access, to be established by the UN Secretary General, as recommended by the report.(2)

(1) The Report of the UN Secretary-General's High Level Panel on Access to Medicines is available at http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf.

(2) The contributions of the South Centre to the UN Secretary- General's High Level Panel on Access to Medicines are available at http://www.unsgaccessmeds.org/inbox/2016/2/26/south-centre ; http://www.unsgaccessmeds.org/inbox/2016/2/28/south-centerb ; http://www.unsgaccessmeds.org/inbox/2016/2/28/south-centrec.

Developing countries at WTO support UN panel's report

At a meeting of the WTO's TRIPS Council, several developing countries spoke in support of the recommendations of the UN high-level panel on access to medicines, while some developed countries were not so favourable. Below is a report by Kanaga Raja, which was published in the SUNS on 14 November 2016.

IOTSD

The building of the WTO in Geneva where the TRIPS Council is based.

By Kanaga Raja

A meeting of the WTO TRIPS Council on 8-9 November discussed a recent report of the UN Secretary-General's high-level panel on access to medicines with many developing countries expressing strong support for the panel's recommendations which advocates amongst others the full use of TRIPS flexibilities. The item on the panel report was placed on the agenda by Brazil, China, India and South Africa.

During the TRIPS Council meeting, many developing countries including Egypt, Indonesia, Bangladesh and Bolivia, welcomed the discussions on the report in the TRIPS Council and voiced their support for the high-level panel's recommendations.

The US, the EU, Japan and Switzerland, supported by Korea differed from developing countries, while some other developed countries said they needed more time to study the panel's recommendations.

India underlined that the TRIPS Agreement tried to strike an appropriate balance between the interests of rights holders and users. The search for a balance between the need to protect IPRs to provide incentives for R&D on the one hand and, on the other hand, to address concerns about the potential impact of such protection on the health sector - in particular its effect on prices - has been an important consideration in the WTO's work, said India.

According to India, the TRIPS Agreement also recognizes that the principles of IP protection are based on underlying public policy objectives, and that a number of safeguards or flexibilities have become an integral part of the TRIPS framework. These flexibilities can be used to pursue public health objectives.

However, many developing countries are constrained by limited technical capacity to make full utilization of the TRIPS flexibilities. Moreover, even where some developing countries have used the flexibilities available to them under the TRIPS Agreement to address public interest objectives through measures which are fully consistent with the TRIPS Agreement, these attempts have been challenged legally as well as politically.

"A slew of regional trade agreements containing TRIPS-plus standards of IP protection and enforcement have the potential to significantly undermine the effective and full use of the TRIPS flexibilities. Investor-State disputes under regional or bilateral investment protection agreements are also emerging as a major challenge to the use of TRIPS flexibilities in the public interest," said India.

Against this background, said India, the recommendations of the HLP, especially on (i) TRIPS flexibilities and TRIPS-plus provisions and (ii) Publicly-funded research are very important with regard to access to health technologies. India read out the relevant recommendations.

India encouraged Members to share their views on the recommendations of the HLP at this session of the TRIPS Council. At the subsequent sessions of the TRIPS Council, it encouraged Members to share their experiences in using the TRIPS flexibilities to address public policy priorities, in particular, related to public health.

(See separate article on India's full statement.)

In its statement, Brazil noted that among the high-level panel report's recommendations, some are directly related to the TRIPS Agreement. One of these calls for WTO members to commit, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies. Brazil read out some of the report's recommendations.

(See separate article on Brazil's statement.)

According to Brazil, engaging in the discussion of recommendations by the High Level Panel might allow members to consider different aspects of the relationship between access to medicines and the Patent System.

Brazil said it is convinced that a

balanced and effective IP system would go a long way toward facilitating access to essential medicines without in any way infringing on market principles.

"We all know access to medicines is a challenge for most countries, whether least developed, developing or developed. We present these views in a spirit of dialogue, convinced that they are in the interest of everyone, without exception, and encourage the whole Membership to work constructively towards achieving the goal of universal access to medicines," said Brazil.

According to trade officials, South Africa said that the panel report calls upon WTO members to commit to and respect the Doha Declaration on TRIPS and Public Health, and that countries should make full use of the TRIPS flexibilities.

China said that it is pleased to be a co-sponsor of the agenda item, adding that the high-level panel gave various recommendations and provides valuable information to members. Public health is one of the most important issues on the agenda, it said, noting that leaders at the Hangzhou G20 summit also made a commitment in this regard.

The United States said that although it is strongly committed to creating effective and affordable life-saving medicines around the world, it was disappointed by the report which it claimed "distracts from rather than benefits" the objective of achieving universal health. It maintained that intellectual property protections needed to be in place to support new research and innovation. "There can be no access to drugs that have not been developed; support in innovation is essential," said the US.

The European Union maintained that the work conducted by the Panel started from an assumption that there was a "policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health". The European Commission does not share this assumption.

The Commission shares the Report's acknowledgement that there are many reasons "why people do not get the healthcare they need, ranging from: under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, exclusion, stigma, discrimination and exclusive marketing rights…However, due to its limited mandate, the High-Level Panel has focused its proposals exclusively on addressing an alleged conflict between a research and development model that (partially) relies on intellectual property rights and the possibility of providing affordable medicines."

"The challenge is to strike the right balance between the need to promote and finance the research of new and better medicines for all, ensuring that medicines are accessible and affordable to those in need, while guaranteeing the sustainability of health systems. We believe that these goals are not contradictory and must be pursued jointly," it said.

The EU claimed that the current innovation model, including the role of trade related to IP, has delivered consistent progress in global public health, leading to key new and improved treatments as well as much extended life expectancy, both in developed and least developed countries.

It also said that the report underplays the fact that the development of new drugs requires significant investment and long-term research, coupled with clinical trials and regulatory approval procedures. The EU said that the exclusive right conferred by a patent is an important incentive for innovator pharmaceutical companies to make the necessary investments into that research and development.

According to trade officials, Switzerland, Japan and Korea expressed similar concerns on the "narrow scope" of the report. They argued that the use of compulsory licences must not discourage innovation.

A few countries, including Canada, Chile, Australia and Norway, said that they needed more time to consider the wide array of recommendations highlighted in the report.

The Holy See, an observer, echoed the concerns on access to medicines, highlighting that health is a fundamental human right, and "millions are left behind". Ensuring success of the sustainable development goals included an end to the epidemics, and it requires global solidarity and initiatives, it said.

The World Health Organisation (WHO), the United Nations Conference on Trade and Development (UNCTAD), and the Joint UN Programme on HIV/AIDS (UNAIDS) also highlighted the work that they have undertaken in this area.

The UNCTAD Secretariat said that the High Level Panel Report recommends the full use of flexibilities inherent in the WTO TRIPS Agreement. UNCTAD said its work over the past ten years shows that these flexibilities, such as the recourse to strict patenting requirements, certain exceptions to patent rights and the availability of compulsory licenses play an important role in promoting generic competition and

WTO

Symposium taking place at the WTO.

UN Photo/Rick Bajornas

A Press Briefing on the UN High-Level Panel on Access to Medicines was held on the opening day of the 21st International AIDS Conference (AIDS 2016), in Durban, South Africa in July 2016. UN Secretary-General Ban Ki-moon is at the centre.

thus decreasing drug prices.

"According to our research many of those countries that now enjoy a fully developed pharmaceutical sector in the past relied on many of those flexibilities that the High Level Panel Report recommends in order to strike a balance between inventors' rights and the realization of certain development objectives."

According to UNCTAD, the High Level Panel's recommendations underline the United Nations' commitment to the realization of Sustainable Development Goal 3, which in its targets expressly refers to the goal of providing "access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health."

On the new incentives for research and development of health technologies, the High Level Panel Report recommends increased investment by governments in health technology innovation to address unmet needs, such as neglected tropical diseases and antimicrobial resistance. The Report refers to various ongoing initiatives in this regard and underlines the need to develop new and innovative sources of financing public R&D.

The Report is not limited to public funding, but underlines the untapped opportunities for increasing private sector funding. The recommendations provide important support to efforts that seek to identify innovative opportunities for both public and private sector funding of health R&D.

UNCTAD also welcomed the High Level Panel Report's recommendation to increase inter-agency coordination.

In its statement, the WHO said that the report's conclusions are sobering. "Millions of people continue to suffer and die from treatable conditions," the report observes, "because of a lack of access to health technologies."

Pharmaceutical research still focuses disproportionately on the treatment of diseases that are common in the developed world, neglecting those that primarily afflict the world's poor. "The report thus echoes conclusions of previous reports done under the auspices of the WHO, which draw attention to disparities in the R&D system and lack of access to essential medicines," said the WHO.

The WHO then went on to go through the different recommendations in the high level panel report, in particular those that are directly addressed to WHO, and highlighted its relevant activities and future plans in this area.

Members agreed to revert to the matter at the next meeting of the TRIPS Council in February 2017.

Kanaga Raja is the Editor of the South North Development Monitor (SUNS).

Report of the UN Secretary-General's High-Level Panel on Access to Medicines released in September 2016.

Health activists picketing and making their views heard, outside the venue where hearings were conducted by the High Level Panel on Access to Medicines.

India's statement at the WTO welcoming the High-Level Panel report

Below is the statement made by India at the meeting of the WTO's TRIPS Council on 8-9 November 2016 during the discussion on the agenda item of the UN Secretary General's High Level Panel Report on Access to Medicines.

MSF

India made a statement at the TRIPS Council giving details of the TRIPS flexibilities that can be used in relation to public health and cited many of the recommendations of the High Level Panel report that promote access to medicines.

In November of 2015, the United Nations Secretary-General, Mr. Ban Ki-moon, convened a High-Level Panel (HLP) on Access to Medicines. The HLP deliberations were informed by and benefitted from a broad consultative process, which included a generous response to a public call for contributions that netted 182 submissions, many of which were of high quality. Hearings and Global Dialogues were held in London and Johannesburg in March 2016 to examine the proposals and incorporate the views and inputs from concerned parties and affected communities.

On 14 September 2016, the High-Level Panel on Access to Medicines released its Final Report. The HLP, *inter alia*, made recommendations on Intellectual Property laws and access to health technologies, especially on (i) TRIPS flexibilities and TRIPS-plus provisions and (ii) Publicly-funded research.

The TRIPS Agreement established minimum standards of protection that each government has to give to the Intellectual Property of fellow WTO members. The TRIPS Agreement tried to strike an appropriate balance between the interests of rights holders and users. Article 7 of the TRIPS Agreement entitled "Objectives" recognizes that the protection of intellectual property should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of users and producers of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations.

The search for a balance between the need to protect IPRs to provide incentives for R&D on the one hand and, on the other hand, to address concerns about the potential impact of such protection on the health sector – in particular its effect on prices – has been an important consideration in the WTO's work.

The TRIPS Agreement also recognizes that the principles of IP protection are based on underlying public policy objectives. Article 8 of the TRIPS Agreement entitled "Principles" states that WTO Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. Article 8 (2) further states that appropriate measures may be needed to prevent the abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

In furtherance of the Objectives and Principles of TRIPS enshrined in Articles 7 & 8, a number of safeguards or flexibilities have become an integral part of the TRIPS framework. These flexibilities can be used to pursue public health objectives. However, to implement these flexibilities, action is needed at the domestic level by incorporating them into national IP regime keeping in mind each country's individual needs and policy objectives.

Key TRIPS flexibilities include transition periods for LDCs (extended by the WTO last year until 01 January 2033), differing IP exhaustion regimes (international exhaustion allows parallel importation of patented products from other countries where they are the cheapest), defining the criteria for grant of a patent (patentability criteria), pre-grant and post-grant opposition procedures, as well as exceptions and limitations to patent rights once granted, including regulatory review exception ("Bolar" exception) to facilitate market entry of generics, compulsory licences, including through para 6 mechanism and government use. For pharmaceutical patents, these flexibilities have been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health that WTO members have the flexibility to interpret and implement the TRIPS provisions in a manner supportive of their right to protect public

health.

Although the TRIPS Agreement provides a substantial degree of flexibility to WTO members, the full utilization of these flexibilities is in the hands of relevant member States. However, many developing countries are constrained by limited technical capacity to make full utilization of the TRIPS flexibilities and therefore they need appropriate technical assistance from relevant multilateral organizations in order to fully utilize the TRIPS flexibilities from the perspective of specific sectors of their economies such as agriculture, manufacturing, public health, environment, etc.

Moreover, even where some developing countries have used the flexibilities available to them under the TRIPS Agreement to address public interest objectives through measures which are fully consistent with the TRIPS Agreement, these attempts have been challenged legally as well as politically. A slew of regional trade agreements containing TRIPS plus standards of IP protection and enforcement have the potential to significantly undermine the effective and full use of the TRIPS flexibilities. Investor-State disputes under regional or bilateral investment protection agreements are also emerging as a major challenge to the use of TRIPS flexibilities in the public interest.

Against this background, the recommendations of the HLP, especially on (i) TRIPS flexibilities and TRIPS-plus provisions and (ii) Publicly-funded research are very important with regard to access to health technologies.

TRIPS flexibilities and TRIPS-plus provisions

World Trade Organization (WTO) Members should commit themselves, at the highest political levels, to respect the letter and spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies. More specifically:

(a) WTO Members should make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that curtail the evergreening to ensure that patents are awarded when genuine innovation has occurred.

(i) The United Nations Conference on Trade and Development (UNCTAD), the United Nations Development Programme (UNDP), the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) should cooperate with one another and with other relevant bodies with the requisite expertise to support governments to apply public health-sensitive patentability criteria.

(ii) These multilateral organizations should strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs.

(b) Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments.

(c) WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform.

(d) Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. Instances of undue political and commercial pressure should be formally reported to the WTO Secretariat during the Trade Policy Reviews of Members. WTO Members must register complaints against undue political and economic pressure, and take punitive measures against offending Members.

(e) Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfill the right to health. As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available.

Publicly-funded research

(a) Public funders of research must require that knowledge generated from such research be made freely and widely available through publication in peer-reviewed literature and seek broad, online public access to such research.

(b) Universities and research institutions that receive public funding must prioritize public health objectives over financial returns in their patenting and licensing practices. Such practices may include publication, non-exclusive licensing, donations of intellectual property and participation in public sector patent pools, among others. Sufficient incentives must be in place in these practices to make it attractive for developers to underwrite the cost of bringing a product to market at affordable prices that ensure broad availability.

(c) Universities and research institutions that receive public funding should adopt policies and approaches that catalyse innovation and create flexible models of collaboration that advance biomedical research and generate knowledge for the benefit of the public."

To conclude, we encourage Members to share their views on the recommendations of the HLP at this session of the TRIPS Council. Further, at the subsequent sessions of the TRIPS Council, we encourage Members to share their experiences in using the TRIPS flexibilities to address public policy priorities, in particular, related to public health.

Brazil's statement at WTO on the High Level Panel report

Below is the statement of Brazil at the WTO's TRIPS Council during the discussion on the agenda item on the UN Secretary General's High Level Panel report on access to medicines, held on 8-9 November 2016.

MSF

Brazil understands that it is important for the TRIPS Council to pay due attention to the issues and recommendations raised by the UN Secretary General's High Level Panel on Access to Medicines.

The High Level Panel on Access to Medicines was established to implement one of the recommendations of the Global Commission on HIV and the Law. This Commission, as many will remember, was comprised of eminent authorities and chaired by former Brazilian President Fernando Henrique Cardoso.

This new High Level Panel was co-chaired by the former President of the Swiss Confederation, Ruth Dreifuss, and by the former President of Botswana, Festus Mogae.

Its final report was released last September. Among its recommendations, some are directly related to the TRIPS Agreement. One of these calls for WTO members to commit, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies. More specifically, it recommends:

1. WTO Members should make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that curtail the evergreening to ensure that patents are only awarded when genuine innovation has occurred.

2. Enhanced cooperation among UNCTAD, UNDP, WHO, WIPO and WTO and with other relevant bodies with the requisite expertise to support governments to apply public health-sensitive patentability criteria.

3. It also recommends these multilateral organizations to strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs.

4. Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments.

5. Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities.

Brazil has a strong commitment to the improvement of public health in our country and in our region. To increase the bargaining power of governments in the acquisition of essential medicines, Brazil has established, in 2015, a regional system of procurement for these life saving goods. This arrangement, with the participation of most South American countries, is one sort of innovative mechanism aimed at helping countries to cope with high prices of pharmaceuticals.

Engaging in the discussion of recommendations by the High Level Panel might allow members to consider different aspects of the relationship between access to medicines and the Patent System. Brazil is convinced that a balanced and effective IP system would go a long way toward facilitating access to essential medicines without in any way infringing on market principles.

We all know access to medicines is a challenge for most countries, whether least developed, developing or developed. We present these views in a spirit of dialogue, convinced that they are in the interest of everyone, without exception, and encourage the whole Membership to work constructively towards achieving the goal of universal access to medicines.

Brazil understands it is important for the TRIPS Council to pay due attention to the issues and recommendations raised by the UN Secretary General's High Level Panel. We would be most interested in the continuation of the discussion in the next TRIPS Council Session.

Uruguay's victory over Philip Morris: a win for tobacco control and public health

By Germán Velásquez

In a landmark decision that has been hailed as a victory of public health measures against narrow commercial interests, an international tribunal has dismissed a claim by tobacco giant company Philip Morris that the Uruguay government violated its rights by instituting tobacco control measures.

The ruling had been much anticipated as it was the first international case brought against a government for taking measures to curb the marketing of tobacco products.

Philip Morris had started proceedings in February 2010 against Uruguay at the International Centre for Settlement of Investment Disputes (ICSID) under a bilateral investment treaty (BIT) between Uruguay and Switzerland. The decision was given on 8 July 2016.

Under the BIT, foreign companies can take cases against the host state on various grounds, including if its policies constitute an expropriation of the companies' expectation of profits, or a violation of "fair and equitable treatment". These investment treaties and arbitration tribunals like ICSID have been heavily criticised in recent years for decisions favouring companies and that critics argue violate the right of states to regulate in the public interest.

In this particular case, the tribunal gave a ruling that dismissed the tobacco giant's claims and upheld that the Uruguayan pro-health measures were allowed.

President Tabaré Vázquez of Uruguay, responding to the ruling, stated on 8 July: "We have succeeded to prove at the International Centre for Settlement of Investment Disputes that our country, without violating any treaty, has met its unwavering commitment to defend the health of its people… From now on, when tobacco companies try to undermine the regulations adopted in the context of the framework tobacco convention with the threat of litigation, they (countries) will find our precedent."

The Award announced by the Tribunal is as follows:

INTERNATIONAL CENTRE FOR SETTLEMENT OF INVESTMENT DISPUTES (WORLD BANK), WASHINGTON, D.C., 8 July 2016

PHILIP MORRIS BRANDS (THE CLAIMANT) and ORIENTAL REPUBLIC OF URUGUAY (THE RESPONDENT)

(ICSID Case No. ARB/1O/7)

AWARD

"For the reasons set forth above, the Tribunal decides as follows:

(1) The Claimants' claims are dismissed; and

(2) The Claimants shall pay to the Respondent an amount of US$7 million on account of its own costs, and shall be responsible for all the fees and expenses of the Tribunal and ICSID's administrative fees and expenses, reimbursing to the Respondent all the amounts paid by it to the Centre on that account."

Background and Details

Philip Morris International (PMI) started legal proceedings against Uruguay's government at the International Centre for Settlement of Investment Disputes (ICSID), based at the World Bank, in February 2010. This was the first time the tobacco industry challenged a state in front of an international tribunal.

Philip Morris claimed that the health measures imposed by the Ministry of Health of Uruguay violated its intellectual property rights and failed to comply with Uruguay's obligation under its bilateral investment treaty (BIT) with Switzerland.

Two specific measures were contested by PMI: The first measure was the Single Presentation Requirement introduced by the Uruguayan Public Health Ministry in 2008, where tobacco manufacturers could no longer sell multiple varieties of one brand. PMI had to withdraw 7 of its 12 products. Philip Morris alleged that the restriction to market only one variety substantially affected its company's value.

The second measure contested by PMI was the so-called "80/80 Regulation". Under a presidential decree, graphic health warnings on cigarette packages should cover 80 percent instead of 50 percent, of the packaging, leaving only 20 percent for the tobacco companies' trademarks and advertisement.

Uruguay adopted strict tobacco control policies to comply with the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC), in light of evidence that tobacco consumption leads to addiction, illness, and death.

According to the Ministry of Health (1), since Uruguay introduced its tobacco control programme in 2003, its comprehensive tobacco control campaign has resulted in a substantial and unprecedented decrease in tobacco use.

From 2005 to 2011 per person consumption of cigarettes dropped by 25.8 %. Tobacco consumption among school -going youth aged 12–17 decreased from over 30 percent to 9.2 percent from 2003 to 2011. Ministry of Health data also indicate that since smoke-free laws were introduced, hospitalization for acute myocardial infarction has reduced by 22 percent.

Since this was the first international litigation, the case is highly important for similar debates taking place in other forums, like the World Trade Organization, where some states are being challenged by other states for their tobacco control measures. It is a significant victory for a state facing commercial threats by tobacco companies fighting control measures.

The decision is supportive of states that choose to exercise their sovereign right to introduce laws and strategies to control tobacco sales in order to protect the health of their population.

This is a David against Goliath victory. "The annual revenue of Philip Morris in 2013 was reported at $80.2 billion, in contrast to Uruguay's GDP of $55.7

billion. The international lawyer and practitioner in investment treaty arbitration Todd Weiler stated in a legal opinion that: the claim is nothing more than the cynical attempt by a wealthy multinational corporation to make an example of a small country with limited resources to defend against a well-funded international legal action…"(2)

An important aspect of the case was that the secretariats of the World Health Organization and the WHO Framework Convention on Tobacco Control (WHO FCTC) submitted an amicus brief during the proceedings.(3)

The brief provided an overview of global tobacco control, including the role of the WHO FCTC. It set out the public health evidence underlying Uruguay's tobacco packaging and labelling laws and detailed state practice in implementing similar measures.

The Tribunal accepted the submission of the amicus brief on the basis that it provided an independent perspective on the matters in the dispute and contributed expertise from "qualified agencies". The Tribunal subsequently relied on the brief at several points of the factual and legal analysis in their decision.

In accepting submission of the amicus brief the Tribunal noted that given the "public interest involved in this case" the amicus brief would "support the transparency of the proceeding".

The Tribunal's ruling upheld that Uruguay could maintain the following specific regulations:

(1) Prohibiting tobacco companies from marketing cigarettes in ways that falsely present some cigarettes as less harmful than others.

(2) Requiring tobacco companies to use 80% of the front and back of cigarette packs for graphic/pictures of warnings of the health danger of smoking.

According to Chakravarthi Raghavan(4) there are several specific legal findings of the panel ruling, including:

1. Uruguay did not violate any of its obligations under the Switzerland/ Uruguay Bilateral Investment Treaty, or deny Philip Morris any of the protections provided by that Treaty.

2. Uruguay's regulatory measures did not "expropriate" Philip Morris' property. They were bona fide exercises of Uruguay's sovereign police power to protect public health.

3. The measures did not deny Philip Morris "fair and equitable treatment" because they were not arbitrary; instead, they were reasonable measures strongly supported by the scientific literature, and had received broad support from the global tobacco control community.

4. The measures did not "unreasonably and discriminatorily" deny Philip Morris the use and enjoyment of its trademark rights, because they were enacted in the interests of legitimate policy concerns and were not motivated by an intention to deprive Philip Morris of the value of its investment.

Conclusion

This is a landmark ruling because it supports the case that it is the sovereign right not only of Uruguay but of States in general to adopt laws and regulations to protect public health by regulating the marketing and distribution of tobacco products.

It is hoped that many other countries, which have been awaiting this decision before adopting similar regulations, will follow Uruguay's example. As President Tabaré said, it is time for other nations to join Uruguay in this struggle, "without any fear of retaliation from powerful tobacco corporations, as Uruguay has done."

Nevertheless, there is still a lot of public concern worldwide about the role that bilateral investment treaties has played in curbing the policy space of countries, including for health policies. There have also been serious concerns about the rulings made by other tribunals of ICSID and other arbitration centres, which have favoured the claims of companies and imposed high monetary awards against states. In the case of Philip Morris versus Uruguay, the tribunal's ruling was correct in supporting the state's right to regulate in the interest of public health. But the concerns in general are still valid. Other tribunals in other cases may or may not be so sympathetic to the public interest.

Notes:

(1) ITC Uruguay National Report 2006 -2012

(2) A. Nightingale, "The Significance Of Uruguay's Win Over Philip Morris International", *IP Watch* (Geneva, 21/07/2016).

(3) http://www.who.int/tobacco/communications/news/international-legal-tribunal-states-right-to-protect-health/en/

(4) Chakravarthi Raghavan, "Uruguay: Wins dispute before ICSID over its tobacco control policies," South-North Development Monitor (SUNS) and TWN Info Service on Health Issues, 18 July 2016.

Germán Velásquez is the Special Adviser on Health and Development of the South Centre .

Pablo la Rosa/Reuters

Public display in Montevideo, Uruguay, of the toxins found in tobacco.

Changes to the Foreign Investment Regime: Recent experiences of developing countries

Dr. Rob Davies, Minister of Trade and Industry of South Africa, delivering a keynote speech to the South Centre side event "Approaches by Developing Countries to Reforming Investment Rules".

By Manuel F. Montes and Adriano José Timossi

Introduction

At UNCTAD XIV, a side event "**Approaches by Developing Countries to Reforming Investment Rules; South-South Dialogue and Co-operation**" was jointly co-organized by the South Centre and the Government of Indonesia, with the focal point being the Indonesian Mission in Geneva.

The aim of the event was to review the approaches adopted by selected developing countries in reforming the investment protection regime, including the treaties and investor-state dispute settlement system, and reflecting on the importance of South-South dialogue in regard to the future of the investment treaty regime.

Held on 20 July 2016, the event was linked to the World Investment Forum at UNCTAD XIV.

The discussion was moderated by Dr. Manuel Montes, Senior Advisor on Finance and Development at the South Centre. A keynote speech was delivered by Dr. Rob Davies, South Africa's Minister of Trade and Industry and a prominent figure in the development debate. Panellists included Mr. Alexandre Parola, Director of the Economic Department, Ministry of Foreign Affairs, Brazil; Mr. Chanchal Sarkar, Director of the National Investment and Infrastructure Fund, Department of Economic Affairs, India and Mr. Noorman Effendi, Deputy Director for Trade, Industry, Investment, and IPRs, Ministry of Foreign Affairs, Indonesia. The programme was complemented with an interactive discussion.

Opening remarks

In his welcoming remarks, Dr. Montes underlined that there is no more controversy over whether the international regime for protecting foreign investors needs fundamental reform. Indeed, the system is broken, expensive, and in many instances serves as a hindrance to development.

According to UNCTAD, since 2012, at least 110 countries have reviewed their national and/or international investment policies and at least 60 countries have developed or are developing new model IIAs. UNCTAD points out that "today, the question is not whether or not to reform, but about the what, how and the extent of such reform".

The question is how to approach reform. Several countries, both developed and developing, have been reviewing their approaches to investment treaties and investor-state dispute settlement, including looking at ways of balancing the rights and responsibilities of investors and safeguarding the sovereign right to regulate.

While the reform process of international investment protection treaties is evolving, it is still at a nascent stage. Moreover, while there seems to be a majority opinion among States that reform is needed, it is clear that approaches to proclaimed reforms substantively vary among countries.

Several developing economies have been withdrawing from investment treaties, and seeking to find alternatives either through national laws or through designing new investment treaty models that reflect a more balanced approach. In their reviews, they are more attentive to finding a balanced approach and reducing legal liability under investor-state dispute settlement when it comes to regulatory action taken in the public interest. During the year 2015, Indonesia continued the review of its investment treaty model. India released its new investment treaty model. South Africa adopted a new national investment law that entered into force at the end of 2015. Brazil developed its 'Investment Facilitation and Cooperation' treaty model.

Dr. Montes pointed out that the proposed reforms from developing countries are "reality-tested" based on their experiences. These reforms are not "faith-based", an approach which relies on the few exceptional times when the system appears to "work". On the other hand, many developed countries, while advocating democracy, good governance, and rule of law continue to promote a system that embodies fundamental defects contradicting these goals. The moderator stressed that it is time for the South to cease being a rule taker and transform itself into being a rule maker.

The moderator also acknowledged the support of the Government of Indo-

nesia in co-hosting the side-event. He stressed that Indonesia has also been innovating in its investment protection model agreement. He pointed out that there are many similarities between African countries and Indonesia in terms of foreign direct investment (FDI) flows, as both are focusing on mineral and extractive industries directed towards exporting markets.

The keynote speaker and the panellists commended the South Centre and the Government of Indonesia for organizing the side-event and for focusing on a topic of great importance for developing countries.

Keynote speech by Mr. Rob Davies, Minister of Trade and Industry, South Africa

Minister Davies began by expressing his gratitude to the South Centre and its director Mr. Martin Khor. Minister Davies noted Mr. Khor's support to the government of South Africa in the journey of addressing development problems. He recalled Mr. Khor's visits to South Africa on a number of occasions, and the role of the South Centre as a source of input to the government.

Minister Davies noted that there have been competing paradigms in regard to investment flows and investment protection. South Africa was persuaded at one stage to adopt the prevailing dominant paradigm. In the period of the first democratic government in 1994 and the development of the constitution, the country had to face many questions pertaining to uncertainties about the intentions of the new democratic government in regard to the treatment of investors. Eventually, officials were persuaded to follow a model providing extensive protections to investors against the possibility of direct or indirect expropriation. The hope was that this would lead to inflows of foreign investment that would help to diversify the economy.

Consequently, South Africa became part of the architecture that UNCTAD describes as proliferation or multiplicity of more than 3000 bilateral investment treaties (BITs). South Africa signed a number of BITs and ratified a number mostly with developed countries and with some developing countries. These agreements were based on the OECD model, which provided imprecisely defined standards of protection, including 'fair and equitable treatment' and national treatment. Many of these treaties provided for automatic renewal, unless timely notice of termination was given.

The problem of these treaties became evident when public policies, such as black empowerment, were challenged by investors under investor-state dispute settlement cases. It then became apparent that the government could not afford the continued use of these treaties as basis for its relationship with the investors. Around the year 2007, South Africa commenced a comprehensive review of its investment policies and treaties. The outcome of the review is the basis on which it has been operating.

First, South Africa studied the correlation between BITs and FDI flows. The analysis found no appreciable inflows of FDI from countries with which South Africa has signed investment treaties. Conversely, there were sizeable inflows from countries that South Africa had not signed such treaties with, such as the US and Japan.

Secondly, an analysis of the investor-state dispute settlement system, including the record under the International Centre for Settlement of Investment Disputes (ICSID), highlighted the pattern of increasingly costly cases. Expansive interpretation by arbitral tribunals of standards of protections, such as indirect expropriation or 'fair and equitable treatment' attracted "rogue" investors to introduce frivolous claims. Several of these investors do not contribute to developing productive capacities in host countries. One of the most outrageous of these cases is that brought by a tobacco company against Uruguay challenging tobacco control measures, which showed that States could be found in a vulnerable situation when exercising their public policy responsibilities. In this case, the tribunal ruled in favour of the government. Minister Davies also spoke about the case brought by a mining company against South Africa in relation to a mining license, whereby the investor alleged indirect expropriation.

After its review, the South African government decided to change the model of investor protection, focusing on investment promotion, a similar approach of that adopted by Brazil. The South African approach addresses the reality of the foreign investment landscape, whereby the bulk of foreign investment has shifted into portfolio investments. Most of the FDI flows result from mergers and acquisitions. Minister Davies questioned the need to attract and promote such kinds of volatile, footloose investment.

Minister Davies pointed to several elements that together guide the South African investment framework. The first one is sectoral programmes part of South Africa's industrial policy, which creates an environment that will attract investors in particular sectors. The Minister suggested that identifying a package of development policies around sectoral programmes can be more effective in attracting investments than protections as provided by investment treaties. Minister Davies gave the example of the automotive programme, which needs incentives and some tariff protections. He gave the example of Australia, which after abolishing such incentives, found that the automotive sector is about to close down. In South Africa, the sectoral automotive programme has led to significant investments. The country has also developed a renewable energy programme. A number of investors are coming to South Africa to invest in these sectoral programmes. The lack of BITs has not affected opportunities for the development of the industrial policy through such sectoral programmes.

A second element in the South African investment framework is investment facilitation. South Africa has been acting more efficiently to facilitate targeted investors in the sectoral programmes and to facilitate investments in these sectors. A committee chaired by the President oversees the work of investment agency. It coordinates with legislative bodies' committees and sets targets for decision making.

Third, a key element in the South African investment framework is a new law that provides a set of guarantees for all foreign and domestic investors. The government tried to balance between the rights of investors, protection against expropriation, and the right of the government to regulate. When it was proposed, the law received significant opposition. It was a time during which South Africa started to discontinue many BITs, despite

the survival clauses that will extend the protections of the BITs for 10 or 15 additional years for investments existing at the time of treaty termination. Moving away from BITs has not resulted in a reduction in investment growth. The investment facilitation efforts combined with the domestic law have contributed to a firm environment for investments.

Dr. Davies stressed the importance South Africa gives to the regional context; South Africa's destiny is interlinked with the continent. Efforts for the promotion of regional trade and investment in the continent are part of the diversification and industrialization efforts. In this regard, South Africa has been undertaking efforts to increase its investments in the region. In doing this, South African companies have a code of conduct which includes paying taxes and observing local laws.

Dr. Davies called attention to the ongoing strong push towards resurrecting the OECD-led multilateral investment model. Some of the outcomes of the WTO Ministerial Conference in Nairobi and the 'new issues' being promoted for discussion, such as e-commerce, and competition, could end up being overseen by a strong multilateral investment agreement. Dr. Davies also pointed to the ongoing discussions at ICSID, the debate about a world investment court and the G20 non-binding Guiding Principles on investments, proposed at a very high-level of generalisation and abstraction.

Ways of introducing responsibilities on the part of investors, the right of governments to regulate, the policy space needed for development and industrialization, and reforms in the investor-state dispute settlement mechanisms are all issues that need to be further discussed. Dr. Davies shared news on ongoing discussions with Brazil in regard to a potential new model for South-South investment treaty. Such a treaty could help put into place alternative approaches to investment protection and promotion, which will be very different from that of the OECD model.

Minister Davies also mentioned that discussions are also ongoing on the future of investment agreements with traditional developed country partners. The EU expects that in the next EU-Africa summit there will be some kind of movement towards an EU-Africa investment agreement. There are also discussions on the future of the African Growth and Opportunity Act (AGOA) and its potential replacement. Minister Davies stressed that the challenges of the African continent, such as infrastructure development and investment, must be at the centre of these discussions. Efforts have to be given in these agreements to boost productive capacities of African countries, otherwise the trade agreement will not make a difference.

Panellists at the side event from left to right: Dr. Manuel Montes (South Centre), Mr. Noorman Effendi (Indonesia), Mr. Alexandre Parola (Brazil), Mr. Chanchal Sarkar (India) and Minister Rob Davies (South Africa).

Panel speeches

Mr. Alexandre Parola, Director of the Economic Department, Ministry of Foreign Affairs, Brazil

Mr. Parola remarked on the notion of 'change of paradigm' brought up by Minister Rob Davies. He was of the opinion that all existing paradigms are defective, not only those in the investment area. What has happened in the international economy since 2008 is proof of the need for a change in paradigm. The symptoms are all there, he said, and what is needed is finding the right type of diagnosis. Many countries are having zero interest rates, which is not normal from a long term perspective. There is huge liquidity, which nobody knows how to use, except for asset price speculation. We face today a situation of de-globalization; during the past five years, the global economy has been growing more than trade flows and this is an important indication of de-globalization. He also addressed the issue of global value chains, pointing out that it should be handled carefully as it could be a new and very unfair international division of labour.

Mr. Parola provided an overview of the Brazilian approach to international investment agreements. In recent decades, he said, many efforts have been undertaken to create a comprehensive international regulatory framework for foreign investment. Owing to a lack of consensus between capital exporters and importers, bilateral investment treaties (BITs) emerged as an alternative to multilateral negotiations.

According to UNCTAD, during the 1990s, there has been a proliferation in the number of BITs signed, which currently exceeds 3000 treaties. There were several critical analyses about the limitations of BITs, including in regard to: restrictions on the regulatory autonomy and the ability of States to adopt public policies; more favourable treatment of foreign investors relative to domestic investors; high economic and political costs of arbitration proceedings; imposition on States of costly damages; and lack of transparency of arbitration awards.

These agreements include specific provisions of protection, which aim to give greater assurances to foreign investors, for example, against indirect expropriation, and which consider regulatory measures that adversely affect an investment as an act tantamount to indirect expropriation. These agreements establish investor-state

dispute settlement (ISDS) mechanisms, which create an exclusive forum for claims of foreign investors against host States; and broad definitions of investment, including portfolio investment, such as investments in the financial market. Such concepts are red lines for Brazil.

The significant volume of BITs has led to more than 600 publicly known ISDS cases, and the number of countries that responded to at least one dispute has reached 98. Three-quarters of these cases were brought against developing countries and transition economies, whereas the countries of Latin America and the Caribbean account for the largest share of the total cases (29%).

Excessive litigation resulting from BITs affects the business environment and the effort to attract investments to developing countries, as well as the regulatory capacity of the State to pursue legitimate policy interests of the population in areas such as health, environment and public safety. In this context, dispute prevention becomes a preferred and superior choice, both in attraction and in the maintenance of the investment.

Over the past few years, the negative experience of many countries has exposed the limitations of these agreements and in particular the inadequacy of ISDS. Countries such as South Africa, Indonesia, India, Australia, among many others, have put their BITs under review and, in some cases, have even proceeded toward their termination.

Within this context, the Brazilian government has developed a new investment agreement model with a more constructive approach that seeks to foster institutional cooperation and the facilitation of mutual investment flows between the Parties. The proposal, entitled Cooperation and Facilitation Investment Agreement (CFIA), was developed on the basis of discussions with international organizations and extensive consultation with the Brazilian private sector.

The CFIA, unlike traditional BITs, seeks to meet investor needs in a concrete, pragmatic and proactive manner, while at the same time, respecting the development strategy and the regulatory space of host countries. The CFIA is based on three pillars: a) risk mitigation framework for the treatment of investors and their investments; b) institutional governance; and c) agendas for cooperation and investment facilitation.

In the first pillar, the CFIA provides a set of measures that reduce the investor's exposure to risk and establish a framework for the treatment of investors and their investments. It establishes guarantees of non-discrimination (national treatment and most favored nation treatment), transparency clauses, specific conditions for cases of direct expropriation, compensation in case of conflicts and guarantees for international transfers.

In the second pillar, the CFIA proposes the establishment of focal points or "ombudsmen" in each Party and the creation of a Joint Committee. These elements can be considered the institutional core of the Agreement, as they contribute to the fulfilment of the commitments made and to strengthen the dialogue between the Parties with regard to investments and appropriate assistance to investors. The Joint Committee, composed of government representatives of both Parties, is in charge of monitoring the implementation of the Agreement, the sharing of information regarding investment opportunities, bilateral investment cooperation and facilitation initiatives and, above all, joint action to prevent disputes and amicable settlement of any issues related to bilateral investment.

The Focal Point's role is to act as a facilitator between investors and the government, both in terms of dialogue and by providing government support, with the goal of improving the environment to attract investments. The CAMEX, an inter-ministerial body linked to the Presidency, will act as the Ombudsman.

In its third pillar, the CFIA provides for the establishment of investment facilitation and cooperation agendas in areas that may improve the investment environment. Such agendas may vary depending on the possibilities and challenges of the bilateral investment relationship.

The Agreement also encourages high standards of social, environmental and corporate responsibility on the part of investors and their investments. This contributes to promote quality investments and to enhance the benefits to sustainable development of the local communities and the host State.

Also, while a traditional BIT is primarily focused on ISDS rules, the Brazilian proposal focuses on dispute prevention mechanisms based on bilateral dialogue through the Focal Points and the Joint Committee, responsible for the preliminary examination of specific issues brought by the parties. If a dispute leads to arbitration proceedings, the procedure will take place in a State-State format, much like the WTO dispute settlement system.

The CFIA is an innovative alternative to traditional investment agreements, seeking to overcome the limitations and litigious approach of the latter by fostering a more dynamic, constructive and long-term interaction between the Parties. The model also recognizes the essential role of governments in encouraging a favourable environment for investment that meets both the needs of the private sector as well as the development priorities of host countries.

On negotiations, it is important for dialogue on the draft proposal involving all the relevant government agencies. The technical team in charge of CFIA negotiations involves the Ministry of Foreign Affairs, Ministry of Industry, External Trade and Services, Ministry of Finance, CAMEX, Central Bank and the Office of the Attorney-General.

To date, Brazil has signed CFIAs with Angola, Chile, Colombia, Malawi, Mexico, Mozambique and Peru, the representative of Brazil concluded.

Mr. Chanchal Sarkar, Director of the National Investment and Infrastructure Fund, Department of Economic Affairs, India

Mr. Sarkar presented on the Indian investment treaty model. In 1991 India had started to enter into BITs aimed at attracting FDI and to create a stable legal regime for addressing claims of foreign investors. Till date, India has signed BITs with 83 countries. These reciprocal agreements have been negotiated on the basis of the Model Text adopted in 1993, and amended in 2003. The 1993 Model BIT contained provisions that were susceptible to broad and ambiguous interpretations by arbitral tribunals and that do not adequately take into account the socio-

economic conditions in India and the broad objectives of governmental policy. Since 2009, the Government began receiving a number of dispute notices from foreign investors, based on these treaties.

This led the Government to start an exercise seeking to understand and identify the legal and policy challenges emanating from existing BITs. As part of this exercise, the Government completed the review of the earlier Model BIT and came out with a revised version, which has been approved by the Cabinet on 16th December, 2015.

The Indian BIT regime is based on a fundamental premise that while it is important to have investment treaties to provide a normative institutional framework to foreign investors in order to enforce their rights and claims, it is also important to ensure that BITs do not impede on policy space or impede the Government's power to regulate foreign investments for legitimate public purposes. Furthermore, India's review of its Model BIT was aimed at addressing issues related to overly broad interpretations of certain provisions by arbitral tribunals and to adequately reflect and take into account India's socio-economic policy realities. Accordingly, the Model BIT attempts a delicate balancing act between the competing interests of investors to protect their investments and obligations of the investors as well as the Host State's right to regulate.

The goals behind the Model BIT may be summarized as follows: (i) The objective of the Model BIT is to provide appropriate protections for foreign investors in India while appropriately preserving the regulatory powers of the Government. The fundamental premise is that treaties are to be an additional layer of protection for foreign investors, while well-drafted commercial contracts between investors and the State or private agencies are the primary source of protection. The intention is to ensure that only the "hard cases", i.e., those involving genuine and gross violations of investor rights or manifestly arbitrary treatment by the State, are adjudicated before international arbitral tribunals, whereas other cases are settled before domestic courts.

(ii) The Model BIT also recognises the fundamental principle of exhaustion of local remedies. It is expected that investors will give precedence to the Indian domestic court system rather than invoke BITs for settling all types of disputes. Towards this end, further steps to reform domestic laws and court systems in order to ensure efficient access to justice by foreign investors are also expected in the near future, with a view to complement the objectives of the Model BIT.

(iii) The scope of investment treaties is a key concern reflected in the Model BIT. Traditionally, the fundamental premise for investment treaties is to protect FDI, i.e. investments which are long term in nature. The classical definition of FDI as per the OECD benchmark refers to the objective of establishing a lasting interest by a resident enterprise. Current treaties do not reflect this approach; as a result, all kinds of indirect and minority shareholders are protected under BITs. The new model seeks to align the international investment agreement regime with the FDI regime by taking into account the fundamental premise of FDI, which is that it is long term in nature. Keeping in view this objective, "investment" has been defined in the new Model BIT as an enterprise and reflects the objective of establishing a lasting interest by an investor.

(iv) The Model also recognizes the need to change the asymmetry in the current BIT system, under which investors are provided protections and procedural avenues irrespective of their conduct. From an Indian perspective, investment treaties are not just instruments of investor protection, but also a valid tool to promote sustainable development goals, transparency in corporate dealings and to prevent unethical business practices. The new Indian Model BIT text has adopted a substantive approach to promoting these legitimate policy goals by including a chapter on investor obligations and requiring investors to comply with host state legislation before commencing dispute settlement under the treaty.

(v) Attempts have been made to strike a balance between the costs and benefits of investor-state dispute settlement (ISDS). After extensive deliberations within the Government and with other stakeholders, the model BIT retains the investor state dispute settlement system. However, it has also introduced detailed rules on various elements, including compulsory negotiations, prevention of conflict of interest for arbitrators, transparency, interpretation and review to safeguard the interest of State parties to ensure no exposure to undue liability.

(vi) Another change has been in the form and structure of the agreement itself. Until now, Indian IIAs adopted a minimalistic approach with typical 10-12 pages containing vague provisions, which left too much interpretative authority in the hands of the arbitral tribunals. Provisions in the new Model BIT, are fairly detailed, especially in regard to substantive protections and dispute settlement.

Some of the main features and provisions of the Indian Model BIT are as follows. It includes a number of innovative provisions that aim at maintaining investor's rights while preserving the right of the State to regulate in public interest. These provisions include, among others: (a) A post-establishment model of investment protection; (b) A careful definition of the scope of the treaty and exclusion of sensitive public policy issues from the scope – such as taxation, government procurement and public services; and (c) Exclusion of 'fair and equitable treatment' or 'most favoured nation treatment' provisions. However, the new Model BIT provides for the obligation to afford due process and the protection against manifestly abusive treatment or targeted discrimination on manifestly unjust grounds or denial of justice in any judicial or administrative proceedings.

The Indian Model BIT is based on a realistic approach. Reforming the international investment agreement regime is a gradual process, which must be done step by step taking each treaty and action into account. The Model is merely a first macro level step in the overhaul of the entire system.

The new Model reflects the international investment policy of the Government and is expected to become the basis of all BIT negotiations involving India in the future. Mr. Sarkar expressed hope that the Model BIT would become a template document worldwide for integrating sustainable development concerns in the investment treaty system and will motivate other

States to reform their investment treaty regimes.

Mr. Sarkar concluded by proposing that the latest reforms in its BIT model, could create, in the view of the Indian government, a more stable investment regime and minimize the misuse of the ISDS mechanism.

Mr. Noorman Effendi, Deputy Director for Trade, Industry, Investment, and IPRs, Ministry of Foreign Affairs, Indonesia

Mr. Effendi shared some of Indonesia's views and experiences emerging from the review process of bilateral investment treaties (BITs) and international investment agreements (IIAs) in accordance with Indonesia's national interests and current policy objectives.

Participants at the question time.

Since Indonesia started its BITs' review in 2013, the government has examined 64 BITs as well as 5 investment chapters under various free trade agreements. The review seeks to evaluate the current IIAs and its impact on Indonesian national economy. To date, Indonesia decided to discontinue 20 out of 64 BITs. This process will continue to develop gradually with careful consideration.

Indonesia gave special attention to the ISDS clause. Indonesia faced the highest number of ISDS cases among ASEAN member states. The decision to undertake the review was particularly encouraged by a billion-dollar lawsuit by the UK-listed Churchill Mining and a frivolous claim arising from a bail-out following the collapse of a private bank (Rafat Ali Rizvi v. Indonesia).

Mr. Effendi pointed out that most of these cases arose from toxic elements of the IIAs regime. For example, in the case of Rafat Ali Rizvi against Indonesia, the investor did not comply with the provision of Indonesian law with respect to admission of his investment. The dispute included questioning whether the investment made by Rafat Ali was "granted admission in accordance with Indonesia's Foreign Capital Investment 1967 or any law amending or replacing it". Legally, it is very much related to the scope and definition of the investment, one of the toxic elements for review within the IIA regime. That is why the IIAs' reform seeks to clarify the definition of covered investments and to avoid vague and too broad definitions. Indonesia stressed that only direct investments that were granted admission in a process administered by the national investment agency (BKPM) and under a special legal form of foreign investment company are entitled to the protection of the BIT. The tribunal accepted Indonesia's opinion and stated in the award that the claimant's investment was not granted admission in accordance with the "Foreign Capital Investment Law of Indonesia" as required by the BIT, and therefore did not fall within the scope of the treaty.

The current imbalance of the IIAs' regime and ISDS makes States vulnerable to legal action and potentially liable for huge compensations. It limits the exercise of States' sovereign rights. It clearly diminishes policy space, which is essential for governments to engineer the advancement of public interest. In contrast, investors are granted with a wide range of rights without clear obligations.

In practice under the existing IIAs' regime, many host States already give their consent to investors bringing any dispute to international arbitration without requiring further consent from the host States (i.e. 'automatic consent'). Such "automatic consent" should be modified, and a requirement for prior consent should be included in every investment agreement. Indonesia considers introducing such separate consent requirement before an investor could bring a dispute to any international arbitration. By including such prior consent requirement, any foreign investor who intends to sue the state under ICSID (International Centre for Settlement of Investment Disputes), UNCITRAL or any other arbitration rules would be required to first obtain the consent of the host State.

Mr. Effendi considered this proposition as a fair adjustment, whereby investors may bring the case to international arbitration if the investor and Host State have expressed their consent to settle the case through the arbitration. Thus, a special agreement to settle a dispute through international arbitration would be required on a case-by-case basis.

Article 25 of ICSID Convention provides several conditions for a dispute to be settled before the ICSID forum, including "a written consent" to settle the dispute before the ICSID forum. In legal terms, the Convention requires "consent in writing to submit to the Centre". But Article 25 does not further elaborate the specific form of written consent. Mr. Effendi argued that it is up to the governments to develop such "written consent" while adequately protecting their interests before the arbitration proceedings in every investment agreement they enter into.

Such an approach would be expected to cut down the number of ISDS claims and also promote settlement of cases through the domestic courts or alternative dispute resolution mechanisms. This approach could include exhaustion of all available local and legal remedies prior to invoking international arbitration. Formulating a sound foreign investment policy requires protecting national interests and

policy space within an open global investment climate. Host States should be able to develop better regulations and investment cooperation agreements that thoroughly cover all the issues of legal aspect of the investment such as provisions with respect to deliverable investments, events of default, termination clauses, compensation and remedies, governing law and choice of dispute resolution venue, among other aspects, including by reforming the broken IIAs' system.

Mr. Effendi concluded by stressing that the paramount objective of this process is to develop an approach to investment agreements that eliminate the current "toxic elements" of the IIAs' regime and develop an acceptable dispute settlement model.

Interactive discussion

During the interactive discussion, participants raised three important issues:

The potential trade-off between host country policy space and providing certainty to investors. One participant asked if "policy space", which all the presentations emphasized, could mean that investors are vulnerable to changes in policy approaches of their host countries.

The reaction of "stakeholders", particularly investors and their own governments, to the reform efforts.

The continuing evolution of the IIA system, as reflected in multiple ongoing negotiations, such as on the Regional Comprehensive Economic Partnership (RCEP) in the Asia Pacific region. Having proposed their own alternative models for providing investor protections, developing countries involved in these negotiations have to contend with traditional approaches to investment protection rules proposed by some other countries in these negotiations.

In responding to the issues raised, Minister Rob Davies Minister took the view that the trade-off between policy space and investor certainty could be an artificial construct since many genuine investors base their decisions on the prospect of actively participating in a domestic development program, whose design and implementation depends in turn on the existence of policy space. Minister Davies cited the recent large investments South Africa garnered in its automobile sector development program even after it had withdrawn from old-model investor protection agreements. Director Parola of Brazil emphasized that investment promotion can be more effective than the traditional investor protection approach. This involves host State's responsibilities to facilitate the legitimate business activities of foreign investors.

On the question of stakeholders' reactions, some speakers noted the immense resistance from OECD member States and their diplomatic delegations to the process of innovation and reforms being introduced by developing countries. Speakers emphasized the importance of undertaking the reform process with extensive consultation and transparency - as had been done in the country cases presented in the side event. Such an approach is essential in order to avoid adverse real effects on investment outcomes, which are different from the threats and fear mongering that have accompanied developing country efforts to reform the system. Developing countries also have responsibilities towards their indigenous private sector whose interests and long-term development are often hurt by traditional investor protection models.

Improved coordination and cooperation among developing countries, including convergence over basic principles on investor protection is timely, especially given that developing countries continue to engage in negotiations in fora where traditional investor protection approaches are proposed.

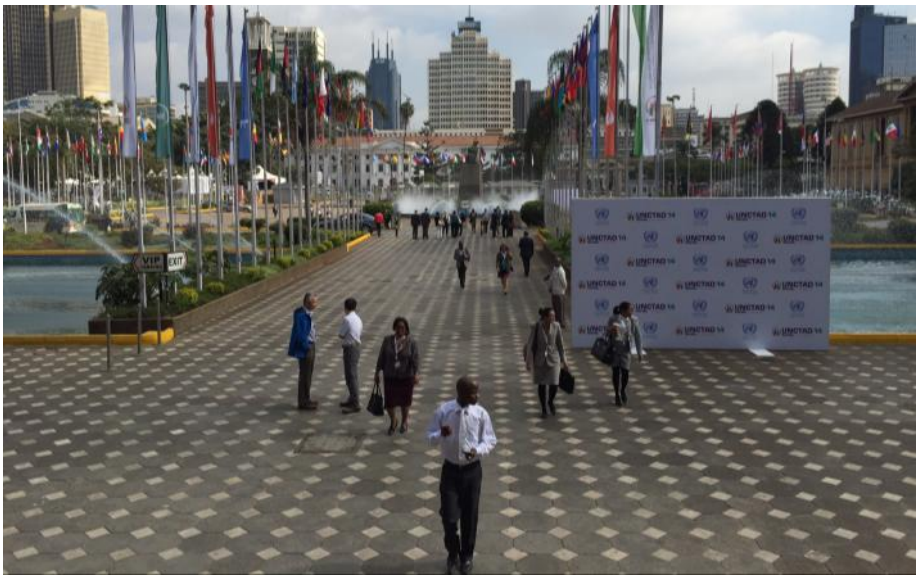
Concluding remarks

In closing the discussion, the moderator encouraged participants to continue the dialogue within and beyond the UNCTAD XIV in the collective search for policy practical measures and recommendations for reforming investment policies and treaty regime, as an important dimension of South-South economic cooperation.

Manuel F. Montes is the Senior Advisor on Finance and Development and Adriano José Timossi is Senior Programme Officer of the Global Governance for Development Programme (GGDP) of the South Centre.

A more detailed report of this South Centre event can be found in the South Centre website:

https://www.southcentre.int/sc-indonesia-investment-side-event-to-unctad-xiv-20-july-2016/



Delegates arriving at the KICC, the venue of the UNCTAD XIV in Nairobi.

India and South Centre hold South-South Co-operation Dialogue in the UN, Geneva

A Dialogue on South-South Cooperation in the context of the Right to Development discourse and the launch of a new book *India's Approach to Development Cooperation* were held on the side-lines of the 32nd Session of the Human Rights Council at the UN in Geneva on Monday, 27 June 2016 on the occasion of the commemorations of the 30th Anniversary of the adoption of the Declaration on the Right to Development.

The event was jointly organized by the South Centre, the Permanent Mission of India to the UN in Geneva, the Research and Information System for Developing Countries (RIS) and the Asia Foundation.

Below is a summary of the dialogue.

By Adriano José Timossi

In commemoration of the 30th Anniversary of the adoption of the Declaration on the Right to Development and held on the side-lines of the 32nd Session of the Human Rights Council, a Dialogue on South-South Cooperation was held in the UN in Geneva on 27 June 2016. This Dialogue was aimed at increasing awareness among delegations of UN Member States, experts, academia and civil society of the role of South-South Cooperation in advancing the Right to Development. A particular focus was given to the Indian experience with regards to development cooperation as the event also marked the launch of a new book entitled *India's Approach to Development Cooperation,* edited by Sachin Chaturvedi and Anthea Mulakala.

In his welcoming remarks, Mr. Vicente Paolo Yu, Deputy Executive Director of the South Centre, said that the international outcomes agreed in 2015 on climate change, sustainable development goals and the Agenda 2030, trade, disaster risk reduction, financing for development are going to be implemented in a world with a much greater level of uncertainty.

Mr. Yu listed the challenges that developing countries face: (1) global economic and financial crises with worldwide impacts, in particular, in their efforts to implement the Right to Development; (2) difficulties to implement their development strategies ranging from technology access to difficulties to implement industrial policy due to impediments arising from international trade regimes; (3) challenges due to climate change and on the implementation of the Paris Agreement as rules on the implementation of the agreed outcome are yet to be written and to be negotiated; (4) on the health agenda, new challenges such as those posed by the crisis of antimicrobial resistance; (5) challenges for sustainable development and how we will implement the Agenda 2030 and SDGs, calling for special attention to the concerns of developing countries particularly the means of implementation which are necessary for the success of the agenda; (6) challenges for multilateralism with a greater emphasis on a universal agenda having commitments and obligations to be applied for all and greater pressure, from developed countries, being placed on developing countries to give up on differentiated and preferential treatment which have been longstanding features of international trade and cooperation regimes.

Finally, he called for attention to the rise of more exclusionary economic trade arrangements with potential emergence of new global norms without participation of developing countries and the increasing lack in providing assistance to developing countries by donors either through official development assistance or means of implementation.

Ambassador Shyam Saran, former Indian Foreign Secretary and currently Chairman of the Research and Information System for Developing Countries (RIS), spoke on the drivers of Indian philosophy on development cooperation that differentiate from traditional cooperation and lessons to be learned from the Indian case. He pointed out that unlike the ODA/ OECD's or International Financial Institutions (IFIs)' approach to development cooperation, which is based on a donor-client relationship, Indian development cooperation see it more as a partnership. "It is a relationship between equal partners" in which priorities are set by our partners based on

H.E. Shyam Saran, a former Indian Foreign Secretary and Chair of the Research and Information System for Developing Countries (RIS) delivering his keynote speech at the Dialogue on South-South Cooperation.

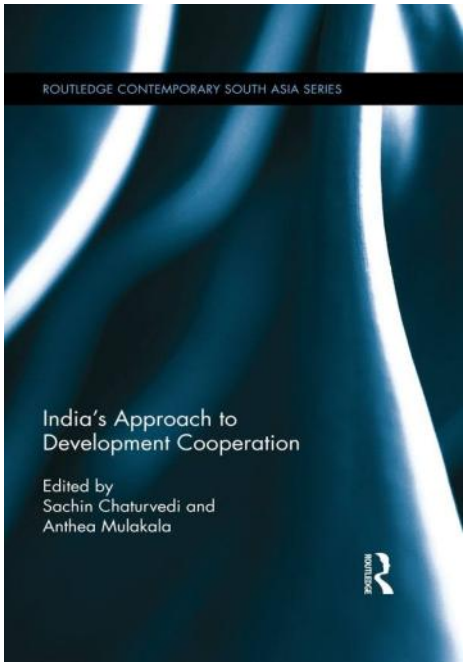
their needs and challenges and how India, even with modest resources, could align itself to cooperate, he said. Capacity building has been a strong component with transfer of know-how through trainings and education programmes put at the centre of Indian's development cooperation for decades.

Ambassador Ajit Kumar of the Permanent Mission of India to the UN in Geneva welcomed the dialogue and the new book on India's approach to development cooperation, which is not so well known by the UN bodies. Ambassador Kumar stressed that two key pillars of Indian development cooperation are partnership for mutual benefit and prosperity and ownership by partners. Indian initiatives aim at providing adequate and affordable technologies. He gave the example of ITEC – Indian Technical and Economic Cooperation which provides training programmes based on the sharing of Indians' development experiences and technology with partners with a focus on their own challenges and priorities. Ambassador Kumar stressed that South-South Cooperation is an important component to support efforts to implement the Right to Development. However, it cannot be not be interpreted as a substitute to North-South cooperation based on the historical responsibilities of developed countries to development cooperation.

The dialogue was moderated by Ms. Anthea Mulakala, Director of International Development Cooperation of the Asia Foundation and co-editor of the book *India's Approach to Development Cooperation.* Ms. Mulakala said that India has emerged as a key player in development cooperation not only because of the increasing volume and reach of its South-South Cooperation, but more so because of its leadership in development with a distinctly Southern development discourse and knowledge generation. The dialogue, she said, comes at a timely moment with the launch of the new book, being a valuable contribution for the literature on South-South Cooperation.

Mr. Sachin Chaturvedi, Director-General of RIS and also co-editor of the book, highlighted that the development discourse based on growth during the 60s and 70s were enriched with the adoption of the Declaration on the Right to Development in 1986 which put human development at the centre stage. He also spoke on the development compact based on five main elements namely capacity building, grants, lines of credit, trade and investment, giving the example of India's initiative at the WTO Ministerial in Hong Kong in 2005 in which India announced its decision to give Duty-Free Quota-Free (DFQF) for Least Developed Countries. Speaking on the issues arising over the global discourse on North-South and South-South development cooperation he stressed that OECD terms for development cooperation cannot be simply implemented in South-South Cooperation. He said that convergence will only come if terms are acceptable for both.

Two contributing authors of the book also spoke. Mr. Prabodh Saxena, Principal Secretary to the Government of Himachal Pradesh and former Senior Advisor at the Asian Development Bank, highlighted the importance of Lines of Credit (LOCs) which have played an important role in past decades and which today reaches already nearly 70 countries. More recently the EXIM Bank of India started to raise money in the international markets which is contributing to multiply the portfolio of the LOCs, he said.



The book *India's Approach to Development Cooperation*, edited by Sachin Chaturvedi and Anthea Mulakala.

Mr. Taidong Zhou, Manager of the China-UK Partnership Programme on Knowledge for Development at the Development Research Centre of the State Council in China, compared China's and India's experiences in development cooperation which in his view have a more complementary rather than competitive role. While India's focus over past decades is mainly in capacity building and the region, China has greater focus on infrastructure and connectivity in the region and in Africa.

Ms. Anita Amorim, Head of the Emerging and Special Partnerships Unit at ILO, highlighted the experiences of IBSA - India-Brazil-South Africa (IBSA) Development Forum which represents three major democracies of the developing world that have undertaken valuable initiatives in development cooperation including with the ILO in the so-called trilateral cooperation format. In June 2012, IBSA Ministers signed a joint declaration to reaffirm the India-Brazil -South Africa (IBSA) commitment to South-South Cooperation and the Decent Work Agenda. Ms. Amorim also recalled the efforts by IBSA in promoting social protection guarantee schemes such as the Mahatma Gandhi Public Employment Guarantee Scheme in India and the Brazilian Bolsa Família. An IBSA conference on public employment was also held in New Delhi in March 2012.

More recently in 2015, the IBSA Fund to fight hunger and poverty supported programmes in Haiti focusing on combating child labour and youth employment. The ILO expert said that the IBSA project in Haiti also has a component on recycling of residues which benefited from Indian transfer of technology on this field. As a longstanding organization supporting cooperation among developing countries, ILO will hold for the first time this year the South-South Academy with climate change, SDGs, child labour, the social dimension and labour migration as key issues, Ms. Amorim said.

Mr. Richard Kozul-Wright, Director of the Division on Globalisation and Development Strategies at UNCTAD, said that South-South Cooperation in the discourse of the development agenda in the 70s was closely associated with the New International Economic Order discourse which aimed at overcoming asymmetries and gaps inherited from the previous decades. UNCTAD played a

central role in that discourse and in supporting developing countries in their calls for restructuring the international division of labour, he said. In the early 80s however, development in the international economic relations discourse has changed. Development disappeared from the international economic discourse driven by market forces and with reduced role for the state, a dominant thinking which prevailed in the last 20 to 25 years. Slow growth in advanced economies in this period impacted their engagement in the global economy and development cooperation, including in achieving longstanding commitments in ODA which are still to be accomplished.

Mr. Kozul-Wright said that over past decades the productive economic agenda was replaced with greater focus on the social component in the development cooperation discourse. At the same time, there has been also fragmentation of the South in the past three decades or so which led to different growth experiences now reflected in their initiatives in South-South Cooperation with differentiated focus on human capital, services and infrastructure. He also said that developing countries' growth in the 2000s led to the idea of decoupling from the historical dependence on the North, a growth that carried out its fragilities as cautioned by UNCTAD and which was based mainly on speculative capital.

This period also saw an impressive rise of South-South Cooperation. Despite their development challenges and based on different principles from that of North-South cooperation, developing countries boosted an agenda of alternative ways of development cooperation focusing on sharing experiences on issues abandoned in the past decades such as industrial policy. In recent history, new alternatives and more democratic structures were formed with the New Development Bank and the Asian Infrastructure Investment Bank which are responses to discontent with the dominant structures of finance and development of the Washington based institutions. As a final remark, he mentioned also the role of policy space as very necessary for developing countries to reach inclusive development for their people and which must be a central element of the Right to Development.

Mr. Youba Sokona, Special Advisor on Sustainable Development of the South Centre, spoke on the linkages between climate change and South-South Cooperation and the Right to Development. He called upon developing countries to be more at the front of the discourse. Developing countries must leave the position of working on the agenda set by others and instead taking a position in which they can set the agenda, he said, referring particularly to the Paris Agreement and the SDGs, two important outcomes in which means of implementation will play a crucial role. Mr. Sokona also highlighted the good example of the African region with the recent decision to establish the African Energy Initiative, a home-bred initiative which will support projects of energy in the continent and with focus on sectors such as small scale farming systems, an important element in development cooperation for the African continent. He also made a strong call for a change in the nature of development cooperation giving strong focus to solidarity and concrete actions on the ground.

In closing the Dialogue, Mr. Yu highlighted that the following "take aways" could be discerned from the presentations and the discussion that took place:

1. A greater level of South-South learning, sharing, and information exchange is needed among developing countries in order to ensure that South-South cooperation reflects and innovates on the experiences of the South;

2. South ownership with respect to South-South development cooperation must be at the foundation of such cooperation;

3. The development focus of South-South cooperation establishes the key link to the Right to Development; and

4. Given the diversity among developing countries, it is necessary that South-South development cooperation will be undertaken through a diversity of models and alternative approaches, making it important for policy space to be present to allow South-South cooperation for development to be innovative and transformative.

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