Improving Access to Medicines: What needs to be done

This South Bulletin provides a summary of the South Centre's three submissions to the UN Secretary General's Highlevel Panel on Access to Medicines on some of the key actions that need to be taken to strengthen the access to medicines for people in developing countries:

- The Need to Assert the Primacy of the Right to Health over Trade and **IP Rules**
- A Binding International Treaty on Medical Product R&D under the Auspices of the UN
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The poor and most vulnerable population in developing countries face huge difficulties in access to medicines, a real threat to universal health.

Super drugresistant gene raises new health alarm



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Access to Medicines: South Centre's views on what needs to be done

The South Centre has made three written submissions on some of the key actions that need to be taken to strengthen the access to medicines for people in developing countries.

These submissions were made to the High-level Panel on Access to Medicines established by the United Nations Secretary-General, Mr. Ban Ki-moon. Below is a summary of the South Centre's three submissions.



The UN High-level Panel on Access to Medicines held a briefing at WHO last February to explain the process of the initiative and present its work to countries and various stakeholders.

By the Development, Innovation and Intellectual Property (DIIP) Programme, the South Centre

A High-Level Panel on Access to Medicines convened by the UN Secretary-General is currently considering a number of proposals to address the policy incoherence between intellectual property (IP) rights, human rights, trade rules and access to medicines.

The High-Level Panel has received 177 submissions from a diverse range of stakeholders including patients' groups, policy-makers, intergovernmental organizations and pharmaceutical companies. It has also conducted two global public hearings and dialogues.

The final report of the High-Level Panel will be submitted to the UN Secretary-General in June 2016. The Secretary-General will present the report to the UN General Assembly to take further action.

The South Centre made three submissions to the High-Level Panel in response to the call for contributions. These submissions are based on the premise that the right to health for all must prevail over trade and intellectual property rules. The three submissions are publicly available on the website of the High Level Panel: http://www.unsgaccessmeds.org/list-of-contribution/, listed as South Centre, No. 67, No. 112 and No. 113.

1. The Need to Assert the Primacy of the Right to Health over Trade and IP Rules

An effective way to address policy incoherence between the right to health over trade and IP rules is first and foremost, to assert the primacy of the right to health for all, over trade and intellectual property rules. The attainment of good health and well-being is an objective as well as a human right, whereas trade or intellectual property are means. Thus there should be primacy of health over trade or IP. In this context, the South Centre submitted a se-

ries of recommendations to the HLP for its endorsement.

First, developing countries should tailor their intellectual property regimes to their own domestic technical, economic and social needs and capacities. To this aim, these countries should incorporate the TRIPS flexibilities into national patent law to enhance access to medical products. The implementation of these flexibilities is a means to balance patent rights with the right to health, stimulate competition, protect consumers, and facilitate access to generic medical products that are accessible and affordable to governments and consumers.

Second, a key flexibility is that countries are free to determine in their own way the definition of an invention, the criteria for judging patentability and patentable subject matter, the rights conferred on patent owners and what exceptions to patentability are permitted, subject to meeting the minimum standards laid down in the WTO TRIPS Agreement. Countries should apply a rigorous definition of patentability criteria. Moreover, revision of national patent laws to allow and effectively use other flexibilities should be promoted. These include: compulsory licenses and government use authorization, parallel importation, research exception, limit the extent of test data protection, and develop robust patent examination systems with pre-grant and post-grant opposition.

Third, patent offices should be encouraged to reject pharmaceutical patent applications as not constituting inventions for the following: new dosage forms of known medicines, new salts, ethers, esters and other forms of existing pharmaceutical products, discovery of polymorphs of existing compounds, enantiomers, therapeutic, diagnostic or surgical methods of treatment and claims for new uses of known products.

Fourth, countries should take measures to control anti-competitive practices and abuse of intellectual

property rights in their jurisdictions. Multilateral trade rules allow substantial flexibility in the development and application of competition law and policy. As a consequence of accommodating the variety of potential competition approaches, remedies available to address anti-competitive behaviour may permit a broader range of remedial action than some other public health-related flexibilities associated solely with patents.

Fifth, developed countries should stop the use of unilateral trade measures and free trade and investment agreements as a means to pressure countries to undertake TRIPS plus commitments. The recent rise of bilateral and multilateral FTAs threatens public health and access to affordable medicines. Strong trade and power asymmetries exist between developed and developing countries during FTA negotiations. Trade-oriented pressures are applied to developing countries to surpass the protection afforded by TRIPS and to diminish the system of the TRIPS flexibilities. These are illsuited 'TRIPS-plus' solutions.

Furthermore, the special rapporteur on the right to health has pointed out that: "TRIPS-plus provisions in FTAs differ from agreement to agreement, but their purposes are by and large to: Extend the patent term, introduce data exclusivity, introduce patent linkage with drug registration and approval, and create new enforcement mechanisms for IPRs. There should be the promotion of reform of African regional IP organizations - ARIPO and OAPI - in order that they accommodate the flexibilities available under TRIPS such as the transition period for LDCs as well as application of strict criteria of patentability. The current operations of ARIPO do not facilitate the full use of TRIPS flexibilities and instead erects patent barriers to the importation and local production of affordable medicines.

Sixth, LDCs should make (and should be provided assistance to do so) effective use of the current transition period that allows them to not apply pharmaceutical patent protection, test data protection or exclusive marketing rights; and recommend that the current waiver be made permanent until the time an LDC graduates from that status. At present, LDCs are not be obliged to implement or apply or to

enforce patents as well as test data protection for pharmaceutical products, or to make available a mechanism for filing patent applications for pharmaceutical products (mailbox) or to grant exclusive marketing rights to such applications, until 1 January 2033 or the expiry of such later transition period that may be granted by the WTO Council for TRIPS. LDCs should actively use the created policy space in this transition period and take immediate steps to amend their respective national laws to provide for such exclusions.

Seventh, there should be a ban on the application of non-violation and situation complaints with respect to the TRIPS Agreement. Introduction of nonviolation complaints under TRIPS could enable legal challenges to regulatory and public policy measures that may be consistent with the obligations under the TRIPS Agreement. For example, public health measures such as issuance of compulsory licenses, or packaging restrictions on harmful products could be challenged even if these are consistent with TRIPS obligations if non-violation complaints are allowed. Unlike non-violation complaints in GATT, where a finding of nullification or impairment of the expected benefits would lead to an adjustment of the impugned tariff measure, in TRIPS this would lead to an amendment of the substantive obligations under the agreement. In this way, it can undermine the balance of rights and obligations and interests of right holders and users in TRIPS. Moreover, non-violation complaints could lead to narrowing the scope of flexibilities under the TRIPS Agreement. The experience of non-violation complaints under GATT suggests that the existence of non-violation complaints has led the panels to adopt a narrow interpretation of the provisions of GATT. For example, while TRIPS requires the grant of patents in all fields of technology if the patentability criteria are satisfied; it does not define novelty, inventive step or industrial applicability. This allows for diversity in the treatment of patent applications in different territories which enables developing countries to define what is patentable very narrowly. If non-violation complaints were allowed, it is possible that decisions to reject a patent based on a strict definition of the patentability criteria may be challenged. Therefore, non-violation complaints would seriously impair the balance of rights and obligations enshrined under TRIPS

Eighth, WIPO and other international organizations should provide technical assistance on IP policy to developing countries that builds their capacity on the use of TRIPS flexibilities.

Ninth, WIPO and WTO should undertake human rights impact assessments prior to any norm-setting activities, especially if they have an impact on public health.

Tenth, the results of publicly funded research should be made available to all, and not be eligible for patent protection. Global, open access to publicly funded research should be promoted to advance collaborative scien-

The High-level Panel on Access to Medicines

The High-Level Panel is co-chaired by Ruth Dreifuss, former President of the Swiss Confederation and former chairperson of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), and Festus Gontebanye Mogae, former President of Botswana. The other members of the High-Level Panel are Andrew Witty, CEO of the multinational pharmaceutical company GlaxoSmithKline, Prof. Sakiko Fukuda-Parr, Awn Al-Khasawneh, the former Prime Minister of Jordan, Celso Amorim from Brazil, Winnie Byanyima, Executive Director of Oxfam International, Shiba Phurailatpam, Director of the Asia Pacific Network of People Living with HIV (APN+), Precious Matsoso from South Africa, Yusuf Hamied, Chairman of the Indian generic pharmaceutical company Cipla, Justice Michael Kirby, former judge of the High Court of Australia, Prof. Ruth Okediji, Prof. Jorge Bermudez, VP of Fiocruz, Prof. Kinga Goncz, Maria C. Freire (UNITAID), and Stephen Lewis.

An Expert Advisory Group of individuals with expertise and experience on matters including human rights, trade, innovation and public health as well as senior technical staff from WHO, UNAIDS, UNDP and other intergovernmental organizations will assist and advise the High-Level Panel.



2 billion people in developing countries remain deprived of adequate access to medicines. As a consequence, access to medicines in developing countries continues to be one of the most important social issues of our time.

tific research and avoid unnecessary and costly duplication of work.

There should be greater transparency by pharmaceutical firms, product development partnerships, biotechnology firms and other entities, in disclosing the real costs of research and development, including in carrying out clinical trials, and for them to share the results of clinical trials.

New initiatives and business models to stimulate R&D in medical products that "de-link" the cost of R&D from prices should be promoted. However, principles need to be established to ensure that if public resources are used to promote de-linkage, there is full transparency on the real costs of activities; disclosure of terms in contractual agreements for R&D and for IP; and that priorities for R&D are defined in accordance to public health needs.

2. A Binding International Treaty on Medical Product R&D under the Auspices of the UN

The second submission by the South Centre recommends that negotiations be undertaken for a UN treaty on R&D for medical products.

The current incentive model for pharmaceutical research and development (R&D) has failed to incentivize R&D for new medicines to treat a number of diseases that do not offer substantially profitable markets to private firms. Several reports and studies, as well as the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

(GSPOA) adopted by WHO Member States (2003-2008) have acknowledged this problem. On one hand, there is little investment in R&D in relation to diseases that are prevalent in developing countries, since large pharmaceutical firms focus efforts on developing products to satisfy the demand of wealthy markets. On the other hand, products that are subject to patents and other forms of exclusive rights are normally sold at prices that are out of reach for large sectors of the population, both in developing and developed countries.

In April 2012, the WHO Consultative Expert Working Group (CEWG) on R&D Financing and Coordination recommended the WHO member States to start negotiations on a binding international instrument on health R&D under article 19 of the WHO Constitution, as the best way to create an appropriate framework to ensure priority setting, coordination, and sustainable financing of affordable medicines for developing countries. The CEWG stated that "... a binding instrument on R&D is necessary to secure appropriate funding and coordination to promote R&D that is needed to address the diseases that disproportionately affect developing countries." The CEWG recommendation was made after considering a number of proposals that recommended the conclusion of a binding R&D treaty, including a proposal by Bangladesh, Barbados, Bolivia and Suriname for WHO discussions on a biomedical R&D treaty. However, this recommendation of the CEWG has still not been adequately considered by the WHO member States owing to political opposition from developed countries to the idea of an alternative R&D mechanism.

After the call for a global pharmaceutical R&D (GSPOA and CEWG), there have been numerous initiatives and policy processes related to global health innovation. In addition, there are ongoing efforts through product development partnerships (PDPs) to step up R&D for neglected diseases. There is a major risk that the multiplication of such proposed R&D frameworks could lead to further duplication and fragmentation and lack of consistent application of the CEWG principles that R&D mechanisms must be based on - affordability, effectiveness, efficiency and equity.

A binding international instrument or international treaty on R&D can be negotiated under the auspices of the UN to provide an adequate framework to define medical R&D priorities and ensure the coordination and sustainable financing of R&D on drugs that could be made available at affordable prices.

The conclusion of a binding R&D instrument under the UN will contribute to the realization of the Sustainable Development Goals (SDGs), and particularly the health related SDG Goal 3 and Targets 3.8 to achieve universal health coverage and access to quality essential health-care services and access to safe, quality and affordable essential medicines and vaccines for all, and 3.11 to support the R&D of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health that affirms the right of developing countries to use to the full the provisions in the TRIPS Agreement regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

A binding international R&D instrument under the UN would provide a global framework for financing R&D in a way that delinks costs from prices for new medical products and for improved coordination to avoid the fragmentation of medical R&D

efforts.

A global instrument on R&D of medical products negotiated at the UN could have the following specific objectives:

- (i) To promote R&D for all diseases, conditions and problems (including non-communicable diseases), while prioritizing those for which there is little R&D investment such as neglected diseases that disproportionately affect developing countries;
- (ii) To set priorities for R&D on the basis of the global disease burden;
- (iii) To provide alternative incentives to the intellectual property systems for the engagement of private and public actors involved in R&D based on public health needs rather than market expectations;
- (iv) To develop sustainable financing mechanisms including pooled financing to increase available resources for R&D;
- (v) To promote coordination of R&D and make better use of existing R&D capacities of the private and the public sector in both developing and developed countries;
- (vi) To build R&D capacity in developing countries;
 - (vii) To promote greater transparen-

cy in the costs of R&D and sharing of data and information, particularly in early research and clinical trial stages;

- (viii) To establish ethical criteria and financial mechanisms for conducting clinical trials with full disclosure of test data:
- (ix) To promote that the results of R & D are in the public domain or otherwise accessible to all populations.

Though the proposed binding international legal instrument on biomedical R&D pursues public health objectives, the establishment of an alternative mechanism for medical R&D will have to necessarily involve multiple government agencies besides ministries of health, such as finance, trade, science and technology, and industry. As this proposed instrument would address a diverse range of government agencies and also a number of the SDGs, it is submitted that it will fall within the ambit of the UN to negotiate a binding international legal framework or convention on medical product R&D.

3. Limitations of the Paragraph 6 System of the TRIPS Agreement

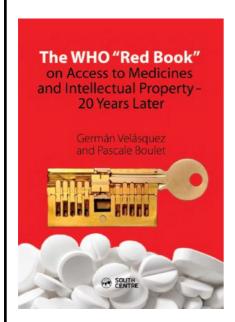
The third submission by the South Centre concerns the ability of countries to procure lower priced medical products.

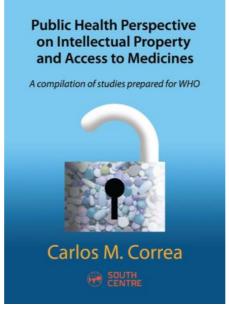
Pursuant to paragraph 6 of the 2002 Doha Declaration on TRIPS and Public Health the WTO General Council adopted a decision on August 30, 2003 allowing WTO members with insufficient or no pharmaceutical manufacturing capacity to import generic medicines under a compulsory license, as a waiver from the general requirement under Article 31 (h) of TRIPS that a CL can be issued only predominantly for being used by domestic manufacturers. In 2005 the WTO General Council adopted a Protocol amending the TRIPS Agreement which incorporated this mechanism as an amendment to the TRIPS Agreement (Article 31bis). The WTO Secretariat is urging member States to ratify the August 30th Decision to bring Article 31bis of the TRIPS Agreement into force.

While the Paragraph 6 system has been celebrated as a 'solution' to the problems faced by developing countries and LDCs in accessing affordable medicines, in actual practice it has not contributed to address such problems. Only a limited number of countries have adopted legislation to implement the August 30th Decision as an exporting country. Moreover, there has been very limited use of the system. Only one importing country (Rwanda) used the mechanism to import cheaper lifesaving medicines from the Canadian generic company Apotex for 21000 HIV/AIDS patients. This is largely due to the fact that the system is unnecessarily burdensome and complicated. The Paragraph 6 system places obligations on importing countries making use of the system that are more onerous than those for countries that can issue a compulsory license (CL) to supply the domestic market.

The experience in making use of the system also suggests that there are hurdles within the Decision that make it difficult for countries to import a generic drug under a CL, and also makes it difficult for generic manufacturers to export a drug under CL. In the Canada-Rwanda case, the only instance in which the Paragraph 6 system has been used, it took almost 27 months to meet all of the requirements. Thus, the system is less effective than it should be. Therefore, it is important that WTO members carefully examine the reasons behind the limited use of the system and address

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Experts from UN agencies at the briefing by the High-level Panel in Geneva, February 2016.

systemic deficiencies before making it permanent as article 31bis of the TRIPS Agreement (currently in the process of approval by WTO members).

Some of the key problems in using the Paragraph 6 system are: Generic companies need to undertake negotiations for voluntary licenses with the patent holder before applying for a CL. Such negotiations may be protracted and complex, and a source of considerable delay and discourage generic manufacturers to participate in the process.

The Decision comprises a succession of complex procedural steps. First, a potential purchaser has to forecast the need for a medicine and identify a generic producer willing to participate in the process and fill the drug order. Second, the manufacturer has to try to negotiate a voluntary license with the patent holder. Third, if the negotiations are unsuccessful, a CL application must be filed in the home country of the generic producer. Fourth, if a patent exists in the country of export the generic producer has to apply for and obtain a CL in that country too. Each of these steps is time-consuming, involves substantial financial expense and holds no guarantee of success.

A country importing medicines using this system must also give a written notification to the TRIPS Council which must include the specific names and expected quantities of the product needed. Unless the importing country is classified as an LDC, it must also specify whether the product is under patent, and provide information that

establishes that it lacks sufficient manufacturing capacity in the pharmaceutical sector to develop the drug being ordered.

The system also imposes conditions for commercialization of the products made under the CL. They must be clearly identified as being produced under the system through specific labelling; they should be specially packaged to be distinguishable from the branded product and in respect of its shape or colour. The generic manufacturer must post specific information about the quantity of the product, its destination and distinguishing features. These 'antidiversion' measures are to ensure that the product will only be exported to the destination stated in the CL.

The Paragraph 6 system requires a drug-by-drug, country-by-country

and case-by-case decision-making process. Indeed, the CL application must stipulate the destination and the quantity of drugs that are to be purchased and exported under the licence. Drug needs must therefore be determined with precision beforehand. If more patients are included, the only way to purchase more drugs is to begin the process again. A stock-out due to the procedural hurdles may lead to the treatment being interrupted and as a consequence patients may develop increased drug resistance (as in case of HIV/AIDS), creating the need for more expensive treatment. Conversely, if the needs have been overestimated, re-exportation of medicines imported under the system to another developing or least developed country in a similar situation is not permitted, unless there is a regional trade agreement between the two and the majority of its members are LDCs.

There is substantial scope for the patent holder to undermine the system. For example, the patent holder may decide at any time to offer the medicines at lower cost or for free, thus frustrating any efforts made to use the system in that particular case. This creates a huge uncertainty and additional risk and disincentives for potential suppliers. In view of these limitations of the paragraph 6 system, WTO members should be dissuaded from ratifying the protocol to the TRIPS Agreement incorporating the system under Article 31bis of TRIPS and should instead undertake a comprehensive review and evaluation of the paragraph 6 system.



A protest outside the UN in Geneva calling for an R&D agreement for medicines.

Super drug-resistant gene raises new health alarm

A recently discovered gene that is resistant to an antibiotic used as a last resort and which can spread easily among bacteria has raised fresh concerns about the coming end of the use of antibiotics – if action is not taken immediately.



A gene conferring resistance to the last-ditch drug colistin has been recently found in E. coli in the United States.

By Martin Khor

A ntibiotic resistance – a process by which antibiotics no longer work because bacteria have become resistant to them – has climbed up the global agenda because of growing awareness of the immense threat this poses to human health and survival.

However, there is still not enough action to tackle this crisis. Health Ministers met at the World Health Assembly in Geneva in May and had an opportunity to review the extent to which a Global Action Plan adopted last year had been implemented.

In the background is the recent disturbing news of the discovery by scientists of a gene, MCR-1, which creates resistance to colistin, a powerful antibiotic used as a last resort to treat infections when other medicines do not work.

Even more worrying is that the gene has the characteristic of being able to move easily from one strain of bacteria to other species of bacteria. This raises the spectre of many infections eventually becoming untreatable, bringing us closer to the nightmare of a postantibiotics era.

The gene was discovered during a study undertaken in China. Last November, Yi-Yun Liu and colleagues published a paper in *The Lancet Infectious Diseases* journal revealing they found the MCR-1 gene in 166 out of 804 pigs at slaughter that they tested, 78 of 523 samples of chicken and pork being retailed and in 16 of 1,322 hospital patients.

The study indicates that there is a chain in the spread of resistance from the use of colistin in livestock feed, to colistin resistance in slaughtered animals, in food and human beings.

One of the authors, Prof. Jian-Hua Liu from South China Agricultural University, was quoted by the *Guardian* as saying these are extremely worrying results, which reveal the emergence of the first polymyxin resistance gene that is readily passed between common bacteria such as E. coli and K. pneumonia.

This suggests that "the progression from extensive drug resistance to pandrug resistance is inevitable", added Liu. Extensive resistance is

when a bacterium is resistant to many drugs while pandrug resistance indicates resistance to all drugs.

Colistin is part of a category of antibiotics known as polymyxins. In the past they had not been widely used as they are known to have toxic effects, but they have been recently more used as a last resort when other antibiotics don't work because of resistance.

"All key players are now in place to make the post-antibiotic world a reality," another of the paper's co-authors, Prof. Timothy Walsh from University of Cardiff, told the BBC News website.

"If MCR-1 becomes global, which is a case of when and not if, and the gene aligns itself with other antibiotic resistance genes, which is inevitable, then we will have very likely reached the start of the post-antibiotic era. At that point, if a patient is seriously ill, say with E. coli, then there is virtually nothing you can do."

A major reason for the emergence and spread of the gene is suspected to be the heavy use of colistin to feed livestock to promote their growth. Much of the worldwide annual use of 12,000 tonnes of colistin in animal feed takes place in China, according to the paper by Liu and colleagues.

The paper mentions that besides China, the MCR-1 gene has also been found in Malaysia and Denmark. It revealed that Malaysian scientists had found bacterial DNA sequences in December 2014 with genes that look like MCR-1. The possibility that E.coli with the MCR-1 gene had spread into other South-east Asian countries is "deeply concerning", said the authors.

After the paper was published, new papers and information have shown that the MCR-1 gene has been found in bacterial samples in many other countries, including Thailand, Laos, Brazil, Egypt, Italy, Spain, England and Wales, the Netherlands, Algeria, Portugal, Canada and the United States.

The most frightening thing about MCR-1 is the ease with which it can spread resistance to other species of bacteria through a process known as horizontal gene transfer.

(Continued on page 9)

World Economy in Serious Difficulty: Call for Bold Measures

This article is based on a presentation by Dr. Yılmaz Akyüz, Chief Economist of the South Centre, at a South Centre conference which was placed in "The Real News" video online.



Dr. Akyuz speaking at the South Centre conference.

By Yılmaz Akyüz

The US was the cause of the crisis but has come out better than anyone else in the advanced world and better than many developing countries. During the crisis there was a widespread perception that this was the end of US hegemony. It was end of the dollar as the major reserve currency.

When we look back now, we see that the US is strengthened a lot more as a result of this crisis. Not only vis-àvis other developed countries – Europe, European Union or Japan – but developing countries including China, in economic terms. The status of the dollar as a reserve currency today is unchallenged because of the crisis in Europe.

The US economy is also fragile. Usually economic expansions are often followed by contractions. This is part of the capitalist system working in boom bust cycles. The US has had 24 quarters of expansion since the beginning of the crisis. And a lot of people think simply on this observation that

after such expansion US recovery or growth is supposed to come to an end on historical evidence.

But apart from that? It is very difficult to get out of the policies that US introduced in response to the crisis. It does not know how to get out of the policy of easy money. It is very hesitant in raising interest rates. But on the other hand if there is a slowdown in the US and a contraction and renewed instability they do not have any ammunition to respond to it, because they used all their ammunition to respond to the last crisis and they are still using the same except in bond purchases.

We have not had a serious debt crisis in an emerging economy in the past 10 – 12 years. However, the risks are very serious now. The world is caught in a debt trap today. Why? Because the resolution of the European and American crisis – which was a debt crisis – required cutting debt. But what we have seen is that the policies implemented to resolve that crisis have given rise to the accumulation of additional debt.

In the US, the ratio of public plus private debt to gross domestic product (GDP) increased from 200% to 280%. In Japan it increased to 500%; in the Eurozone and China it doubled. And in developing countries today it is close to 200% of GDP.

The current situation has an uncanny similarity to the 1970s and 1980s. Developing countries had a boom in commodity markets in the 70s which was accompanied by massive international lending by banks recycling petrodollars [oil surpluses]. And this twin-boom in commodities and capital flows to developing countries in the 70s ended up with a bust when the US raised interest rates in 1979 and 1980. And what we had was a debt crisis in Latin America. And the situation now is somewhat similar. We had a twin boom in commodity prices and capital flows and now we have come to the end of this boom even without the US changing its monetary policy in a big way. And the question is will the outcome be the same as in the 1970s?

We are highly vulnerable to the reversal of commodity prices and capital flows. The vulnerability to commodity prices nevertheless varies among developing countries because different types of commodities fell at different rates. Some developing countries benefit from commodity price declines but no developing country would benefit from tightening of the external financial situation. Now we cannot count on reserves. Traditionally we look at the reserve adequacy in terms of their volume relative to short-term external debt, but now there is a strong presence of foreigners in domestic bond, equity and deposit markets and their exit can cause significant turmoil.

Monetary policy now faces a major dilemma. In order to stimulate demand and growth we have to cut interest rates. A cut in interest rates can trigger capital outflows. So there is a dilemma between growth and stability. If we face a liquidity crisis we no longer have enough reserves to meet our imports and stay current on our debt payments

and keep the capital account open – what do we do? Business as usual? Borrow from the IMF? Keep the capital account open? Continue allowing capital to run out, using reserves and the borrowing from the IMF and practicing austerity?

Now I think there is a strong misgiving vis-à-vis the IMF among the developing countries. And I am sure they will do their best to avoid going to the IMF in the event of a serious liquidity crisis. I am not referring to a solvency crisis, default – I am talking about simple liquidity crisis when you do not have enough foreign exchange to meet your current account needs and debt payments. Then what do you do?

Of course, the unorthodox response is to use reserves to support one's economy, imports, not to support capital outflows. Are we prepared to impose controls over capital outflows? Are we prepared to impose temporary debt standstills? Or, are we prepared to impose austerity on creditors and investors rather than austerity on the people? These are the critical issues.

In conclusion, even if we avoid a fully-fledged financial crisis, the prospects are for sluggish, erratic growth and heightened instability in the global economy. Why? Because of financial excesses we have had in the past 8-9 years. And one cannot easily restructure balance sheets; that is the problem. We need to have a better policy mix than we have been using.

A few suggestions. First, stop relying on easy money which is not good except for speculation in advanced economies, abandon fiscal orthodoxy, invest in infrastructure and create jobs and create demand. Secondly, we need better control over international capital flows not only by recipient countries but also by source countries. Because they are most destabilizing. They are at the heart of the current difficulties that we face. Third, we need a mechanism for adequate provision of international liquidity and finally we need effective and equitable debt resolution mechanisms.

Now these issues should be studied and debated extensively, particularly at the current juncture. But unfortunately Bretton Woods institutions are not the best place to do that; neither to consider the fragilities, nor to resolve the problems. The IMF has missed one of the most serious crises in the world since the second world war, the subprime crisis. The IMF at the Secretariat level is not very efficient in providing early warnings to countries about the global economic situation. And this is not just a technical expertise issue; it is also a political issue. Because such an

early warning – an effective projection of the difficulties in the world requires a critical examination of the policies of countries which exert significant impact on the world economy. It would require criticizing US and European economic policy. The IMF Secretariat cannot do that. In 2008 and 2009 when we were writing that the rise of the South was a myth, the IMF was promoting that the South was becoming a locomotive for the world economy. And they changed their mind only in 2013.

Secondly the IMF is not very bold in innovation. They are not bold in the reform of the international financial architecture. Why? Because the IMF is part of that architecture and that requires to reform that very same institution...So I believe that these matters should be discussed and debated among developing countries and in other fora such as the United Nations Conference on Trade and Development (UNCTAD), which has a much better record in anticipating these difficulties and providing proposals, which eventually became part of the mainstream.

Yılmaz Akyüz is the chief economist of the South Centre.

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Super drug-resistant gene...

(Continued from page 7)

A few years ago, there was a similar scare about NDM-1, a gene with the ability to jump from one bacteria to other species, making them highly resistant to all known drugs, except two, including colistin.

If the colistin-resistant MCR-1 were to combine with NDM-1, then the bacteria having the combined gene would be resistant to virtually all drugs.

In 2010, only two types of bacteria were found to be hosting the NDM-1 gene – E. coli and Klebsiella pneumonia. Within a few years, NDM-1 had been found in more than 20 different species of bacteria.

The discoveries of NDM-1 and now of MCR-1 add urgency to the task of addressing anti-microbial resistance.

In 2012, World Health Organization Director General Dr Margaret Chan warned that every anitibiotic ever developed was at risk of becoming useless. "A post-antibiotic era means in effect an end to modern medicine as we know it. Things as common as strep throat or a child's scratched knee could once again kill."

The World Health Assembly was an opportunity to take stock of the Global Action Plan on antimicrobial resistance.

An immediate action needed is to ban the use of colistin in livestock production. The well-respected *Lancet* journal published a Comment in February that we must take the call to curtail the use of polymyxins (including colistin) in agriculture to the highest levels of government or face more patients for whom we need to say, "Sorry there is nothing I can do to cure your infection."

Other antibiotics that are used by human beings should also be prohibited or heavily restricted in the livestock sector, especially if they are used as growth promoters. The Global Action Plan has five objectives: to use medicines properly in human and animal health; reduce infection by sanitation, hygiene and infection prevention measures; strengthen surveillance and research; educate the public as well as doctors, veterinarians and farmers on proper use of antibiotics; and increase investment in developing new medicines, diagnostic tools and vaccines.

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The Rise of Investor-State Dispute Settlement in the Extractive Sectors

The investor-state dispute settlement (ISDS) system has been used by foreign investors against several African governments, constraining or hindering their use of pro-development policies and subjecting them to the threat of payment of monetary compensation.



Mining is a sector that became a source of investment cases against many African governments.

By Kinda Mohamadieh and Daniel ry actions of host countries in a wide range of areas, including public ser-

A frican countries have been active in concluding international investment treaties. According to the United Nations Conference on Trade and Development (UNCTAD), as of end 2013, 793 bilateral investment treaties (BITs) have been concluded by African countries, representing 27% of the total number of BITs worldwide.

UNCTAD reports as well that several African countries are actively negotiating additional agreements. For example: the Southern African Customs Union is negotiating with India and the East African Community, including Burundi, Kenya, Tanzania, and Uganda, are in discussions with the United States.

Moreover, African countries are increasingly subject to investor-state dispute settlement (ISDS) cases, including claims that challenge the regulato-

ry actions of host countries in a wide range of areas, including public services and race relations. Out of all cases registered under the International Centre for Settlement of Investment Disputes (ICSID), Sub-Saharan Africa accounts for 16% of these cases. In 2014, cases against Sub-Saharan Africa amounted to 20% of the overall number of new cases brought under ICSID during that year.

At the same time, African States have developed the Africa Mining Vision, which is aimed at introducing policy and regulatory frameworks intended to maximize the development of the region through the use of natural resources as catalyst for industrial development in order to diversify the economy. Africa is one of the most important producers of mineral commodities; however most of the minerals are exported in raw form (ore concentrates or metals).

In response, the Africa Mining Vi-

sion is intended to promote addedvalue mechanisms within the region with a view to fully benefiting from the potential of mining. The approach reflected in the Africa Mining Vision is similar to policies several other developing countries have been considering in order to increase their participation on strategic sectors and enhance benefits from resource wealth in order to serve development and industrialization objectives. For example, several Latin American countries, including Ecuador, Bolivia and Venezuela, have applied active policies to regain the States' policy space to develop, plan, regulate and actively participate in strategic sectors such as mining, water, energy and telecommunication in order to guarantee the use of natural resources for an economically, environmentally and socially sustainable development of the State.

Since 2006, several African countries, including Ghana, Congo DR, Zambia, Liberia, Zimbabwe, Guinea, Cote d'Ivoire, Malawi, Sierra Leone, Burkina Faso, Kenya, Tanzania and Madagascar have taken actions in terms of regulatory or institutional changes, including amending laws or initiating the renegotiation of contracts with mining firms or indicated an intention to take one or both steps. A number of countries are debating approaches to the conception of domestic/local content within the context of the 'Africa Mining Vision'.

In the case of African countries, similar to other developing countries, the expansion of international investment agreements could carry significant risks to policy space and policy tools necessary for industrialization and development. In the case of African countries, this implies risks to the potential use of sectoral policies, such as policies in the extractive industries and the Africa Mining Vision, in order to support and promote African countries' industrialization objectives.

Much of the recent debate and controversy in regard to the international

investment protection regime have revolved around their implications on policy space that developing countries need to promote development. The rising number of ISDS cases revealed how the rules established under international investment agreements, and the way they have been expansively interpreted by private investment arbitrators, encroach on government's ability to regulate in the public interest.

The majority of the ISDS cases registered at ICSID are in the gas, oil, and mining sector; out of all the ISDS cases registered at ICSID until 2014, 26% were concentrated in the oil, gas, and mining sectors. This figure is 35% for the year 2014 alone. By contrast, in the year 2000, there were only three pending ICSID cases related to oil, mining, or gas. Through resorting to investorstate dispute settlement (ISDS) mechanisms, investors are challenging a broad range of government measures, not only challenging outright expropriation. Investors brought cases in relation to revocations of licenses (e.g., in mining, telecommunications, tourism), alleged breaches of investment contracts, alleged irregularities in public tenders, changes to domestic regulatory frameworks (gas, nuclear energy, marketing of gold, currency regulations), withdrawal of previously granted subsidies, tax measures and other regulatory interventions.

Similarly, ISDS has increasingly been used by investors in the extractive industries in several African countries, challenging governmental reform action, such as policy against speculation in the oil industry as well as tax measures. For example, Vanoil Ltd., a Canadian oil company, threatened to bring a case against Kenya after failure to secure extension of a pair of production-sharing contracts for onshore oil exploration in Kenya. African Petroleum Gambia Limited brought a case (contract-based) against Gambia disputing termination of hydrocarbon licenses for exploration of oil. Total E&P Uganda BV (Dutch), subsidiary of French company Total S.A., brought a claim in relation to a stamp duty imposed by the Uganda Revenue Authority on the acquisition of stakes from London-listed Tullow Oil.

The problem of the investment protection regime is multilayered and is rooted in the following deficiencies: an imbalance in the provisions of the investment treaties (including broad definitions of investment and investor, free transfer of capital, rights to establishment, the national treatment and the most-favoured-nation (MFN) clauses, fair and equitable treatment, protection from direct and indirect expropriation and prohibition of performance requirements), which focus on the investors' rights and neglect investors' responsibilities, while often lacking express recognition of the need to safeguard the host states' regulatory authority; vague treaty provisions, which allow for expansive interpretation by arbitrators and for the rise of systemic bias in favour of the investors in the resolution of disputes under investment treaty law.

Such trends are often not in line with the original intent of the States negotiating the treaty. The investor-state dispute settlement mechanism is led by a network of arbitrators dominated by private lawyers, whose expertise often stem from commercial law. Arbitrators have asserted jurisdiction over a wide range of issues, including regulatory measures on which constitutional courts had made a decision in accordance with the national law.

The way the ISDS system has operated so far generates deep concerns in regard to democratic governance and accountability; the lack of transparency and available public information on ISDS procedures limit the space of public participation and accountability. Currently 608 ISDS cases are known.

However, since most international investment agreements allow for fully confidential arbitration, the actual number is likely to be higher. Within this context, claims or threats by investors to bring forward a claim against a particular state are increasing.

Several countries, both developed and developing, have been reviewing their approach to investment treaties, including looking at ways of reducing their legal liability under bilateral investment treaties (BITs), especially given the surge in investor-to-state dispute cases from these treaties.

According to the UNCTAD, at least 40 countries and four regional integration organizations are currently or have been recently revising their model of international investment agreements, and at least 60 countries have developed or are developing new mo-

del IIAs since 2012. UNCTAD points out that "the question is not whether to reform or not, but about the what, how and extent of such reform".

Developing countries seeking to reform their approach to investment protection treaties have reviewed their existing international investment agreements and their implications. Some have set a moratorium on signing and ratifying new agreements during the time of the review. Some countries like South Africa, Indonesia, Ecuador and Bolivia chose to withdraw from all or some treaties. South Africa chose to replace BITs with a new national Investment Act entitled Promotion and Protection of Investment Bill, that clarifies investment protection standards consistent with the South African constitution. Indonesia chose to develop a new model BIT, so did India. Ecuador reverted to investment contracts as the main legal instrument defining the relation with investors, including setting clear obligations on the investor, such as performance requirements. Some states are pursuing alternatives at the regional level, through developing model rules that take into consideration the developmental con-

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"Free trade" in trouble in the United States

As an anti-free trade wave sweeps across the United States, developing countries have to rethink their own trade realities for their own development interests.







US Presidential candidates Hillary Clinton, Bernie Sanders (centre) and Donald Trump have attacked US free trade agreements.

By Martin Khor

Getty Images, Associated Press

"Free trade" seems to be in deep trouble in the United States, with serious implications for the rest of the world.

Opposition to free trade or trade agreements emerged as a big theme among the leading American presidential candidates.

Donald Trump attacked cheap imports especially from China and threatened to raise tariffs. Hillary Clinton criticised the Trans-Pacific Partnership Agreement (TPPA) which she once championed, and Bernie Sanders' opposition to free trade agreements (FTAs) helped him win in many states before the New York primary.

That trade became such a hot topic in the campaigns reflects a strong antifree trade sentiment on the ground.

Almost six million jobs were lost in the US manufacturing sector from 1999 to 2011.

Wages have remained stagnant while the incomes of the top one per cent of Americans have shot up.

Rightly or wrongly, many Ameri-

cans blame these problems on US trade policy and FTAs.

The downside of trade agreements have been highlighted by economists like Joseph Stiglitz and by unions and NGOs. But the benefits of "free trade" have been touted by almost all mainstream economists and journalists.

Recently, however, the establishment media have published many articles on the collapse of popular support for free trade in the US:

- Lawrence Summers, former Treasury secretary, noted that "a revolt against global integration is under way in the West". The main reason is a sense "that it is a project carried out by elites for elites with little consideration for the interests of ordinary people".
- The *Economist*, with a cover subtitled "America turns against free trade", lamented how mainstream politicians are pouring fuel on the antifree trade fire. While maintaining that free trade still deserves full support, it cites studies showing that the losses from free trade are more concentrated and longer-lasting than had been assumed.

- Financial Times columnist Phillip Steven's article "US politics is closing the door on free trade" quotes Washington observers saying that there is no chance of the next president or Congress, of whatever colour, backing the TPPA. The backlash against free trade is deep as the middle classes have seen scant evidence of the gains once promised for past trade deals.
- In a blog on the Wall Street Journal, Greg Ip's article The Case for Free Trade is Weaker Than You Think concludes that if workers lose their jobs to imports and central banks can't bolster domestic spending enough to re-employ them, a country may be worse off and keeping imports out can make it better off.

Orthodox economists argue that free trade is beneficial because consumers enjoy cheaper goods. They recognise that companies that can't compete with imports close and workers get retrenched. But they assume that there will be new businesses generated by exports and the retrenched workers will shift there, so that overall there will be higher productivity and no net job loss.

However, new research, some of which is cited by the articles above, shows that this positive adjustment can take longer than anticipated or may not take place at all.

Thus, trade liberalisation can cause net losses under certain conditions. The gains from having cheaper goods and more exports could be more than offset by loss of local businesses, job retrenchments and stagnant wages.

There are serious implications of this shift against free trade in the US.

The TPPA may be threatened as Congress approval is required and this is now less likely to happen during Obama's term.

Under a new president and Congress, it is not clear there will be enough support.

(Continued on page 18)

South African Minister Rob Davies calls for pro-development approach to IP policy, at WIPO conference

The World Intellectual Property Organization International Conference on Intellectual Property and Development that took place in Geneva on 7-8 April 2016 was opened by a Keynote Address by Dr. Rob Davies, Minister of Trade and Industry of South Africa. Below are excerpts of the Keynote Address by Minister Rob Davies, which advocates that IP policies should be formulated taking account of the development needs of developing countries.

I want to start by situating my remarks on IP protection in a wider historical view that all countries that have succeeded in breaking out of poverty and underdevelopment – beginning with Venice in the middle ages, through Britain in the 18th and 19th century, to the Asian newly industrializing economies, and to China and India today – all of them without exception have done so by nurturing a cluster of industrial activities characterized by increased, rather than diminishing, returns.

Nurturing has involved the identification and targeting of appropriate value adding activities, the deployment of public and private resources to support innovation, entrepreneurship and infrastructure development as well as the judicious use of tariffs and other forms of protection.

This understanding has informed South Africa and indeed Africa's recognition that its sustainable development will, in great measure, be dependent on pursuing structural transformation of its economies through industrialisation.

Let's step back for a moment: Over the last decade or so, Sub-Saharan African countries have shown impressive economic growth, outpacing advanced economies. That growth rate has also been above the average for all emerging and developing economies and while only Asia has recorded higher growth rates, the differential has been narrowing.

Seven of the top ten fastest growing economies in the global economy are African and Africa now offers the highest return on investment of any region in the world economy. Africa's abundant natural resources, the growing consumer power of Africa's emerging middle class and favourable demographics offer enormous potential for sustainable economic growth and development across the continent.

While all this has been positive, and suggests prospects for future growth and development are much improved, Africa's growth path has been based primarily on commodity exports, particularly to Asian countries, as well as by strong consumption based on the rise of middle class consumers.

There is a now widening consensus among African government and business leaders that growth on this path will not be sustainable in the longer term and that, to place the continent on a firmer footing towards sustainable development, Africa will need to pursue structural transformation of its economic base and build a more diversified productive capacity, through industrialisation. The recent dramatic decline in a range of commodity prices, many of which are the mainstay of African production for export, should only redouble our efforts at industrialisation and economic diversification.

South Africa's Industrial Policy Action Plan

In South Africa, the Government has chosen a growth and development path that prioritises industrial upgrading in more labour intensive sectors to generate sustainable and decent employment. Upgrading South Africa's



Minister Rob Davies speaking at the WIPO conference.

industrial base in this way and encouraging the production and export of more sophisticated value added products, require purposeful intervention in the industrial economy aimed at achieving dynamic, competitive advantages.

Our National Industrial Policy Framework and Trade Policy and Strategic Framework depart from the view that deliberate policy interventions are needed to address impediments to economic diversification, and that specific measures are considered on a sector-bysector basis, dictated by the needs and objectives of sectoral strategies.

Two dimensions of this process may be instructive for the remarks I will make later more directly on IPR and economic development. First, our sectoral work is grounded in a 'self-discovery' process of engagement between government, business and labour, through which we collectively identify the specific measures and programmes needed to advance industrial development.

Second, our approach to tariff policy is one in which we make no *a priori* presumption of the benefits or costs of maintaining either low or high tariffs.

Instead, tariff setting is assessed on the evidence obtained at firm and sector levels through detailed investigations that consider the impact of proposed tariffs on, amongst other things, economic output and employment across the value chain.

In short, tariff setting is evidencebased and the product of intensive consultations between affected stakeholders. Of course, the upper limits for tariffs are set by the binding obligations South Africa has undertaken in the WTO and in bilateral trade agreements.

IPR and Economic Development

If the proposition that industrial development and structural transformation are necessary for sustainable development in many developing countries is correct, a relevant question is whether and how IP protection can be designed to support these objectives.

Considerable work has been undertaken in the relationship between IPR and economic development, including excellent work under the aegis of WIPO. In our reading of this literature, it seems clear that the international community is far from reaching a convergence on the question. Indeed, this field of work remains a site of contestation.

While few policymakers, commentators or academics deny the importance of IP protection and enforcement, the questions revolve around nature of the standards that should be implemented and enforced, and whether this changes over time as countries industrialize and develop.

Strengthening and extending IPR regimes and enforcement are strongly advanced by countries at the cutting edge of innovation globally. One may recognise that, for those countries, it is of strategic value to use IP protection as a mechanism to preserve the rentgenerating and other advantages that arise from the technological capabilities built up by their firms. In this sense, such an approach could well be understood as a de facto industrial policy and there is a compelling argument to be made that this should be balanced by approriate diffusion policies in catching-up countries.

In any case, in the history of devel-

opment and 'catching up', successful strategies always appear to have involved 'emulation' that requires measures that are targeted at acquiring knowledge in increasing returns activities. Furthermore, all successful catching-up episodes occurred under condition of weak IPR regimes that permitted easier knowledge acquisition and imitation. During the 19th Century, today's advanced economies used the IP system and the flexibility it accorded in a judicious manner as they pursued their industrialization. This allowed those countries to strengthen their IP regimes at their own pace, and in support of overall progress in their economic development.

We may recall that Switzerland did not institute a national patent law until 1888. When the law was introduced, it was narrow in scope and did not provide protection to chemical inventions. It is argued that this allowed domestic chemical industries to develop imitative capacity. Today, Switzerland boasts some of the most innovative and accomplished chemical and pharmaceutical industries in the world. Similarly, countries such as Germany, Switzerland, France and Japan only introduced pharmaceutical product patent protection in the 1960s.

Only a handful of countries have made the transition from "developing" to "developed". If one looks at the performance of the "Asian Tigers", it is clear that they relied on a heterodox of policy measures to achieve industrialisation. For example, Korea relied less on FDI and initially acquired most of its technology through trade, reverse engineering and technology licensing. When it became competitive, its own companies began to invest heavily in R&D to develop their own innovative technology.

Singapore followed a different model. Singapore has long had an open trade regime and depended very much on FDI for its technology. While generally working with market principles, the government was heavily involved in attracting the kind of foreign investment that it believed would bring cutting edge technology that could underpin wider economic development. The development story of Singapore may be characterised as one of moving quickly from cheap un-

skilled labour to a knowledge-based economy. The government continued to invest heavily in education, skills and, in time, research and development. It has now become an important regional hub for many knowledge-based services

More recently, we see that India pursued an alternate path in so far as it has taken advantage of the transitional provisions in TRIPS to develop a globally competitive pharmaceutical industry. By so doing, India has been able to increase global output and competition, thereby enhancing economic welfare. In the process, the industry in that country has become increasingly innovative and has sought to make greater use of the patent system.

The essential point of drawing on these examples is simply to reiterate that countries have taken different paths in pursuing economic development and they have used IP protection in different ways and at different times to support their development effort.

Some Theoretical and Empirical Questions

Opponents of strong IPR typically raise concerns that stronger IPR raises the costs of protected goods and reduces the accessibility of innovations. They often argue that a stronger IPR regime is costly including with respect to the fact that stronger patents confer a greater degree of monopoly power on the patent holder that are often foreign-based multinationals.

Opponents also contend that stronger IPR regimes can retard industrial development, as weak IPR can function as a kind of infant industry policy, allowing indigenous firms to learn from, absorb and experiment with foreign technology at low cost. Said differently, establishing a strong IPR regime prematurely limits the diffusion of innovative technology more widely and by imposing high prices for patent-protected goods, lower consumer welfare.

The role of patent protection in promoting innovation has also been controversial. There are arguments that patents are unlikely to foster innovation in developing countries at early stages of industrialization. The evidence on the extent to which patent protection contributes to encouraging innovation

is, at best, inconclusive. This point is of particular relevance to industrial poliother factors, notably 'first mover' advantages, are more decisive in promoting innovation.

Proponents of stronger IPR regimes, by contrast, suggest that IPR protection fosters innovation in reforming countries. They also argue that stronger IPR facilitates transfers of technology to reforming countries, increases foreign direct investment (FDI), and spurs industrial development. They point to the growing literature that shows a correlation between IPR reform and industrial development and argue that the concerns that a shift to stronger IPR would undermine industrial development are overstated.

As the policy debate unfolds, there nevertheless seems to be a wide acceptance that research on these and related topics must be extended and deepened if we are to have a better grasp of the complex relationship between IPR reform and FDI flows, technology transfer and industrialization.

While generalized conclusions can offer insightful guidance, it may not be applicable at all times to all countries. If that is the case, it is vital that research is undertaken in a manner that is context specific, taking into account the level of development of the country under consideration, with a clear focus on its industrial profile and capabilities

In countries at an early stage of industrialization where technologically mature technologies may be embedded in equipment, strong IPR regimes may be unnecessary. As the manufacturing production of a country becomes more diversified and higher value added is sought (e.g. fine chemicals, electronic equipment and consumer goods) IPRs may growingly narrow down the freedom to operate in the absence of a license authorizing the use of the protected technologies and designs. Where countries begin to develop their own innovation through greater investment in R&D, the demand for stronger IPR protection is likely to grow in tandem.

What are we to make about these complex, varied, and sometimes divergent accounts of the historical, theoretical and empirical dimensions of the question of IPR and industrialization?

I would summarize the answer as follows: First, historically, different cies since some studies contend that paths have been taken to economic development and the IPR protection provided. Second, IP protection has been strengthened and evolved in different countries over time. Third, there is no unambiguous evidence that stronger IPRs foster industrial development, and countries may require different approaches and policies depending on their level of industrial develop-

> This all suggest the need for a cautious approach to the reform of IPR. It also suggests the need to strengthen capacity to assess the costs and benefits of IPR reform in the specific contexts where the reform is being considered or undertaken. Reform should be based on robust evidence and should be the product of extensive consultations with affected sectors, industries and firms. There are no simple answers or short-cuts.

TRIPS and Flexibilities

Having made all these points, it is also clear that as many developing countries pursue industrialization, they do so in the context of an international IP regime that is more constrained than it was in the 19th century. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) establishes extensive standards of IP protection that are almost without exception legally binding on all WTO Members.

While developing countries are committed to implementing and enforcing these standards, it is also clear that the TRIPS Agreement contains flexibilities that can be exploited to craft a greater developmental role for IP protection in respect to industriali-

Patents are likely to impact technologically dynamic sectors where domestic value added is higher as compared to sectors where more mature technologies predominate. Therefore, as countries pursue industrialization, we need to explore how best patent regimes can be designed to expand the opportunities for access and diffusion of technology.

As noted, whether or not IPRs in fact generate net benefits or costs to any particular country will depend on its productive profile, its R&D infrastructure, and the extent to which policy space is preserved to adapt the IPRs regime to local conditions and needs. In that context, governments retain an important role in ensuring that patentability standards such as the requisite level of inventiveness are appropriate and rigorous in order to avoid the introduction of patents that unnecessarily stifle local innovation and production.

Compulsory licenses are another avenue of policy flexibility permitted under the TRIPS Agreement that may be used as an instrument to promote domestic production where voluntary licenses are not available on reasonable commercial terms. There are several examples around the world where compulsory licenses were issued and employed successfully to ease access to affordable medicines.



Delegates at the WIPO conference on IP and Development.

An update on the Green Climate Fund

The Green Climate Fund was set up by the UNFCCC's Conference of Parties to be the premier financial institution to mobilise and disburse funds for use of developing countries for climate action. Below is an update of the Fund's progress, focusing on the Board meeting held in March 2016.



The Green Climate Fund is the premier financial institution dedicated to mobilise and disburse funds for use of developing countries for climate action.

By Mariama Williams

Policies, Partnerships and (Project)
Pipeline were the three key watch words of the 12th Meeting of the Board of the Green Climate Fund (GCF) which took place in Songdo, South Korea, on March 8-10, 2016. Created by the 194 Parties to the United Nations Framework Convention on Climate Change (UNFCCC), the GCF is the premier financing mechanism to significantly alter the landscape in climate finance. One of the key drivers behind its creation was the aim of the Group of 77 and China countries to ensure that developing countries have direct access to the funds they need to undertake transformative, innovative and country - owned climate change adaptation and mitigation actions on the ground.

The Board of the GCF takes decision on a consensus basis among the 12 developing and 12 developed countries' board members, each with an alternate member. In general, Board Members serve a three-year term. However, developing countries' board members may rotate according to internal agreements within the UN region or constituency groups which selected them. Currently, holding membership seat on the GCF board for developing countries are: Bangladesh (LDCs, with Malawi as alternate), Belize (GRULAC, with Uruguay as alternate), China (Asia-Pacific, with Maldives as Alternate), Democratic Republic of the Congo (Africa, with Sudan as alternate), Cuba (GRULAC, with Antigua and Barbuda as alternate), Egypt (Africa, with Senegal as Alternate), Mexico (GRULAC, with Chile as alternate), India (Asia Pacific, with Malaysia as alternate), Kingdom of Saudi Arabia (Asia Pacific, with Pakistan as alternate, Samoa (SIDs, with Seychelles as Alternate) and South Africa (Africa, developing countries' co-chair of the Board, with Tanzania as alternate). Georgia (which is outside regional groups and constituency) occupies the 12th developing countries board seat (with Burkina Faso as alternate).

With a pledged resource envelope of \$10.2 billion for the period up to 2018, the GCF is seen to be the largest climate change fund. However, the current funding, achieved in its initial resource mobilisation process, is considerably less than the amount expected by the Group of 77 & China and global civil society. The Fund was conceived to distribute 'a major share' of the mobilised \$100 billion per year by 2020 of climate finance promised by developed countries since the 2010 Cancun Climate meeting. It has also been identified as the financing mechanism for the flow of funds for the implementation of the Paris Agreement (2015). Of the amount so far mobilised, of which approximately \$ 5- 6 billion

has been made available, the GCF's Board has set a target of approving US\$2.5 billion for projects and programmes to developing countries' entities as well as the global private sector in 2016.

At its eleventh meeting, held in Livingston, Zambia in November 2015, the GCF's Board began the process of approving projects. All 13 projects from Africa, Asia, Latin America were approved. With this meeting the Board also finalised its five investment priorities which include: transforming energy generation and access, creating climate-compatible cities, encouraging low-emission and climateresilient agriculture, scaling up finance for forests and climate change and enhancing resilience in Small Island Developing States (SIDS).

At this 12th Board Meeting, the board focused on developing a strategic plan, which had been long pushed for by developing countries. The Board also firmed up its policies, further developed its project pipelines and consolidated its partnership arrangements with accredited entities, through which the bulk of its resources will be sourced to developing countries.

Allowing live webcasting of meetings

Among the series of policy decisions made by the Board was the adoption of its first strategic plan and its work plan. It also has agreed to live webcasting of future board meetings (starting in 2017) so that interested stakeholders may follow the decision-making process in real time.

Live webcasting of the meeting of the board had been a bone of contention. Developing countries' board members have pushed for this since at least 2012.

Arguing that with the limited pool of funding for a small number of advisors made available to them, they were at a severe disadvantage, relative to their counter parts from developed countries, who often have a large contingent of advisers, developing countries' board members, particularly from SIDS and LDCs, advocated for

live web casting of board meetings. But this argument held no strong sway with some of their counterparts from the developed countries. Hence the webcasts of the meetings of the board were only publicly available three weeks after any board meeting concluded.

Developing countries' board members sought live web casting on the grounds of transparency and efficiency (their colleagues in capital could watch the proceedings and so would be able to offer support on technical issues in real time). CSO observers to the meetings have argued for live webcasting, noting that this is common and best practice among many climate finance and related entities of the UNFCCC. Nonetheless, until the meeting, live web casting in real time, has been strongly resisted by developed countries such as the US and Australia.

Projects being funded already

To date the GCF's Board has approved funding proposals totalling \$1.5 billion. The Board approved USD 1.5 million for Rwanda as the first grant under the Fund's Project Preparation Facility (PPF), an innovative instrument to support accredited entities from developing countries to generate high-quality projects. The GCF's pipeline is growing with 22 private and public projects requesting funds from the Fund of over \$5 billion.

The Board also took steps to expedite the disbursement of USD 11.2 million under grant agreements already signed with 13 countries under the Fund's readiness and preparatory support programme.

The GCF Secretariat, which is head-quartered in Songdo, South Korea, was supposed to implement a readiness programme totalling approximately USD 30 million (capped at \$1 million, per country per calendar year). The readiness programme was expected to provide 'early support for readiness and preparatory activities to enhance country ownership and access'. A minimum of 50% of country readiness funding is expected to be targeted to support African states, LDCs and SIDs.

This would have undoubtedly contributed to the presence of more accredited developing countries' entities, as well as, build the pipeline of projects by and from developed countries. But,

so far, while about \$11 million in proposals have been approved, significant fund disbursement have not occurred. As of the time of the meeting as reported by the Secretariat, only about \$300,000, to four countries, Mali, Cook Islands, Ethiopia and Rwanda, have been disbursed.

The slowness of the implementation of readiness projects and disbursement of funds is a serious challenge for many developing countries' board members. This is especially so in light of the GCF's current trajectory of project submissions occurring through the usual suspects—the MDBs and UN agencies.

Many developing countries as well as CSOs are uneasy with what they see as signifying a business-as-usual trajectory of the Fund that runs counter to the narrative of the GCF as an innovative and transformative fund dedicated to ensuring that developing countries have simplified and timely access to the funds they need to undertake climate change activities and to fulfil their obligations under the UNFCCC, in particular the implementation of the Paris Agreement and related decisions from that meeting.

Partnerships

A total of 33 entities have been approved to partner with the GCF and implement its projects and programmes. While 20 of these were approved in 2015, at this 12th meeting, the Board accredited 13 new entities, including four national public entities, one regional public entity applying under direct access, two private sector entities, and six international public entities. Developing countries with accredited entities include: Argentina, Ethiopia, Morocco, and South Africa.

Civil Society Organisations and some developing countries have raised concerns about the selection of the usual suspects of accredited entities and the implications of this for direct access and enhancing direct access. Concerns are that the progress on developing countries' own national accredited entities would be forestalled as the international entities such as the UN agencies and the MDBs will dominate the landscape. Due to the aforementioned slowness of the readiness programme and a process, which gave MDBs, and UN Agencies, who were previously accredited to existing funds, such as the CIFs and the Adaptation Fund, privileged

'fast start' accreditation, direct access might be under threat.

Some developing countries as well as CSOs, in particular, are concerned about the accreditation of international commercial banks, such as Deutsche Bank (2015) and HSBC (2016) as well as the European Investment Bank, Credit Agricole CIB, the International Finance Corporation (IFC) and bilateral entities such as KfW which may have adverse implications for the provision of grant to developing countries as well for the access of community groups and micro and small enterprises.

It is therefore important that developing countries take actions to promote their own national institutions as accredited entities to the GCF in order to both ensure and assure country ownership. This is beyond the setting up of National Designated Authorities, NDAs, to interface with the International Entities and the Fund.

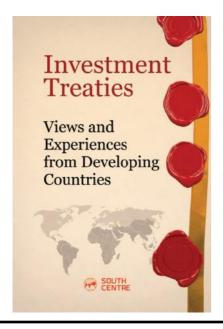
In addition to the key areas of policies, pipelines, partnerships, the GCF board also decided on a number of procedural issues, including:

- Increasing the secretariat from the current 56 permanent staff to 100 by the end of 2016 and 140 by the end of 2017. It is hoped, by many developing countries' board members and civil society observers to the Fund, that a significant number of these staff will be from developing countries.
- Promoting transparency, an information disclosure policy was adopted, which includes the aforementioned provision for live web streaming of future GCF Board meetings, with a review of its utility in 2017.

The GCF will also begin the search for a new Executive Director (ED), as the first and present ED, Héla Cheikhrouhou (Tunisia), will not seek renewal of her three-year term, which ends in September this year. The search for a new Executive Director will commence soon. Developing countries should begin to think about potential qualified candidates from their countries and regions.

Mariama Williams is a Senior Programme Officer of the Global Governance for Development Programe (GGDP) of the South Centre.

South Centre's New Investment Book



The international investment treaty regime is at a conjuncture. There is increasing recognition among the international community that reform of the investment treaty regime is needed. Several countries, both developed and developing, are seeking to reform their investment treaty models. The book Investment Treaties: Views and Experiences from Developing Countries examines the experience of five developing countries (South Africa, Indonesia, India, Argentina, and Ecuador) reviewing their approach to international investment agreements and discussing alternative approaches. It also addresses the relationship between foreign direct investment, investment agreements and economic development.

The book also discusses options for rethinking investment-related dispute settlements, including the option to reform the arbitration rules that apply to disputes. Through reviewing investor-state dispute settlement (ISDS) cases, the book highlights how investment protection rules and the way they have been interpreted by arbitral tribunals have undermined States' right to adopt measures to protect public health and challenged the use of policy tools essential for industrialization.

The book is available in paperback and PDF.

To order this book, please contact: bernardo@southcentre.int

Free trade in trouble in the US..

(Continued from page 12)

If the US does not ratify the TPPA, the whole deal may be off as the other countries do not see the point of joining without the US.

US scepticism on the benefits of free trade has also now affected the multilateral arena. At the World Trade Organization, the US is now refusing attempts to complete the Doha Round.

More US protectionism is now likely. Trump has threatened to slap high tariffs on Chinese goods. Even if this crude method is not used, the US can increasingly use less direct methods such as anti-dumping actions. Affected countries will then retaliate, resulting in a spiral.

This turn of events is ironic.

For decades, the West has put high pressure on developing countries, even the poorest among them, to liberalise their trade.

A few countries, mainly Asian, staged their liberalisation carefully and benefited from industrialised exports which could pay for their increased

However, countries with a weak capacity, especially in Africa, saw the collapse of their industries and farms as cheap imports replaced local products.

Many development-oriented economists and groups were right to caution poorer countries against sudden import liberalisation and pointed to the fallacy of the theory that free trade is always good, but the damage was already done.

Ironically, it is now the US establishment that is facing people's opposition to the free trade logic.

It should be noted that the developed countries have not really practised free trade. Their high-cost agriculture sector is kept afloat by extremely high subsidies, which enable them to keep out imports and, worse, to sell their subsidised farm products to the rest of the world at artificially low prices.

Eliminating these subsidies or reducing them sharply was the top priority at the WTO's Doha Agenda. But this is being jettisoned by the insistence of developed countries that the Doha Round is dead.

In the bilateral and plurilateral FTAs like the TPPA, the US and Europe have also kept the agriculture subsidy issue off the table.

Thus, the developed countries succeeded in maintaining trade rules that allow them to continue their protectionist practices.

Finally, if the US itself is having growing doubts about the benefits of "free trade", less powerful countries should have a more realistic assessment of trade liberalisation.

As free trade and trade policy reaches a crossroads in the US and the rest of the West, developing countries have to rethink their own trade realities and make their own trade policies for their own development interests.

Martin Khor is the Executive Director of the South Centre.

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