



## Need for South to use policy space to expand access to medicines

Access to medicines has recently been a major topic of intense discussion at various forums. Representatives of developing countries and leaders of civil society and experts are advocating that more policy space and political empathy be given to countries of the South (as well as to people in the North) so that they can make use of flexibilities in the IP regimes and provide medicines at affordable prices.

This issue of South Bulletin publishes many reports on this issue, including on events at the WTO and the Human Rights Council that promote the need to use “TRIPS flexibilities” and to not sign on to new treaties that block the use of these flexibilities.



The South Centre held a side event to the WTO TRIPS Council on the UN High Level Panel on Access to Medicines.

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# Trump's first 100 days: a serious cause for concern

Mr. Donald Trump completed his first 100 days as President of the United States on 29 April 2017. Although it may be still too early to predict the implications of his Presidency, his first three months have given rise to several serious concerns. Most worrying for developing countries are his willingness for military action, his trade protectionist tendencies, the about-turn in the US approach to climate change, and his proposals to cut back on foreign aid and international cooperation.



President Trump has been using the slogan "Buy American, Hire American" and backed this up with policies or proposals to reduce imports while expanding exports, thus raising alarm around the world that the US is now turning to trade protectionism, with serious implications for developing countries.

## By Martin Khor

On 29 April 2017, Donald Trump marked his first one hundred days as US President. It's time to assess his impact on the world, especially the developing countries.

It's too early to form firm conclusions. But much of what we have seen so far is of serious concern.

Recently there have been many U-turns from Trump. Trump had indicated the US should not be dragged into foreign wars but on 6 April he attacked Syria with missiles, even though there was no clear evidence to back the charge that the Assad regime was responsible for using chemical weapons.

Then his military dropped what is described as the biggest ever non-nuclear bomb in a quite highly-populated district in Afghanistan.

Critics explain that this flexing of

military might be aimed at the domestic constituency, as nothing is more guaranteed to boost a President's popularity and prove his muscular credentials than bombing an enemy.

Perhaps the actions were also meant to create fear in the leaders of North Korea. But North Korea threatens to counterattack by conventional or nuclear bombs if it is attacked by the US, and it could mean what it says.

Trump himself threatens to bomb North Korea's nuclear facilities. With two leaders being so unpredictable, we might unbelievably be on a verge of a nuclear war.

As the Financial Times' commentator Gideon Rachman remarked, there is the danger that Trump has concluded that military action is the key to the "winning" image he promised his voters.

"There are members of the president's inner circle who do indeed believe that the Trump administration is seriously contemplating a 'first strike' on North Korea. But if Kim Jong Un has drawn the same conclusion, he may reach for the nuclear trigger first."

The New York Times columnist Nicholas Kristof says the most frightening nightmare is of Trump blundering into a new Korean war. It could happen when Trump destroys a test missile that North Korea is about to launch, and the country might respond by firing artillery at Seoul (population: 25 million).

He cites Gen. Gary Luck, a former commander of American forces in South Korea, as estimating that a new Korean war could cause one million casualties and \$1 trillion in damage.

Let us all hope and pray that this nightmare scenario does not become reality.

This may be the most unfortunate trend of the Trump presidency. Far from the expectation that he would retreat from being the world policeman and turn inward to work for "America First", the new President may find that fighting wars or at least unleashing missiles and bombs in third world countries may "make America great again".

This may be easier than winning domestic battles like replacing former President Obama's health care policy or banning visitors or refugees from seven Muslim-majority countries, an order that has been countered by the courts.

But the message that people from certain groups or countries are not welcome in the US is having effect: recent reports indicate a decline in tourism and foreign student applications to the US.

Another flip-flop was on NATO. Trump condemned it for being obsolete, but recently hailed it for being "no longer obsolete", to his Western allies' great relief.

Another note-worthy but welcome about-turn was when the US President conceded that China is after all not a currency manipulator. On the campaign trail, he had vowed to name China such a manipulator on day 1 of his presidency, to be followed up with imposing a 45% tariff on Chinese prod-





Chinese President Xi Jinping (second from left) and wife Peng Liyuan (leftmost) with US President Donald Trump (second from right) and wife Melania Trump (rightmost) in Mar-a-Lago.

ucts.

Trump continues to be obsessed by the US trade deficit, and to him China is the main culprit, with a \$347 billion trade surplus versus the US.

The US-China summit in Florida on 7-8 April cooled relations between the two big powers. "I believe lots of very potentially bad problems will be going away," Trump said at the summit's end.

The two countries agreed to a proposal by Chinese President Xi Jinping to have a 100-day plan to increase US exports to China and reduce the US trade deficit.

For the time being the much anticipated US-China trade war is off the radar. But it is by no means off altogether.

Trump has asked his Commerce Secretary Wilbur Ross to prepare a report within 90 days on the US' bilateral trade deficits with its trading partners, and whether any of them is caused by dumping, cheating, subsidies, free trade agreements, currency misalignment and even unfair WTO rules.

Once Trump has the analysis, he will be able to take action to correct any anomalies, said Ross.

We can thus expect the Trump administration to have a blueprint on how to deal with each country with a significant trade surplus with the US.

If carried out, this would be an unprecedented exercise by an economic super-power to pressurise and intimi-

date its trade partners to curb their exports to and expand their imports from the US, or else face action.

During the 100-day period, Trump did not carry out his threats to impose extra tariffs on Mexico and China. He did fulfil his promise to pull the US out of the TPPA but he has yet to show seriousness about revamping NAFTA.

A threat to the trade system could come from a tax reform bill being prepared by Republican Congress leaders. The original paper contains a "trade adjustment" system with the effect of taxing US imports by 20% while exempting US exports from corporate tax.

If such a bill is passed, we can expect a torrent of criticism from the rest of the world, many cases against the US at the WTO and retaliatory action by several countries. Due to opposi-

tion from several business sectors in the US, it is possible that this trade-adjustment aspect could eventually be dropped or at least modified considerably.

In any case, as the new US trade policy finds its shape, the first 100 days of Trump has spread a cold protectionist wind around the world.

On another issue, the icy winds have quickly turned into action, and caused international consternation.

Trump has moved to shred Obama's climate change policy. He proposed to cut the budget of the Environmental Protection Agency (EPA) by 31% and eliminate climate change research and prevention programmes throughout the federal government.

The EPA, now led by a climate change skeptic, was ordered to revise its standards on tailpipe pollution from vehicles and review the Clean Power Plan, which was the centrepiece of Obama's policy to reduce carbon dioxide emissions.

The plan would have shut down hundreds of coal-fired power plants, stop new coal plants and replace them with wind and solar farms.

"The policy reversals also signal that Mr Trump has no intention of following through on Mr Obama's formal pledges under the Paris accord," said Coral Davenport in the New York Times.

Under the Paris agreement, the US pledged to reduce its greenhouse gases by about 26% from 2005 levels by 2025. "That can be achieved only if the US not only implements the Clean



President Trump signs executive order eliminating Obama-era climate change regulations at the Environmental Protection Agency in Washington, March 28, 2017.



The world is facing its worst humanitarian crisis since the end of the Second World War, thus it is disastrous for the US President to propose steep budget cuts for overseas aid and international cooperation.

three years to the World Bank and other multilateral development banks.

The foreign affairs community in the US itself is shocked by the short-sightedness of the Trump measures and 121 retired US generals and admirals urged Congress to fully fund diplomacy and foreign aid as these were critical to preventing conflict.

The proposed Trump budget will likely be challenged at the Congress which has many supporters for both diplomacy and humanitarian concerns. We will have to wait to see the final outcome.

Nevertheless the intention of the President and his administration is clear and depressing. And instead of other countries stepping in to make up for the United States' decrease in aid, some may be tempted to likewise reduce their contributions.

For example, the United Kingdom's Prime Minister Theresa May in answer to journalists' questions refused to confirm that the UK would continue its tradition of providing 0.7% of GNP as foreign aid.

This has led the billionaire and philanthropist Bill Gates to warn that a cut in UK aid, which currently is at 12 billion pounds, would mean more lives lost in Africa.

Besides the reduction in funding, the Trump foreign policy approach is also dampening the spirit and substance of international cooperation.

For example, the President's sceptical attitude towards global cooperation on climate change will adversely affect the overall global efforts to reduce greenhouse gas emissions and build resilience to global warming.

With one of the world's largest emitters of greenhouse gases becoming a disbeliever that climate change is man-made and could devastate the Earth, and no longer committing to take action domestically and helping others to do so, other countries may be tempted or encouraged to do likewise.

The world would be deprived of the cooperation it urgently requires to save itself from catastrophic global warming.

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Power Plan and tailpipe pollution rules but also tightens them or adds more policies in future years," says Davenport.

She quotes Mario Molina, a Nobel prize-winning scientist from Mexico, as saying: "The message clearly is, we won't do what the United States has promised to do...They don't believe climate change is serious. It is shocking to see such a degree of ignorance from the US."

Will the US pull out of the Paris Agreement? An internal debate is reportedly taking place within the administration. If the country cannot meet and has no intention of meeting its Paris pledge, then it may find a convenient excuse to leave.

Even if it stays on, the new US delegation can be expected to discourage or stop other countries from moving ahead with new measures and actions.

There is widespread dismay about Trump's intention to stop honouring the US pledge to contribute \$3 billion initially to the Green Climate Fund, which assists developing countries take climate actions.

Obama had transferred the first billion, but there will be no more forthcoming from the Trump administration unless Congress over-rides the President (which is very unlikely).

Another adverse development, especially for developing countries, is Trump's intention to downgrade the importance of international and development cooperation.

In March Trump announced his proposed budget with a big cut of 28% or \$10.9 billion for the UN and other

international organisations, the State Department and the US agency for international development, while by contrast the proposed military budget was increased by \$54 billion.

At about the same time, the UN humanitarian chief Stephen O'Brien urgently requested a big injection of donor funds to address the worst global humanitarian crisis since the end of the second world war, with drought affecting 38 million people in 17 African countries.

The US has for long been a leading contributor to humanitarian programmes such as the World Food program. In future, other countries will have to provide a greater share of disaster assistance, said Secretary of State Rex Tillerson.

"The US is turning inward at a time when we are facing these unprecedented crises that require increasing US assistance," according to Bernice Romero of Save the Children, as quoted in the Los Angeles Times. "In 2016 the US contributed \$6.4 billion in humanitarian assistance, the largest in the world. Cutting its funding at a time of looming famine and the world's largest displacement crisis since World War II is really unconscionable and could really have devastating consequences."

Trump also proposed to cut the US contribution to the UN budget by an as yet unknown amount and pay at most 25% of UN peacekeeping costs. The US has been paying 22% of the UN's core budget of \$5.4 billion and 28.5% of the UN peacekeeping budget of \$7.9 billion. Trump also proposed a cut of \$650 million over



# Reflections on World Health Day



**By Martin Khor**

**W**hat's the most precious thing in the world which unfortunately we take for granted and realise its true value when it is impaired? Good health, of course.

That's something many people must have reminded themselves as they celebrated World Health Day on 7 April.

Attaining good health and well-being may be a top priority goal, but achieving it is elusive for almost everyone, and next to impossible for the poor.

In the 1980s, the World Health Organization's Director-General Halfdan Mahler steered through a declaration with the popular slogan 'Health for All by the year 2000'.

We crossed into the 21<sup>st</sup> century without realising that noble goal. Although health has improved in most countries, due mainly to cleaner water and sanitation, but also due to better treatment, much remains to be done.

In recent years, the slogan 'Health for All' has been strengthened by the recognition in the United Nations of health as a human right. It has been further boosted by the adoption of the principle of universal healthcare.

This means that no one should be deprived of health care even if they are too poor to afford it. Unfortunately, while the prices of old medicines

whose patents have expired have gone down, there are many newer medicines which are too expensive for the ordinary person to afford.

That's because a company that owns the patent has a monopoly over the production and sale of the medicine. Since there are no competitors, the price can be skyrocketed to high or to even astronomical levels. The patent normally lasts 20 years.

For example, the prices of medicines for HIV AIDs had been at the level of US\$15,000 per person per year in the United States. For most AIDS patients in Africa and other developing countries this meant they could just not afford them.

Since those medicines were not yet patented in India, because India had until 2005 to implement the TRIPs Agreement of the World Trade Organization, an Indian drug company, CIPLA, was able to sell and distribute a three-in-one combination drug for about US\$300 per person per year. Later, the price levels of the generic producers fell further to about US\$60.

Millions of lives around the world were saved by competitor generic companies which could sell the medicines at a more affordable price. Health agencies like the Global Fund for AIDS, TB and Malaria were set up and took advantage of the falling prices to make AIDS medicines available to poor

countries.

In recent years a similar storm has been brewing over the prices of new drugs for Hepatitis C, a life-threatening disease which millions around the world suffer from. One of the drugs is Sofosbuvir, which has an efficacy rate of 95% and with fewer side effects, but is being sold in the US for about US\$85,000.

Some generic companies in India have been allowed by the patent-holding company to produce and sell it at their own price level, which is currently around US\$200-400 per patient for a course of treatment. They sell these drugs in India and in lower income countries at these much cheaper prices.

But they are not allowed by the patent holder to sell in most middle income countries, so almost two billion people in developing countries cannot have the medicine at the affordable price.

What can be done?

Under the TRIPs Agreement mandates that patents have to be granted for genuine inventions, countries are also allowed to issue a compulsory licence or a government use licence to import or manufacture generic versions of the patented drug, if the original medicine is found to be too expensive. Thus those countries taking this action can access affordable generic drugs.

The patent owner will receive a remuneration (usually a percentage of sales revenue) from the generic company or the government that is selling the generic product.

Countries can also carefully examine companies' application for patents and reject those that are not genuine inventions, for example if a new patent is applied for a product with just a different dosage or the use of the same drug for another disease.

In reality, there are many new medicines already in existence or coming on stream that are patented and therefore out of reach of most patients. This tension between monopoly for patent holders (usually the big drug

companies) and access to medicines for all has become acute and there are social movements around the world, both in developing and developed countries, that are fighting for patient's rights and against excessive monopolies by companies.

Another interesting recent development is the recognition that too much sugar consumed can lead to and has led to an epidemic of many ailments, such as obesity, heart problems, diabetes. The authorities in more and more countries are taking action to limit the sugar content for example of soft drinks. The WHO has guidelines on sugar consumption and on how to avoid excessive sugar in many foods, especially those taken by children.

For world health day, consumers should resolve to cut down on sugar in their drinks and food.

An emerging threat that endangers human life is the resistance of bacteria and other pathogens to antibiotics and other antimicrobials.

Many antibiotics can no longer work on an increasing number of patients in a wide range of ailments, including TB, malaria, gonorrhoea and stomach ailments. Diseases that were once easily cured are now developing resistance, meaning the drugs don't work anymore.

We have stark warnings from top public health officers like the WHO Director-General Margaret Chan and the United Kingdom's Chief Medical Officer Dame Sally Davies, that we are approaching a post antibiotic era. In the future, even a simple scratch on a child's knee or infection during surgery could lead to death, according to these officials.

Last September, political leaders meeting at the UN General Assembly pledged to take serious action to deal with antibiotic resistance. A coordinating group from UN agencies and selected individuals has been formed to review the situation and to recommend further action.

Finally, the World Health Assembly in May this year will be electing a new Director-General for the WHO. There are three candidates from Pakistan, Ethiopia and the United Kingdom. May the successful candidate do a superb job in addressing all the ailments, diseases and problems in world health.

# Avoid patent clauses in trade treaties that can kill millions

**A recent article in a prestigious journal reminds us of how the intellectual property chapter of free trade agreements can prevent the sick from getting treatment. This article also critiques the TPP clauses and warns that they should not be translated to national laws or copied into other FTAs being negotiated.**

**By Martin Khor**

**R**ecently a very interesting article on why there are inequalities in access to health care and how medicine prices are beyond the reach of many people was published in The Lancet, one of the most prestigious medical journals in the world.

The authors, who are eminent experts in development and public health, pinpointed trade and investment agreements for being one of the greatest health threats.

Reading their powerful commentary leads one to think: What's the point of having wonderful medicines if most people on Earth cannot get to use them? And isn't it immoral that medicines that can save your life can't be given to you because the cost is so high?

The article picks on the Trans-Pacific Partnership (TPP), together with the Transatlantic Trade and Investment Partnership (TTIP) as the worst culprits. It says the TPP's chapter on intellectual property is "particularly intrusive to health and restricts access to the latest advances in medicines, diagnostic tools and other life-saving medical technologies."

This agreement, say the authors, contains many provisions that "strengthen patent protection that provides monopolies and inevitably leads to high prices." They mention provisions that extend the patent terms beyond 20 years required by the WTO; lower the criteria of what can be granted patents; and "data exclusivity" provisions that put up barriers to generic manufacturers entering markets after the expiry of patents.

This viewpoint article was co-authored by Prof Desmond McNeill (University of Oslo); Dr Carolyn Deere (Oxford University); Prof Sakiko Fukuda-Parr (The New School, New York, and formerly the main author of the UNDP's Human Development Report for many years); Anand Grover (Lawyers Collective India and formerly the Human Rights Council's Special Rapporteur for the Right to Health); Prof Ted Schrecker (Durham University, UK); and Prof David Stuckler (Oxford University).

They said that growing evidence suggests that the agreements "will have major and largely negative consequences for health that go far beyond earlier trade agreements. This situation is particularly disturbing since the agreements have created blueprints for future trade agreements."

The Nobel Peace Prize winning medical group, Médecins Sans Frontières (MSF), is even more scathing in its criticism. "The TPP represents the most far-reaching attempt to date to impose aggressive intellectual property standards that further tip the balance towards commercial interests and away from public health...In developing countries, high prices keep lifesaving medicines out of reach and are often a matter of life and death."

This condemnation is just as relevant despite President Donald Trump withdrawing the United States from the TPP. There are efforts underway for the remaining 11 countries to put the TPP into effect without the US.

Moreover, these countries have prepared changes to their laws and policies to comply with the TPP's provisions, and may implement these even if the TPP actually never comes into effect.

This would be an immense tragedy for public health, because most of these countries did understand that the chapter on intellectual property would have negative effects, but they accepted it as part of a bargain for getting better market access, especially to the US.

Since the TPP is now in suspension, it does not make any sense for the countries to change their patent laws when the benefit of market access is no longer available.

During the TPP negotiations, the other countries managed to dilute some of the very extreme demands of the US, but only to a small extent. The final intellectual rights chapter still reflects the extreme proposals of the US.

Moreover, the major developed countries can be expected to make use of the TPP's intellectual property chapter to inject into negotiations for new trade agreements, for example the RCEP, the Asian regional agreement.

Negotiators, especially from developing countries, and civil society groups should thus be vigilant that the TPP's provisions that have adverse effects on health are not reproduced in other trade agreements.

Members of the World Trade Organization are required to implement its intellectual property agreement, known as TRIPS, but they are not obliged to take on any additional obligations.

There are many provisions in TRIPS that allow a country to choose policies that are pro-health. The TPP has clauses that prevent a country from making use of many of these options because they are "TRIPS-plus", going beyond the TRIPS obligations.

First, there is a TPP provision that lowers the standards a country can adopt to grant a patent. Some patent applications are not for genuine inventions but are only made to "evergreen" a patent, to enable its term to continue after it expires. Under TRIPS, a country can choose not to grant secondary patents for modifications of existing medicines.

The TPP (Article 18.3) requires countries to grant patents for at least one of the following modifications: new uses of a known product, new methods for using a known product or new processes for using a known product. Examples include a drug used for treating

AIDS is now granted a new patent for treating hepatitis, or a drug in injection form is given a new patent in capsule form.

Second, there is a provision that enables extending the patent term beyond the 20 years required by TRIPS. Most countries now count this 20 years from the date of filing the patent application.

The TPP requires the patent term to be extended beyond that if there are "unreasonable" delays in issuing the patents (Article 18.46) or if a delay is caused by the marketing approval process (Article 18.48). Extending the patent term means delaying affordable treatment for patients for so many more years.

Third, a provision (Article 18.50) to create "data exclusivity" or "market exclusivity", that prevents drug safety regulators from using existing clinical trial data to give market approval to generic drugs or biosimilar drugs and vaccines. Under TRIPS, the clinical test data of a company can be used by a country's drug regulatory authority as a basis to give safety or efficacy approval for generic drugs with similar characteristics, thus facilitating the growth and use of generic drugs.

Under the TPP, the data of the original company is "protected" and approval of similar drugs on the basis of such data is not allowed. The period of "exclusivity" is at least 5 years for products containing a new chemical entity, or 3 years for modifications (a new indication, new formulation or new method of administration) of existing medicines.

Fourth, a provision on Biologics (Article 18.51). For the first time in a trade agreement, the TPP obliges its members to undertake data protection obligations for "biologics", a category of products for treating and preventing cancer, diabetes and other conditions. They are very expensive, some priced above \$100,000 for a treatment course, and the clause will enable the prices to remain high for longer periods. The exclusivity for biologics is for at least 8 years, or 5 years if other measures are also taken.

These provisions on exclusivity give drug companies extra protection, even if the product is not patented or if the patent has expired. The drugs

will be out of reach except for the very wealthy for longer periods.

Fifth, a provision (Article 18.76) that requires TRIPS-plus extra enforcement of intellectual property. Countries are obliged to provide that the right holder can apply to detain any imported product that is suspected to be counterfeit or having "confusingly similar trademark".

This can block legitimate generic medicines from entering the country. There have already been many cases of drugs being detained and later released when no infringement was found, thus needlessly delaying treatment to patients. The provision will increase the incidence.

All in all, these TRIPS-Plus TPP obligations would make it more difficult for patients to obtain cheaper generics. If these clauses are widely adopted in other trade agreements and made into national laws, this would shorten the lives of millions of people who would be denied treatment.

For example, many millions of people worldwide are afflicted with Hepatitis C, which can lead to liver failure and death. They need the new medicines that have nearly 100% cure rates close but the prices are over \$80,000 for a 12-week treatment course. Even with discounts, very few can afford this.

Some developing countries, making use of TRIPS flexibilities, are able to provide treatment with generic drugs at around \$500 per patient, a very small fraction of the original drug's price. But if the TPP clauses are translated into domestic law, this access could be blocked.

People in the developing countries are the most affected by patent over-protection, but patients in developed countries are not spared. The mainstream Time magazine in October 2016 listed the need to "Reform the Patent Process" as one of the issues the US Presidential election should address.

The Time article commented that many people believe drug companies are "gaming" the system. "Instead of focusing on developing new cures, they are spending millions tweaking

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# South Centre Side Event to the WTO TRIPS Council highlights recommendations by the UN Secretary General's High Level Panel on Access to Medicines



The panel during the South Centre side event, from left to right: Prof. Carlos Correa, Special Advisor on Trade and Intellectual Property, South Centre; Ms. Ruth Dreifuss, Co-chair of the High Level Panel on Access to Medicines and Former President of Switzerland; Dr. Suerie Moon, Director of Research, Global Health Centre and Visiting Lecturer of the Graduate Institute of International and Development Studies, Geneva; Mr. Celso Amorim, Chairman of the UNITAID Board, former Minister of Foreign Affairs of Brazil and member of the High Level Panel; H.E. Mr. Evandro Didonet, Ambassador of Brazil to the WTO; and H.E. Mr. Shameem Ahsan, Ambassador of Bangladesh to the UN in Geneva.

**By Mirza Alas and Viviana Muñoz Tellez**

On March 1<sup>st</sup> 2017, the South Centre together with the United Nations (UN) Secretariat of the High Level

Panel on Access to Medicines, and co-sponsored by the Governments of India, Brazil and South Africa, held an event on the Report of the UN Secretary General's High Level Panel on Access to Medicines.

## ***Avoid patent clauses...***

*(Continued from page 7)*

the way existing drugs are administered or changing their inactive ingredients. Those moves have the effect of extending a drug's patent and upping the amount of time it can be sold at monopoly prices, but they don't necessarily help consumers."

It is high time for a re-think to the system of drug patents. At the least the situation should not be allowed to worsen further, which would happen if TRIPS-Plus measures are adopted.

The lives and health of millions are at stake. Sometimes this is forgotten or

put as a low priority when pitted against the promise of getting more exports in a free trade agreement.

But with the TPP in limbo and perhaps in perpetual suspension, there is really no reason why the provisions that have adverse effects should be implemented in the countries that had negotiated the TPP, when there are no benefits to be obtained to offset them.

More generally, in all countries, policy makers and people should be on guard not to agree to TRIPS-plus clauses in the trade agreements that they negotiate or sign.

As a side event to the WTO TRIPS Council, it provided an opportunity for WTO members, observers and all interested stakeholders to engage in an open discussion with some Members of the High-Level Panel and its Expert Advisory Group. It also provided input to the formal WTO TRIPS Council session on the agenda item on the High Level Panel report.

**Dr. Suerie Moon, the Director of Research, Global Health Centre and Visiting Lecturer of the Graduate Institute of International and Development Studies,** in opening the event, highlighted the importance of discussing the UN High Level Panel's recommendations, particularly at the WTO. The UN Secretary General convened the panel at the UN's highest level. This reflects the realization that health and access to medicines is not an issue that can be resolved primarily or only by the health sector. It requires contributions by all sectors including trade. It is significant that WTO Members are discussing the report at the TRIPS Council.

Ms. Moon noted that the initial idea of the High Level Panel came out of the Global Commission of HIV and the Law that recommended the UN Secretary General to find a way to remedy the policy incoherence between the justifiable rights of the inventors, international human rights law, trade rules and public health in the context of health technologies. Ms. Moon pointed out that the panel was convened in 2015 with two former Heads of State as Co-chairs, Ms. Ruth Dreifuss and Mr. Festus Gontebanye Mogae.

Ms. Moon also observed that the Secretary-General convened this panel in the context of transitioning from the Millennium Development Goals into the Sustainable Development Goals (SDGs). SDG 3 in particular focuses on health. Access to medicines has to be guaranteed for people in all countries and for all diseases and across all technologies - not only medicines and vaccines but other types of technologies as





Ms. Ruth Dreifuss speaking at the event.

well. Health is not only contained exclusively in SDG3. Health should be understood as precondition, indicator and outcome of sustainable development. It is interlinked with all the other SDGs.

**Ms. Ruth Dreifuss, Co-chair of the High Level Panel and Former President of Switzerland**, was the first panelist to take the floor. Ms. Dreifuss drew emphasis on the mandate of the panel and made a call to make transparency a central topic in the discussions on innovation and access to medicines.

Ms. Dreifuss noted that the Panel mandate was both broad and very narrow. The mandate was broad because the context is no longer what it was 10 years ago in which access to medicines was seen as a problem mainly of poor countries and transmissible disease. During these 10 years the problem of access to medicines has become a truly global problem. The burden of diseases today is higher for Non Communicable Diseases (NCDs). It is in this area where the cost of new medicines is the highest today. How to deal with transmissible diseases is now known, and knowledge for how to deal with new epidemics is improving, as in the case of HIV. In contrast, medicines for cancer and medicines for neurodegenerative diseases are the biggest expense for all countries and no longer only for people who pay out of pocket but also for people in countries providing universal coverage. They are now struggling with having to introduce health rationing because of the high price of these treatments.

The aim of the panel was not to only look at medicines, vaccines but also at the important issue of diagnostics and medical devices. As a Minister of Health for 10 years, Ms. Dreifuss witnessed that the issue of medical devices was often neglected, more so than the issue of medicines. This being so despite the fact that the prices of medical devices are heavily influenced by patents. Moreover, the link between medicines and medical devices can render the prices of some treatments very expensive. Even for medicines that no longer have a patent, the prices may be very high, because they are delivered through medical devices that are patented.

Ms. Dreifuss then focused her presentation on the section of the report that dealt with governance, accountability and transparency. She highlighted that there is a clear need for transparency in an innovation system in which there is strong collaboration between public and private sectors and where the public sector is financing basic research. Some medical technologies, as in the case of vaccines, have been largely developed by the public sector and through public financing. In medical innovation, the pharmaceutical industry has an important role to play, as well as regulatory and procurement authorities. The public sector acts to promote access to good quality medicines.

Currently, in the chain there is a “black box”. It is a box of not knowing what is the system of production of new knowledge inside the pharmaceutical industry, now knowing what are the true costs of research and development (R&D) and how they are pricing final products. One of the boldest and strongest recommendations of the panel was to put light into this black box.

In looking forward, it will be important to gain more light of why certain health needs are not met by pharmaceutical companies and on how the negotiation of prices between pharmaceutical companies and public authorities occur. There is a need to ensure this is done in a fair way so that what is paid by the public, usually at the beginning of the R&D process, will not be paid again through high prices.

**Mr. Celso Amorim, Chairman of the UNITAID Board, former Minister of Foreign Affairs of Brazil and mem-**

**ber of the High Level Panel**, focused on the recommendations of the High Level Panel report on the use of flexibilities contained in the TRIPS Agreement and the impact of TRIPS plus obligations on policy space for public health. Mr. Amorim noted that as ambassador at the WTO when the TRIPS agreement was negotiated and agreed, he was reluctant to agree because of the restrictions imposed by the agreement on Brazil’s capacity to industrialize, despite the “ambiguities” contained in the agreement that could be used. Mr. Amorim reflected on the evolution of the debate, noting that challenges such as HIV AIDS changed the political context. The United States brought a legal challenge against Brazil concerning the intellectual property law but was unsuccessful. This was part of the process when “ambiguities” became “flexibilities”. The reaffirmation of flexibilities is embodied in the Doha Declaration on TRIPS and Public Health. The Doha Declaration in paragraph four states that WTO members agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, the TRIPS agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and in particular to promote access to medicines for all.

Mr. Amorim stressed that the main challenge in using the flexibilities has been the strong political pressure that countries have had to face. Mr. Amorim echoed the UN High Level Panel recommendation that WTO Members should commit themselves at the highest political level to respect the letter and spirit of the Doha Declaration on TRIPS and Public Health. If presidents and prime ministers don’t respect this agreement, he said, it won’t be given the importance that it needs to have. Mr. Amorim observed that countries have faced threats that go beyond trade, so they refrain from issuing compulsory licenses and other measures for public health. He urged WTO members to consider the recommendation by the High Level Panel on the use of the trade policy review process to object to such pressures.

What is at stake here, he said, is not only intellectual property and access to medicines, but also the future of

multilateralism. The pressures that have been applied are contrary to what has been agreed. Mr. Amorim urged for take up of the measures proposed by the High Level Panel.

**H.E. Mr. Evandro Didonet, Ambassador of Brazil to the WTO**, recalled that Brazil has been a key player in the WTO discussions on intellectual property and access to medicines, and continues to believe that these issues should not be mutually exclusive. IP rights should be implemented in a manner that is conducive to social welfare. Accordingly, the TRIPS flexibilities serve the purpose of providing policy space. Moreover, there must be a balance between IP and health. This remains the policy of Brazil which has not been affected by changes in government. It is Brazil's state and foreign policy.

Mr. Didonet said that the status of domestic procurement of medicines is concerning. For Brazil the cost of medicines procurement by the Ministry of Health has increased as much as 10% in real terms every single year from 2004 to 2013 with medicines alone accounting for 15% of the budget for 2014.

Mr. Didonet noted that Brazil asked for the inclusion of the High Level Panel report in the agenda of the TRIPS Council and would like to focus on what the panel has recommended in terms of what can be done at the WTO. Mr. Didonet said that the entry into force of the TRIPS amendment was in line with the recommendations of the panel and that it provides a much more solid legal framework for countries that wish to import medicines through compulsory licenses. He cautioned that there is still work to do in the implementation of the Protocol and called on the WTO Secretariat to provide technical assistance for countries to take the necessary legal measures to incorporate the Protocol into their national legal systems.

Mr. Didonet recalled that the Panel recommended that governments that engage in trade negotiations should not include provisions that go against the right to health. He noted that Brazil does not negotiate TRIPS plus provisions in trade agreements.

**H.E. Mr. Shameem Ahsan, Ambassador of Bangladesh**, expressed that the report of the High Level Panel is very significant and a bold step. The

High Level Panel calls for change, not only in the current IP production and marketing regime. It also calls for change of our ideas and approaches. He noted that additional useful observations and recommendations could not be included in the report due to lack of consensus. Mr. Ahsan highlighted that LDCs will use occasions at different fora to raise and discuss the High Level Panel report to find ways to implement the worthwhile recommendations for the benefit of all.

Mr. Ahsan described that we are now witnessing the progress of the fourth industrial revolution. Science and technology had never facilitated our life better than today. However, humanity today is at a crossroads. On one hand the scientific knowledge, technological developments, infrastructure and productive capabilities are tremendously benefiting few of us while majority are still out of the benefits originating from them and many a times these advancements are creating more divide than gains for everyone due to our own gaps and failures. Against this backdrop, while we consider that right to life is the most fundamental right, then the next most immediate right, i.e., right to health cannot be far behind. With this goal in view, we are fortunate to have this report of the High Level Panel, to ensure and establish our right to health and subsequently, the right to life and achievement of SDG 3.

Mr. Ahsan further stated that although access to health and medicine are equally important for all the countries, whether developed, developing or LDCs, when it comes to ensuring physical access, the LDCs are the hardest hit. The UN High Level Panel report put forward many important recommendations applicable for all the countries irrespective of their level of development. It firstly mentioned the lack of development of medicines for Neglected Tropical Diseases from which an estimated 1.7 billion peoples are suffering. To overcome this, the report observed that coordinated and collaborative efforts of public-private partnerships and product development partnerships (PDPs) had been key in bringing together the resources and strengths of the private, philanthropic and public

sectors to innovate and deliver several important health technologies. Here, both private and public sectors in the LDCs are extremely weak to undertake any such collaboration and investment. To implement this recommendation, LDCs will need active support and transfer of technology from the developed countries and their private enterprises.

Mr. Ahsan remarked that LDCs will support the recommendation to make full use of the TRIPS flexibilities, noting that LDCs currently benefit from a transition period under the TRIPS Agreement in terms of extending patent protection to pharmaceutical products, among others. Mr. Ahsan noted that the Paragraph 6 system is now officially a part of TRIPS Agreement. This should enable swift and expedient export of biomedical products from countries with production capacity to LDCs without production capacity. However, this will require genuine goodwill from the producers of medicine and the governments and the administrative authorities to facilitate production and transport unencumbered by any contrary supply-side or administrative action.

Mr. Ahsan also observed that balancing and rationalizing priorities in any free trade agreement is a recommendation that LDCs need to pay particular attention to since this is appearing more and more in FTAs and RTAs every day. In case of an LDC being member of any FTA or RTA, governments and the private sectors of other members of the same FTA/RTA must refrain from explicit or implicit threats, tactics or strategies that undermine the use of TRIPS flexibilities. In that case, is important to agree that in such instances of undue political and economic pressure this should be reported to the WTO Secretariat during the Trade Policy Review of those WTO Members. He also supported the recommendation that the LDC Governments should undertake public health impact assessments before they enter into such agreements.

He further elaborated that the Report recommends that 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 benefit 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. However, public funding in LDCs is not common. Mr. Ahsan proposed that any patent grant awarded to an LDC that was supported by public funding should not require disclosure to public domain, and LDCs or their concerned entities should enjoy natural commercial benefit and data exclusivity which is associated with usual patent rights.

Mr. Ahsan stressed that LDCs would like to see a binding global R&D convention that delinks the costs of R&D from the end prices. He noted that LDCs would gladly participate in any negotiation to establish a Working Group for preparing a Code of Principles for Biomedical R&D, as proposed in the High Level Panel report. Given that LDCs acutely lack resources, it may not be possible for them to arrange, incentivize and reward public health R&D. An alternative source or model of funding is required. He noted that if developed countries sincerely carry out their obligations under TRIPS articles 66.2 on transfer of technology and 67 on technical assistance, this gap of funds and technology would be greatly reduced.

Mr. Ahsan also noted that LDCs want implementation of the High Level Panel recommendation that all the governments, both from the developed, developing and least developed countries, address the issue of access to medicines in the light of human rights principles. For the LDCs, beleaguered by multi-faceted political, economic and environmental problems, ensuring any kind of right to its people is always an uphill task. Mr. Ahsan thus requested patience if LDCs appear to be slow to deliver on this particular issue. To avoid gaps and duplication, LDCs also support the recommendation for an independent review body tasked with assessing progress on health technology innovation and access and also an inter-agency taskforce to increase coherence between multilateral organizations working on the same issue of health technology innovation and access, and hoped that the proposed UN General Assembly Special Session on health technology innovation and ac-



Participants at the South Centre side event to the WTO TRIPS Council on the UN High Level Panel on Access to Medicines.

cess could be convened by 2018.

Mr. Ahsan further pointed out that there are various factors which may impede access to required medicine in the LDCs but that the single most important factor is the cost and especially the cost of the patented medicines. It would be important for all manufacturers and distributors to disclose the cost of R&D, production marketing and distribution of their products, with each category separated, as recommended by the High Level Panel. Because marketing and distribution in an LDC will be of a fraction of the cost that is incurred in a developed country, this will in turn reduce the price of the medicine substantially in the LDCs. Data for clinical trials should also be made public, for the same reason. The WHO should establish and maintain a database of prices of patented, generic and biosimilar medicines in countries where they are registered. Similarly, with the help of WIPO, all Governments should establish and maintain publicly accessible databases with patent information status on medicines and vaccines including standard names for biological products, international non-proprietary names, dates of patent grant and expiry.

In closing, Mr. Ahsan stressed that while including TRIPS flexibilities in national legislation is essential, this alone does not guarantee implementation or assure any benefit, if the capacity to utilize them is missing.

**Professor Carlos Correa, Special Advisor on Trade and Intellectual**

**Property of the South Centre**, emphasized that intellectual property should not constitute an obstacle for the realization of the right to health. He discussed in detail the role of three flexibilities in the area of intellectual property that were highlighted by the UN High Level Panel: rigorous patentability standards, compulsory licenses and competition law.

Mr. Correa stressed that the High Level Panel report can be used to encourage governments to change the law or the practices under the law. The report serves to add confidence that the IP flexibilities in the TRIPS Agreement are legitimate. The High Level Panel report adds evidence that countries can use this policy space in compliance with human rights obligations in the area of public health.

On the subject of patentability criteria, Mr. Correa emphasized the recommendation by the High Level Panel that high quality standards should be applied in the examination of patent applications in the area of pharmaceuticals. He noted that it is common for pharmaceutical companies to file for patents when there is no real innovation. There are multitudes of patents on polymorphs, salts or minor developments related to known medicines, which are the outcome of routine activities rather than inventive activities. The problem is that price competition is reduced because generics are not allowed to enter the market. Procurement practices are also affected, as well as subsequent research and de-



velopment. Mr. Correa further explained that while there are some cases where changes to existing medicines may imply some improvement, as recognized in the report, it does not mean that a patent should be granted for the improvement.

Mr. Correa noted that the High Level Panel report recommends governments to look critically at how patents are examined in the field of pharmaceuticals. He pointed that despite the many problems, there are some good examples. Developing countries such as India, Argentina, Brazil and Egypt are applying rigorous standards for establishing whether or not there is an innovation and whether it merits a patent. Mr. Correa stated that some countries have suffered pressures for the application of these rigorous standards, yet those pressures have not led to changes to national policies. These pressures have also not led to formal complains. This is a confirmation that these policies are legitimate and are aligned to public health needs.

Mr. Correa noted that there are many organizations such as UNDP, South Centre and UNCTAD that can provide technical assistance and advice to countries to improve practices in the area of pharmaceutical patents. He emphasized that in many cases there is no need to change the laws when considering how patentability standards can be best applied. He stressed the importance for government to consider the High Level Panel recommendations on technical assistance to improve how patentability standards are applied.

Mr. Correa also discussed the recommendation of the High Level Panel report on the subject of compulsory licenses. Mr. Correa noted that the report makes it clear that compulsory licenses are legitimate and should be used as and when needed. Governments are not restricted to use compulsory licenses only in emergencies. Compulsory licenses can be applied on the grounds determined by national law. This is a flexibility confirmed by the Doha Declaration. Compulsory licenses are an important tool in order to ensure that public health objectives are attained. It is a tool that is not of exclusive interest for developing countries. It is a legitimate tool because the issue of medicines affects all countries. Mr. Correa stressed that referencing the High Level Panel report at the national

level could help streamline the grant of compulsory licenses and prevent obstacles or burdens from parties requesting them. It can also serve to increase awareness that this tool should be available and used to satisfy public health needs.

Mr. Correa noted that the High Level Panel report provides evidence on this. Many cases of use of compulsory licenses show that it can be an effective tool to reduce prices and increase access to medicines. Mr. Correa recalled that there are many countries that have granted compulsory licenses, including Zimbabwe, Malaysia, Mozambique, Zambia, Indonesia, Thailand, Brazil and Ecuador. Some developed countries have also granted compulsory licenses. Mr. Correa noted that a large number of compulsory licences have been granted in the US. The US legislation is flexible in this regard, particularly for government use. Other good examples of developed countries using the compulsory licensing flexibilities in Europe can be found in Italy. Mr. Correa noted that most recently, Germany through its Federal Court issued a compulsory license on 31<sup>st</sup> August 2016 on grounds of public interest that benefited the firm Merck, recalling that paradoxically, the same firm was very hostile in Thailand for its grant of a compulsory license.

On the subject of competition law, Mr. Correa pointed out that it is often neglected in the analysis related to the TRIPS agreement. Competition law can help support policies to increase access to medicines. Competition policy may be used to deal with restrictive practices relating to licenses agreements and cases of voluntary licenses of pharmaceutical patents where restrictions are applied such as requirements to buy the active ingredient from the licensee source, price restrictions or restrictions on the geographical scope of the license. There are also situations of refusal by the patentee to grant a license under reasonable commercial conditions. Competition law can be applied in these cases of restrictive licensing conditions or excessive pricing. Cases of excessive pricing have been subjected to an investigation and remedies accorded by the competition authority.

Mr. Correa recalled that the pur-

pose of competition law is not only for competitors but to protect consumers. He noted that competition law is underused in most developing countries, and pointed to a guide by the UNDP that is helpful in providing guidance on the application of competition law in the area of public health.

## Q&A and Closure

Following the presentations, there was interaction between the audience and the panelists. Some of the issues discussed were the obstacles to the use of TRIPS flexibilities due to TRIPS plus provisions in trade agreements, the role of public health impact assessments, the role of the High Level panel in re-energizing the issue of access to medicines in relation to intellectual property, the need to discuss the High Level Panel report and its recommendations in more fora, the importance of new models for innovation and expanding consideration of deficits in innovation in broader disease areas, including non-communicable diseases.

To close the event, panelists emphasized the global nature of the access to medicines problem. It was noted that tackling the problem requires increased global collaboration and an inter-sectoral approach, integrating health, trade, human rights and intellectual property. A call was made for more in depth discussions in the TRIPS Council on the recommendations of the report, including those on rigorous patentability standards and use of compulsory licenses and competition law.

*Mirza Alas is a Research Associate and Viviana Muñoz Tellez is the Programme Coordinator of the Development, Innovation and Intellectual Property Programme (DIIP) of the South Centre.*

## Resources:

The report of the High Level Panel on Access to Medicines is available at <http://www.unsgaccessmeds.org/final-report/>

For video feeds of this event, see <https://www.facebook.com/SouthCentre/>

For additional coverage of this event, see <https://www.ip-watch.org/?s=side+event>

# Human Rights Council panel highlights how access to medicines is impeded by patents

The UN Human Rights Council held a panel discussion on human rights and access to medicines in Geneva. Panellists included members of the UN Secretary General's High Level Panel on Access to Medicines. The panel presentations highlighted how patents have impeded the affordable access to medicines and called for impact assessments to be done on the effects of free trade agreements on the right to health. (This article was originally published in the SUNS.)

By Kanaga Raja

Members of an official panel of the Human Rights Council highlighted that access to medicines and the right to health are being impeded by high prices of medicines caused by patent monopolies, and urged that the Council facilitate studies of the human rights impact of trade agreements that contain intellectual property provisions.

The UN Human Rights Council on 8 March 2017 held a panel discussion to review the key challenges to ensuring access to medicines as well as exchange views on good practices, including exploring the recommendations of the UN Secretary-General's High Level Panel on Access to Medicines.

The Council had decided in July 2016 to convene "a panel discussion to exchange views on good practices and key challenges relevant to access to medicines as one of the fundamental elements of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,

taking into account all relevant reports, and that the discussion shall be fully accessible to persons with disabilities."

The panel discussion was chaired by the Vice President of the Human Rights Council, Ambassador Mouayed Saleh of Iraq, and moderated by Ambassador Maria Nazareth Farani Azevedo of Brazil.

The panellists included Ms. Ruth Dreifuss, former President of Switzerland, and Co-Chair of the Secretary-General's High Level Panel on Access to Medicines; Mr. Michael Kirby, former Justice of the High Court of Australia and a member of the High Level Panel; Dr. Marie-Paule Kieny, Assistant Director-General, Health Systems and Innovation, World Health Organization; Mr. Anthony Taubman, Director of the Intellectual Property Division at the World Trade Organization; Mr. Thomas Bombelles, Head of Global Health at the Global Issues Sector, World Intellectual Property Organization; Mr. Carlos Correa, Special Advisor on Trade and Intellectual Property, South Centre; and Mr. James Zhan,

Director of the UNCTAD Division on Investment and Enterprise.

The UN Deputy High Commissioner for Human Rights, Ms. Kate Gilmore, who opened the panel discussion, said that the right to health and its associated obligations calls on States to ensure universal access to good quality health care, including essential medicines, on the basis of equality and non-discrimination.

In this, she said, the protection of those who are otherwise marginalised, those with the fewest options, those who routinely are left behind, their protection is essential. For without access to life saving commodities, the realisation of the right to health will remain an unattainable goal for numerous countries and millions of people.

She said further enjoyment of the benefits of scientific progress is a right in and of itself. It is recognised in the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights, and among its key elements is the affirmation that innovations essential for a life with dignity should be accessible to everyone, without discrimination.

These human rights norms are so fundamental - so intertwined with numerous other rights as to be binding on all States. And yet today, she noted, millions live without access to es-



Panellists of the panel discussion on human rights and access to medicines at the UN Human Rights Council

sential medicines not due to an inherent lack of these commodities, but due entirely to policy deficits and entrenched practices, due to our choices, choices that place in the balance the lives and well being of millions the world over - and not only those that are resident in low-income countries.

For example, as of June last year, 18.2 million people were living with HIV but only one half of them had access to antiretroviral therapy. That the 50% of those living with HIV have such access is a vast improvement on previous periods, but it is simply not enough.

Referring to International Women's Day, Ms. Gilmore said "we are indeed celebrating globally women, their achievements and their contribution and yet today, still falsely packaged as cultural and political preferences, we witness the denial of women's and girls' access to essential medicines with the consequence for their wellbeing of injury and death."

She emphasised it is unconscionable that today young women can be old enough to catch a sexually transmitted infection (STI) but deemed too young to have autonomous access to services for its treatment. It is indefensible that a young woman can be old enough to be pregnant but too young to have access to contraception. "It is unconscionable that we should condemn young women for becoming pregnant, expel them from schools, and refuse to provide them with the medicines, the information, the education and services they need to be in control of their own fertility."

When medicines are put beyond the reach or means of those who most need them, families and communities are left to manage tragic consequences. Concrete steps can and must be taken to course correct, when course correction is urgently required, she said.

As the Special Rapporteur on health has pointed out, States do need to shift from the dominant more market-oriented perspective on access to medicines towards fulfillment of the right-to-health paradigm. Powerful commercial and other interests should not dictate public health policy to the detriment of the fulfillment of human rights.

This means among other things rec-

ognizing, and responding to a number of challenges. Among the challenges cited by the Deputy High Commissioner for Human Rights are:

- \* The protection of intellectual property rights must not be allowed to trump enjoyment of the right to health. Strong competition laws and policies together with forceful enforcement are required to prevent companies from indulging in anti-competitive practices and to promote competitive pricing of medicines.

- \* Human rights and stakeholder participation both must influence trade agreements. Stakeholders do have a right to influence health policy formulation, implementation, and its monitoring and under the human rights-based approach - trade and investment agreements should be negotiated with human rights in mind and concluded with human rights input.

- \* Availability, accessibility, and acceptability of good quality medicines for everyone on the basis of non-discrimination must be integrated into all public health policy frameworks.

- \* Policy makers and other actors responsible for the implementation of health policy should be made accountable - an accountability to the users of health services.

For this to take place, "we have the opportunity - not only the responsibility - to undo the power imbalances that lie at the heart of this issue by empowering rights-holders to be partners in health, to claim their health and health-related rights and to enable health policy makers to make people-centred decisions and hold them accountable for delivering on this."

According to Ms. Gilmore, perhaps the greatest obstacle to fulfilling the obligation to ensure access to essential medicines for all is political will. She said it is also a question of health economics, it is a matter of the ethics of the pharmaceutical industry, it's the responsibility of health care providers and health professionals and indeed their schools.

She added: "Today we call on all these authorities and actors under the banner of the state health plans incorporating human rights to stand up for the right to health. It's a call of true poignancy given that today is International Women's Day and given how

many women's, newborns', children and adolescents' lives hang in the balance of this determination, that indeed the right to health should be available to one and all."

The moderator, Ambassador Maria Azevedo of Brazil, explained that this panel discussion will provide a platform for states and all relevant stakeholders to review key challenges applicable to ensuring access to medicines and to exchange views on good practices in this regard. The discussion will also explore from a human rights perspective, the recommendations presented by the United Nations Secretary-General's High Level Panel on Access to Medicines.

She said every human being is entitled to the enjoyment of the highest attainable standard of physical and mental health conducive to living a life in dignity. States are obliged to respect, protect, and fulfill this right, including ensuring access to medicines, recognising the essential importance of international cooperation and technical assistance to this effect.

She noted that even with the great potential of science and technology to advance health care, at least one-third of the world population has no regular access to medicines. The recent outbreaks of highly infectious diseases and epidemics have demonstrated the importance of developing new and innovative medicines and vaccines.

Ms. Ruth Dreifuss, Co-Chair of the UN Secretary-General's High Level Panel on Access to Medicines, explained the mandate and work of the High Level Panel. She said that the panellists had scrupulously confined themselves to the limited mandate that they had been given.

She pointed out that the mandate was not confined only to access to medicines. On the one hand, prevention, treatment, rehabilitation and social integration required access by all not just to medicines but to vaccines, diagnostic tools and all sorts of medical equipment.

On the other hand, the mandate also addressed shortcomings in biomedical research and in the development of medicines. Incentives provided by intellectual property rules are based on the existence of a viable market, and are thus inapplicable to many



diseases.

In this context, she highlighted as examples the neglected tropical diseases and rare diseases in particular, vaccines, child formulas, and new solutions to growing antibiotic resistance.

Ms. Dreifuss pointed out that when R&D particularly for non-infectious diseases which now represent the most serious health burden both in the North and South, leads to new medicines, the time-limited monopoly afforded by patents and licenses leads to high prices. This prevents many persons suffering (from the diseases) from benefiting from the progress in science, not just when they have to pay for these medicines out of their own pockets but even leading to problems in health systems which are designed to guarantee universal coverage but are forced to introduce restrictions and rationing of such treatment and medical technologies.

She said the mandate (of the High Level Panel) refers to the legitimate rights of inventors. Inventors by their very nature are physical persons and they are entitled to fair remuneration and recognition for their contribution to science. But the legitimate rights of inventors are not the same thing as intellectual property rights, Ms. Dreifuss said.

Intellectual property rights are usually given to companies who are given a time limit to the exclusive right to use an invention. These are intellectual property rights, and not the legitimate rights of inventors, which come under the rules of international trade and which have positive and negative consequences on the development of medical technologies and on access to them.

"That was the focus of our [the High Level Panel's] deliberations," she said. Doing its work, the Panel built on the deliberations of the World Trade Organization and of the World Health Organization.

She said that trade rules and intellectual property rights were developed in order to promote economic growth and to stimulate innovation. On the one hand governments seek to get the economic benefits of international trade.

On the other hand, the obligation to respect the medical technology patents

can in some cases be an impediment to public health objectives. "We therefore must welcome the Doha Declaration [on the TRIPS Agreement and public health] introducing flexibilities for states in meeting these obligations," she said.

"But we must also emphasise the fact that there is continuing incoherence particularly because subsequent negotiations have reduced the Doha Declaration flexibilities or put countries under pressure, preventing them from invoking the flexibilities," Ms. Dreifuss added.

She highlighted that the High Level Panel had recognised that it is a matter of state sovereignty for states to lay down the criteria for granting patents and also for states to determine health emergencies which require them to take particular measures.

"We also emphasised the importance of transparency as an absolute precondition for ensuring the coherence we were called upon to address with proposals in order to achieve that coherence," she said.

Mr. Michael Kirby, a member of the High Level Panel on Access to Medicines, said that the issue that is before us is not just a matter of ethics. It is also a matter of international law.

He said great developments have been achieved in inventions relevant to the right to health, in the distribution of those inventions and in global solidarity. However, high amongst the impediments for the attainment of the right to health have been the clash of policy incoherence and the weaknesses of market mechanisms in stimulating invention and in promoting just distribution in accordance with human rights principles.

He said the High Level Panel unusually conducted public hearings in London, Johannesburg, and with links to Bangkok, so as to listen to the nation states, to listen to industry, civil society and individuals effectively denied access to essential medicines.

"We will never forget the voices of those who are left behind, who came before our public hearings. Many of them women and girls, representing families forced to beg for charity and the supply of patented drugs that would save lives, but often denied that charity as outside the guidelines for

selective assistance. We will never forget the people of Africa and Asia who have contracted multi-drug resistant tuberculosis and who cannot afford the prohibitively costly therapies of limited effectiveness that is presently all that is available," said Mr. Kirby.

"It is therefore necessary to say bluntly at this session that unless the world and the United Nations and this Council act now, there is no way that we will attain Sustainable Development Goal No. 3 by 2030," he underlined, warning that millions will be left behind and millions will die.

[Goal 3 states: Ensuring healthy lives and promoting the well-being for all at all ages is essential to sustainable development. Significant strides have been made in increasing life expectancy and reducing some of the common killers associated with child and maternal mortality. Major progress has been made on increasing access to clean water and sanitation, reducing malaria, tuberculosis, polio and the spread of HIV/AIDS. However, many more efforts are needed to fully eradicate a wide range of diseases and address many different persistent and emerging health issues.]

"In the High Level Panel some of us would have gone further than in the report which we produced. Some of us would have taken a different path than in this report. But all of us agreed on the core of essential conclusions which represented our consensus," he said.

Among those conclusions were, first, that the WTO members must respect the flexibilities in the TRIPS Agreement and respect human rights protection in the Doha Declaration. "There must be no more pressuring to force countries to surrender their rights in a health necessity, to invoke compulsory licenses and to contest 'ever greening' and other misuse of market power," said Mr. Kirby.

Second, he said, the international community should negotiate a global R&D treaty to repair the market failures in the invention and availability of essential medicines for all.

Thirdly, the United Nations Secretary-General should initiate an independent review body for health and technology innovation with a high level meeting by 2018 to address global market weaknesses once and for all, he said.



Delegations attending the panel discussion on human rights and access to medicines at the UN Human Rights Council.

"Of all the evidence that I heard during the High Level Panel public hearings, curiously the voice that was most haunting was actually the call in London by the Ambassador of the Netherlands." He quoted the Ambassador as saying: "Don't assume that this is just a problem for poor countries or poor people. This is a challenge for us all - a challenge for the Netherlands, a rich inventive country. The cost of essential drugs is now excessive for our budget. We must all combine to tackle these excesses and failures in the uncorrected market."

The policy incoherence therefore needs to be addressed, stressed Mr. Kirby. The High Level Panel report is the minimum prudent package that is placed before this Council. Its foundation is indisputably universal human rights, he said, and respectfully we suggest it deserves the support of this Council."

Dr. Carlos Correa of the South Centre focused on the recommendation contained in page 28 of the High Level Panel report which states: "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. 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."

Referring specifically to these impact assessments, he said that there is a long tradition of impact studies on the environment, but there are also examples of impact assessments in other areas such as food security.

He then cited a study carried out in 2006 by the National Commission for Human Rights of Thailand on the potential impact on public health of the intellectual property provisions that were being negotiated at that time in a trade agreement with the United States.

A number of academic studies also ex ante have taken place prior to trade agreements being brokered such as CAFTA (the agreement of the US with the Central American countries). There have also been methodologies proposed by a number of academics.

Following the recommendation made by the High Level Panel, it would be important for this Council to decide to embark upon the development of some methodologies and guidelines for impact assessment studies (on how trade agreements impact on the human right to health).

Correa said that the report also covers access to medicines, which is a concern not only of the developing countries but also developed countries. Many patients in developed countries today cannot have access to treatment as a result of extremely high prices of

some medicines.

He underlined that the majority of the impact assessments on public health have been carried out ex ante, in other words, before the negotiation of bilateral or regional trade agreements that typically increase intellectual property protection, extend the term of monopoly of patents and result in countries establishing exclusive rights pertaining to the outcome of clinical studies.

As a result of this ex ante approach, there is a lack of appropriate methodologies to address the ex post consequences of the adoption of certain intellectual property rights protection standards.

Frequently, it is said that developing countries who ratify free trade agreements which contain provisions that raise intellectual property rights protection that can be at odds with human rights also get other trade advantages through these agreements, so there is no overall problem.

In reality that is not the case. Developing countries that accept these maximalist IPR provisions do so in the context of asymmetric power relationships, and they do not have the power to resist the imposition of these protectionist provisions as far as intellectual property is concerned in the agreements they ratify, said Dr. Correa.

The impact assessment must be done ex ante and ex post, and it would need to look at the current effects of intellectual property standards. Correa said we need to look at the effects of the TRIPS Agreement and also other agreements in which TRIPS-plus standards have been adopted.

He emphasised that the outcome of this wave of over-protectionism in the area of intellectual property rights should not be deemed to be irrevocable. None of this is carved in stone, concluded Dr. Correa.

Correa referred to the statement of the international organizations represented at the panel competent in the area of intellectual property and trade, and indicated that if they would have actually been as efficient as they claimed in promoting TRIPS flexibilities, there wouldn't be such a large number of developing countries where those flexibilities have not been implemented. He also mentioned that,

as noted by the HLP report, countries such as Thailand and Colombia have been subject to pressures when they intended to use those flexibilities. Correa also observed that despite the statements of some developed countries' delegations, they demanded TRIPS-plus provisions in the FTAs they sign (like in the case of the FTAs under negotiation between the EU and Tunisia and the EU and MERCOSUR) that can negatively affect access to medicines.

Dr. Marie-Paul Kieny of the WHO highlighted the activities of the organisation in supporting access to medicines and the challenges faced in this context. She said that the WHO has a long tradition of commitment and activity to support access to medicines as one of the fundamental elements of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

Mr. Taubman of the Intellectual Property Division of the WTO said that today's discussion is a welcome step forward in the journey together to-

wards the shared goal of access to medicines for all, and promoting the development of urgently needed new medicines, recognizing the centrality of the human rights perspective for this collective effort.

For the WTO, the Doha Declaration was a significant milestone on this same journey. Unanimously, at the highest political level, Doha framed the legal, practical and policy context of TRIPS squarely within a public health setting.

Doha remains a benchmark for policymakers today, all the more pertinent in the light of the SDGs, the growing complex of regional and bilateral trade agreements, and the renewed multilateral dialogue exemplified by the very Resolution that established this panel, he said.

Mr. Bombelles of WIPO said that WIPO's founding documents stress that WIPO should pursue its mandate in coordination with other UN bodies, and also participate in the relevant work of other UN bodies.

He said WIPO and its Member States have long understood and appreciated that intellectual property has transcended the confines of legal issues relating to IP and touched on many of the most important public policy issues.

On global health specifically, the question of how to simultaneously sustain innovation in new medicines and other health technologies, while also ensuring access for all, is a central challenge, he said.

Mr. Zhan of UNCTAD highlighted that his organisation has been working on access to medicines since 2005, from the specific angle of intellectual property rights and investment in local pharmaceutical production.

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

*An earlier version of this article was published in the SUNS of 14 March 2017.*

# South Centre Paper Sees IP In Free Trade Agreements Interfering With UN SDGs

By Kim Treanor

A new paper from the intergovernmental South Centre argues that intellectual property provisions in recent free trade agreements would impair countries trying to fulfil the United Nations Sustainable Development Goals.

The South Centre, the Geneva-based developing country group, has released the research paper entitled, "[Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements](#)," by Special Advisor on Trade and Intellectual Property Carlos Correa.

In the paper, Correa argues that free trade agreements, using examples of primarily US-led FTAs, contain intellectual property provisions that constrain countries' abilities to fulfill Goal 10 of the UN Sustainable Development Goals, reducing inequality within and among countries.

Correa argues that many FTAs contain provisions that require countries to implement regulations beyond those required under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which all WTO members are required to adopt.

[TRIPS requirements](#) include the standardisation of patent terms to a uniform 20 years, and demand that domestic institutions adopt measures to register and enforce patents. While countries are bound to these rules, the TRIPS agreement allows each country to use "[flexibilities](#)" within the agreement, notably the ability to issue compulsory licences or parallel imports when necessary to protect public health.

Correa argues that FTAs often contain additional requirements, called "TRIPS-plus" and "TRIPS-extra" provisions. Demands in these categories, per



The South Centre paper by Carlos Correa can be accessed from: <https://www.southcentre.int/research-paper-74-february-2017/>

Correa, include the obligation of extending patent protection to known medications when a new use or method is found, extending patent terms to account for regulatory delays in approval, or requiring "[data exclusivity](#)" for



[biologic](#) drugs. This exclusivity is essentially the practice of preventing regulators from reviewing clinical trial data of a brand name drug in order to compare the safety and efficacy of any biosimilar or generic competitor, and preventing generic manufacturers from using this data to make competing medicines.

Correa criticises the impact of the TRIPS agreement, stating that the implementation of the agreement hurt access to medicines in low and middle income countries, that the agreement did not assist in generating the research and development funding for the diseases which affect developing countries, and that there is no evidence that strict IP protection has led to increased foreign investment.

It is not only the IP requirements within FTAs, the paper argues, that place onerous requirements on countries. Correa points to the [certification](#) process used by the Office of the US Trade Representative to argue that after an FTA is signed and prior to its entry into force, the trade representa-

tive can review the other party's laws and apply pressure to limit any flexibilities retained in their domestic law. Correa also argues that further pressures are placed on trading partners by the US by placing them on the USTR "watch list" under the annual [Special 301 report](#), which assesses the United States opinion on global protection of US IP.

These extra pressures seem especially poignant as Correa moves to discuss the flexibilities within many FTAs that can be utilised by national governments. Correa argues that depending on the requirements of the FTA, authorities in member states can limit protections on test data and restrain [patent linkage](#), a system that links a drug's patent status to its marketing approval. Flexibilities for test data exclusivity may include protecting only undisclosed test data, waiving data exclusivity if a compulsory licence is issued or for public health reasons, and ensuring that data exclusivity only applies to the commercialisation of a product, and not distribution for humanitarian reasons.

In order to mitigate ill effects on public health from patent linkage, Correa advocates for making the patentee liable for damages when linkage claims are "unduly used to exclude generic products from the market," and recommends that linkage provisions only apply to patents of active ingredients in a drug.

Correa's argument is that TRIPS-plus and TRIPS-extra provisions such as those discussed above will exacerbate inequalities between countries and place a strain on access to medicines within low and middle income countries. To this end, he recommends that countries must use the flexibilities within TRIPS and within any free trade agreement which they sign to the fullest extent, in order to mitigate the negative impacts of requirements in these agreements.

*This article was published by the Intellectual Property Watch (IP-Watch) on 27 February 2017.*

## Brazilian Legend Celso Amorim Recounts Negotiation For TRIPS Flexibilities

The former Foreign Minister of Brazil, Mr. Celso Amorim, who was also much involved in the negotiations that set up the World Trade Organization, gave a long interview to IP-Watch with his inside story on the issues and negotiations that led to the 2001 Declaration on TRIPS and Public Health. This is the article carrying the interview.

By William New (IP-Watch)

Minister Celso Amorim of Brazil has had a significant impact on the state of global negotiations in his professional lifetime, including on global intellectual property rights.

As his new book, [Acting Globally: Memoirs of Brazil's Assertive Foreign Policy](#), sets out, in the first decade of the 2000s Brazil played an assertive role in foreign policy in areas such as the Iran nuclear issue, relations in the Middle East, and the Doha Round of multilateral trade negotiations at the World Trade Organization.

Amorim (see [bio here](#)) was at the centre of that, and reaching back to the early 1990s, took the lead role in negotiating the 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

In an interview this month with *Intellectual Property Watch* conducted in the atrium of the WTO after he spoke at



Mr. Celso Amorim (left) in the panel of the South Centre side event to the WTO TRIPS Council on the UN High Level Panel on Access to Medicines.

a South Centre side event ([IPW/ WTO/TRIPS, 7 March 2017](#)), Amorim briefly retold the story of the TRIPS agreement negotiations that resulted in flexibilities for developing countries. He also negotiated the landmark 2001 [Doha Declaration on TRIPS and Public Health](#), which reinforced those flexibilities.

The TRIPS negotiations were mostly completed in 1991, he said, and “the whole [time], we were negotiating under pressure, under duress.” Brazil and many other developing countries spent all of the time under threats like suspension of financing at the International Monetary Fund.

The original [Punta del Este Declaration](#) launching the Uruguay Round in 1986 focused the negotiations on intellectual property rights only on counterfeit products, he noted. This was under the General Agreement on Trade and Tariffs (GATT), before the creation of the WTO.

“What people had in mind, at least we thought, ... that it was trade in counterfeited goods. So we thought that would be it,” he said. “Well then of course it evolved.” The developed countries led by the United States and others “were able to bring in all of the question of patents and intellectual property which normally would be the remit of the World Intellectual Property Organization through the GATT at the time.”

In addition, he said developed countries ensured “that there could be cross-retaliation so that a violation in intellectual property would enable a country to retaliate in goods, steel or orange juice or whatever, like if the Motion Picture Association, for instance, didn’t like something we did on film, or any pharmaceutical company.”

When they came out of the TRIPS negotiations, developing countries thought it didn’t look good for them as developed countries seem to have gotten their way. “All the things that they wanted they were able to put,” he said.

## Silver Lining

But he saw a silver lining in some areas of the agreement, he said, thinking then, “There are some ambiguities here and there.” For instance, he said, “you were not able to say compulsory licence is not permitted. It was not legal to say that.”



They left it in a way that could be interpreted that there should be no preventing it, including a general article on non-discrimination. “We were not able to say compulsory licence is permitted, but [they were] not able to say CL is prohibited,” Amorim said. “I said to my colleague, ‘Don’t be so pessimistic. After all, these ambiguities we can someday use in our favour.’ But I did not have much expectation.”

Then something happened beyond negotiators’ control: “During the 90s, public opinion changed because of HIV/AIDS and because of the public opinion of the United States,” he said.

So when the US pursued a WTO legal dispute against Brazil, “against the provisions of our law on compulsory licensing,” he said, “a great deal of the US public opinion was with us because of people affected by HIV. In the United States, the rates were going down but still there was solidarity in that respect.”

At that time, he was now Brazil’s ambassador to the WTO (having been the trade minister who signed the Uruguay Round earlier).

And Brazil also made a “small manoeuvre which helped,” he said. “We looked for provisions in the United States patent law that had discriminatory aspects, especially in relation to grants to universities and things like that, because they say the product has to be patented in the United States, it has to be produced in the United States. So we said, ‘Okay you asked for consultation on that, we will ask for consultation on that as well.’”

“Well, I don’t know what was the thing that weighed more, but they gave up,” said Amorim. “They gave up and the only thing we agreed was not even negotiations, we agreed to have conversations. These things are very subtle.”

Then, as the WTO moved into the Doha Round of negotiations, the issue became big again, and many developing countries were worried, he said.

“To make a long story short, I saw that there was a big danger that instead – because the Europeans said, ‘Let us spell out the regulations how this will be applied. And then I thought, no, that will be against us,’ as the regulation will be for subtract from the flexibilities. Developing countries sought to make them clear, so it did not happen.

## TRIPS ‘Does Not and Should Not Prevent’

The result was Paragraph 4 of the Doha Declaration on TRIPS and Public Health. It states:

*4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.*

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility





Former Minister of Foreign Affairs and Ambassador of Brazil to the WTO, Mr. Celso Amorim, in an interview with IP Watch at the headquarters of the WTO in March 2017.

for this purpose.

There were two formulations for this before it was finalised. The developing countries text said 'nothing agreed prevents' ["Nothing in the TRIPS agreement shall prevent members from taking measures to protect public health"], and the developed countries said 'everything in the TRIPS agreement allows', he said, the latter potentially a way to disallow exceptions.

One of the reasons for the failure of the 1999 WTO ministerial in Seattle, in addition to the US labour movement and disagreement on agriculture, Amorim said, was that the negotiating text was all in brackets – "hundreds, maybe thousands of brackets."

"I remember when we left the last meeting here [at the WTO before heading to Seattle], I said, well the motto of the WTO has always been, 'nothing is agreed until everything is agreed', but in this case, it is 'nothing is agreed, full stop'," he said.

So WTO General Council Chair Stuart Harbison (Hong Kong) had the idea to have a clean text with no brackets, and asked negotiators, including Amorim, for their opinion in what he called "confessions".

At that time, Brazil had a "very important policy" to combat HIV/AIDS with the use of generic drugs, Amorim said, adding, "I'm not speaking of something abstract. Our health minister was a very strong minister."

So when Harbison called, Amorim told him, "it's fine that you have a clean text" if it has the developing country formulation. "If you have the one by the developed countries, forget it," he said. "And I'll tell you something, don't try to arbitrate, because if you try to arbitrate at that point it would be negative for us."

That's because "in Geneva, everything's obscure, nobody sees the pressures, so it's good to have that 'shock' in the public, in Doha [at the next ministerial to be held in late 2001]. "So I said, if you can't accept ours, don't put theirs and don't arbitrate, put the two. And if you go to the history, it was the only paragraph that went with two formulations to Doha. It doesn't mean the others didn't change, but it was the only paragraph that went with two formulations. That was really because of Brazil."

That was the first battle, he said, ensuring their formulation made it to Doha. The second battle? "To ensure that our formulation would be the basis for the negotiation."

In the second battle, he said he doesn't know exactly how it happened, but it was agreed in the end that their formulation would be the basis of the negotiations. He listed possible influences: a revolt, the perception that it was necessary to solve this problem before moving into the bigger questions of the round as if it was a "gateway" for other things, the attacks in the US on September 11 giving the Bush administration an imperative to

have an agreement in Doha. Many developing countries came with Brazil, such as many African countries, and India.

Of course, he said, the text did not stay as their proposal, instead ending up stating, 'the agreement will not prevent,' ["We agree that the TRIPS agreement does not and should not prevent members from...."] "in a less aggressive way."

The negotiation continued, and the groups were getting smaller, with the smaller group chaired by the former Mexican trade minister and later foreign minister. There were three ministers from Brazil in Geneva and Amorim was ambassador and had focused on that subject so he was in the negotiation.

"So we went to the room, and I had a very serious and honest negotiator on the other side, an American called Alan Larson. He was a lawyer from the State Department, which was a piece of luck," he recounted. "Instead of having someone from the USTR [the Office of the US Trade Representative], there was this lawyer."

The chair said at some point that he wanted only the US and Brazil in the room.

The European Union wasn't happy to be left out. And Amorim said no, he wanted to have an African negotiator with him. Then the African who was there, who was from Cameroon, said no, 'if Brazil is there we feel represented', said Amorim, adding, "That was one of the best moments I had."

So the two negotiated and came to an agreement, which was submitted to the small group and approved.

But when it came to the bigger group, a country from Brazil's group tried to reopen the agreement, and he said he could not accept that, "an agreement is an agreement," so it didn't change.

"That was very useful, I didn't do that with any purpose, that was honestly a negotiation," he said. Later on, the laboratories went after Larson, because they were not happy with the agreement, "and he said – I know this – the Brazilians were honest, were correct, with me, I have to be correct with them, and he didn't change," Amorim said.



Still later, there were pressures on Brazil's foreign minister, so he even had to call the health minister.

The final part of the story is told in a book by Paul Blustein, entitled, "Misadventures of the Most Favored Nations," he noted.

The text of paragraph 4 was negotiated word by word, he said, adding, "That's why you find a difference between 'can' and 'should'." This means it is possible and it is desirable, he said. Yet some things may be desirable and not possible and some things may be possible and not desirable. So he had to put the two of them in the text.

This word combination appears twice, in the positive and in the negative, as it also says cannot and should not in the same sentence.

Brazil has only issued a compulsory licence once, he said, for a drug it imported from India. "But the fact that we have this allowed us to negotiate with the laboratories from a better position," he said.

That is why he emphasises preserving the TRIPS flexibilities. "Ambiguities became flexibilities because they were sanctified, so to say, as flexibilities," he said. "This is the essential thing that has to be preserved, and this is something that has to be respected."

Bringing the conversation to the present, that's why he has said that in the UN High-Level Panel report, Article 2.6.1 is the most important paragraph, "because it requests countries at the highest level to commit themselves to respect the TRIPS flexibilities."

"The TRIPS agreement was to a large extent a victory for the developed countries and a victory for the multinational companies, because they thought they got a lot of things that were not there, of course, intellectual property in the WTO not WIPO, they got cross-retaliation, which in the end worked against them - with Brazil cotton and Ecuadorian bananas," he said. "But with the changing political situation, social culture, we were able to extract the Doha Declaration. I didn't know that I would ever be able to have something like the Doha Declaration."

"I was more dejected when I left [the TRIPS negotiation]," said Amorim. The political climate in 1991 was

"totally neo-liberalism, Washington Consensus and so on, and all these ambiguities would work against us."

But when the problem of HIV/AIDS appeared, Seattle failed, and sadly, 9/11 made it "absolutely imperative" to launch a new round, not to bring trade into collapse, it changed the climate.

## **Doha Declaration Everywhere**

"I said well, maybe we were able to preserve some ambiguities," he said once more. "But in the end, it was really the Doha Declaration that made the difference. You see it mentioned everywhere. You see it mentioned in the UN Human Rights Council, the World Health Organization, in the SDG [UN 2030 Sustainable Development Goal] number 3, etcetera, respecting the flexibilities established by the Doha Declaration on TRIPS and Health."

What was distinctive about the Doha Declaration was that "the things that might have been seen as ambiguous - I don't say that they were - they were clarified in a way that was compatible with our interests," he said. That's why so many bilateral and regional agreements since then have been TRIPS-plus, he said.

As to whether TRIPS ended up hurting developing countries as much as they feared, he said: "It would have, except for the Doha Declaration. It still is a difficulty, but it is a smaller difficulty than it would be if not for the Doha Declaration. Mind you, the developed countries gained a lot, on patents, everything other than health that's in there, patents for other things."

Asked about the argument that TRIPS is out-of-date and needs updating through bilaterals, he said: "I have heard that story before. I have great respect for President Obama, he did great things, but when it comes to trade, he lost an occasion because when he came to this impasse in 2008 [at WTO], we were very near. Bush didn't do it, the Indians were difficult and so on, but Obama didn't want to go forward. I even tried to flag with [then-USTR] Ron Kirk, I don't know if he even understood me."

And as to what is going to happen

now, he said, "I'm scared. Anyone will be right once or twice a day. With the TPP [the Trans-Pacific Partnership which President Trump pulled out of], I think it was a question of whether it was good for the United States. I heard people from the left wing in the United States, like Stiglitz, were against TPP, I would agree."

He added a remark that some political journalists "make a conceptual error," confusing TPP with multilateralism, or confusing NATO with multilateralism. "These are organisations of regional interests, good or bad, but these are not multilateralism involving the whole world," the negotiator said. "The WTO is multilateral. The UN is multilateral."

And on where he thinks the world will be in 5 years, he said, "I'd like to know where we're going to be in six months. If Washington resorts to unilateral sanctions, what can I say, I don't know, it will depend on the [position] of each country."

"This is not the same world as the 1980s or the 1970s, when the Uruguay Round was launched," Amorim concluded. "This is the time of the BRICS [Brazil, Russia, India, China, South Africa], where exists China, so we'll be working for the fragmentation of the world, and not necessarily in the US's favour. People will have to think."

[Update:] Asked after the interview if Brazil is "against IP", Amorim vigorously stated, "No, no, not at all. We have a very important IP system, one of the most developed IP institutes in the developing world, which gives expertise to other countries. So no, we're not against IP at all. But we have to see that life is above profit, and health is above patents."

*This article was published by the Intellectual Property Watch (IP-Watch) on 16 March 2017.*

# In Memoriam: Dr. Leticia Ramos-Shahani (1929-2017)



Dr. Leticia Ramos-Shahani

The Council of Representatives, the Board, and Secretariat of the South Centre are deeply saddened at the passing of former Philippine Senator Leticia Ramos-Shahani on 20 March 2017. The South Centre expresses its deep condolences to the people and Government of the Republic of the Philippines, and to the family of former Senator Leticia Ramos-Shahani on their loss. She served with distinction and commitment on the Board of the South Centre from 2008 to 2012.

Senator Leticia Ramos-Shahani was a trailblazing pioneer in the Philippine diplomatic service and an influential voice in Philippine national politics. She was among the first women to join the Philippine foreign service, rose to the rank of ambassador, and eventually appointed as vice-minister of the Philippine foreign ministry in 1986. For many women who entered the Philippine foreign service after her, Dr. Ramos-Shahani was a role model not only in showing that women can rise to the top of a traditionally male-dominated service and in supporting women in the career service, but also in effectively asserting both national and developing country interests in multilateral negotiations.

She also served as one of the highest-ranking Filipinos in the United Nations system in the mid-1980s as the UN Assistant Secretary General for Social and Humanitarian Affairs. She served as the Secretary General of the UN World Conference on the UN Decade of Women in 1985.

In 1987, she was elected a Senator of the Republic of the Philippines and served two six year-terms (from 1987 to 1998), chairing various Senate committees and eventually rising to serve as Senate President Pro-Tempore. During her time in the Senate, she championed women's rights, agricultural reform, and environmental protection, and was among the twelve senators who voted in 1991 against the renewal of the Philippine-US military bases treaty, leading to the closure of permanent US military bases in the Philippines in 1992.

After finishing her terms of office in the Philippine Senate, Dr. Ramos-Shahani continued to remain in public service, serving at various times as the presidential adviser on culture and as the chair of the National Commission on the Role of Filipino Women, as well as serving as the Dean of

the College of International, Humanitarian and Development Studies of Miriam College in the Philippines.

The South Centre had the privilege of benefiting from Dr. Ramos-Shahani's expertise, experience, and insights, from 2008 to 2012 when Dr. Ramos-Shahani was elected by the Council of Representatives of the member States of the South Centre to serve on the Board of the South Centre, filling one of the three Asia-Pacific seats on the Board. She was instrumental in having the Board of the South Centre hold one of its meetings in the Philippines and enabling it to engage with high-level Philippine officials and academia, thereby further strengthening the working relationship between the Board of the South Centre and the Philippines as one of the founding member States of the South Centre.

Dr. Ramos-Shahani was a shining exemplar of the modern feminist leader and mentor in the course of her life and career both nationally and internationally. She showcased what is best and noteworthy among developing country political leaders and intellectuals, holding true to principled positions on all issues; morality in government; carrying out the duties and responsibilities of a true nationalist; promoting effective South-South cooperation; and serving as a mentor in her professional and academic life to future generations of leaders.



Dr. Leticia Ramos-Shahani (woman at centre) with the Board Members of the South Centre pose for an official photo with the then President of the Philippines, Benigno Aquino III (centre), at Malacañang Palace, Manila, on 1 August 2011.

# Non Aligned Movement and Bandung Principles as Relevant Today as Ever: South Centre

In a world of so many crises affecting the developing countries, the Non Aligned Movement (NAM) and the Bandung Principles that led to the NAM's formation are as relevant as ever.

This was stated by the South Centre at a forum held by the NAM to commemorate the adoption of the Bandung Principles in Bandung by leaders of the newly independent countries 62 years ago.

Below is the statement presented by Vicente Paolo Yu, Deputy Executive Director of the South Centre, at the NAM Forum held at the Palais des Nations (Geneva) on 20 April 2017.

Thank you very much, Ambassador Valero, Chair of the NAM in Geneva, for your kind invitation to the South Centre to make a statement at this important forum of the NAM on the relevance of the NAM in today's times on the occasion of the 62<sup>nd</sup> anniversary of the Principles of Bandung.

Today's celebration of the 62<sup>nd</sup> anniversary of the Principles of Bandung is highly appropriate because of the deeply uncertain times that we are in, and the challenges and opportunities that developing countries face.

The strong solidarity which has guided this Movement in the past decades and its founding principles that underlie such solidarity continue to be important and are even more relevant today as it was in 1961 at the founding

of the NAM in Belgrade and in 1955 at the Bandung African-Asian Conference.

The South Centre, as the intergovernmental policy research and analysis think tank of developing countries, like the NAM itself, traces its roots of fostering South-South cooperation and solidarity to the Spirit of Bandung. We stand ready to continue working together with the NAM in its endeavours.

The result of the 1955 Asian-African Conference in Bandung, known as the Ten Principles of Bandung, was a political statement containing the basic principles that would guide the efforts of developing countries to promote peace and cooperation in the world. These prin-

ciples are worth recalling now:

1. Respect for fundamental human rights and for the purposes and the principles of the Charter of the United Nations.
2. Respect for the sovereignty and territorial integrity of all nations.
3. Recognition of the equality of all races and of the equality of all nations large and small.
4. Abstention from intervention or interference in the internal affairs of another country.
5. Respect for the right of each nation to defend itself singly or collectively, in conformity with the Charter of the United Nations.
6. Abstention from the use of arrangements of collective defense to serve the particular interests of any of the big powers, abstention by any country from exerting pressures on other countries.
7. Refraining from acts or threats of aggression or the use of force against the territorial integrity or political independence of any country.
8. Settlement of all international disputes by peaceful means, such as negotiation, conciliation, arbitration or judicial settlement as well as other peaceful means of the parties' own choice, in conformity with the Charter of the United Nations.
9. Promotion of mutual interests and cooperation.
10. Respect for justice and international obligation.



The hall of Gedung Merdeka where the Bandung Conference in 1955 took place.



As we look at our world today, these principles are deeply threatened, and yet, by the same token, their observance is even more needed.

Born out of the struggle against colonialism, and with a common aspiration to develop economically and provide better lives for their peoples, the Non-Aligned Movement remains relevant as one of the most important platforms to promote unity among the countries of the developing world which is so necessary to face their longstanding, emerging and growing challenges. This is particularly true inside the United Nations, where most of the NAM's daily business takes place, as its member states debate, agree on and advance common positions quite successfully on many issues in the multilateral arena, including on political and security issues, health, the right to development, human rights, among others.

The NAM continues to be relevant in providing support to specific member states such as Palestine which continues to face occupation and Cuba which has long been suffering from an embargo by the United States for decades. It remains a strong pillar of support for developing countries fighting against racism, occupation and neo-colonialism. NAM also takes up social and economic issues, so its coordination on these issues with the G77 and China continues to be very important.

The South Centre most recently was at the 60<sup>th</sup> anniversary of Bandung in 2015 and at the 17<sup>th</sup> NAM Summit in Isla Margarita in Venezuela in 2016.

Both of these important events highlighted for us the importance of South-South cooperation, unity, and progress as exemplified by the NAM. The 17<sup>th</sup> NAM Summit Isla Margarita Declaration, with its 21 goals, and its Final Document of more than 200 pages, both provide the framework for the continued relevance and unity of the NAM in promoting development, maintaining peace, and preventing war.

Development and poverty eradication continue to be the main challenges that face the South. While the past decades have seen great strides in the development of the South, that progress has not been widespread nor equitable. It is also increasingly becoming more difficult to do so because of the many crises that developing countries are now facing such as climate change and other environmental crises; wars that impact on the peace and stability of developing countries; continuing adverse global economic conditions arising from the responses of developed countries to the global financial crisis; continuing structural economic deficiencies in international trade, investment, intellectual property, health and other policy regimes that make it difficult for developing countries to maintain their policy space for development; the rising threat of global pandemics; and the impact and challenges of the North-South technological divide and the advent of new technology-based automated modes of production on the development prospects of developing countries.

In the face of these myriad of development challenges to the South, the NAM together with other developing groupings such as the G77 and China and the many regional organizations that have emerged as an expression of South solidarity in the past decades inspired by the Bandung and NAM spirit, are more important than ever in fostering real development-oriented South-South cooperation, unity, and progress.

To conclude, from the lessons that we have learned in working with developing countries and their organizations in various multilateral arena, including with the NAM, it is important for the NAM to continue and enhance those actions that enable it to maintain and advance its positions consistently and coherently. This is much needed especially in a world that has become much more unstable, politically and economically; where South-South solidarity and cooperation are very much in need; and where some developing countries are emerging in some areas which could provide both new opportunities and new challenges for the rebalancing of global power relationships. It is up to the NAM to grasp these opportunities and to effectively address these challenges through its greater unity and solidarity.

In this context, the South Centre looks forward to working closely with the NAM and its Member States.

Thank you.

## SOUTH BULLETIN

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Bandung, 24 April 2015: Asian and African leaders take a commemorative walk 60 years after the original Afro-Asian Summit in Bandung, which was the precursor to the Non-Aligned Movement.