



REPORT OF THE INTERNATIONAL CONFERENCE ON THE TRIPS CBD LINKAGE: ISSUES AND WAY FORWARD

(March 15-17, 2017)

**Organised by the Centre for WTO Studies at Indian Institute of Foreign Trade,
New Delhi**

Introduction

The relationship between the TRIPS Agreement and the Convention on Biological Diversity is an important issue in the Doha Round. Successful resolution in this regard, is particularly relevant in the context of containing bio-piracy and would be commercially meaningful for developing countries that are rich in traditional knowledge and genetic resources. The negotiations at the WTO have, however, been dormant over the past 5 years. With a view to brainstorm on this issue and find a way forward, the Centre for WTO Studies, Indian Institute of Foreign Trade organized an International Conference on TRIPS-CBD Linkage on March 15-17, 2017 at the Indian Institute of Foreign Trade, New Delhi.

The Conference brought together an eclectic mix of policy makers, experts, senior officers from the WTO and WIPO, representatives of the key country groups, Geneva based delegates, members of the international civil society organisations and media. The objective of the Conference was to examine the concerns involved and the views expressed on the subject in the TRIPS Council and in other international organizations such as World Intellectual Property Organization (WIPO) and the Convention on Biological diversity (CBD). It looked at possible ways to revive negotiations on the subject in the WTO and explore the role of regional trading agreements and plurilateral treaty on the subject.

The Conference had three themes-with one day devoted to each of the themes. Theme I comprised three sessions dedicated to examining the need, if any for the TRIPS –CBD Linkage. The sessions focussed on the possible conflicts in the implementation of the TRIPS Agreement and CBD, and discussed the evidence of bio-piracy and the rationale for protection in this context. The sessions also encompassed deliberation on the economic construct that supports protection of genetic resources and associated traditional knowledge. Theme II comprised three discussions on the state of play of the discussions in the TRIPS Council, World Intellectual Property Organization (WIPO) and the Convention on Biological Diversity (CBD), and the experience of countries on developing national regimes for disclosure and access and benefit sharing. Theme III on the way forward considered the role of the Civil Society and media in building awareness and understanding of the issue. It also examined the new ways and alliances to help move forward.

The report comprises the main points of the presentations made by each speaker at the Conference. A synopsis of the discussion following the presentations has also been included at the end of each session.

**INTERNATIONAL CONFERENCE ON THE TRIPS CBD LINKAGE: ISSUES AND WAY
FORWARD**

DAY 1

THEME I: ESTABLISHING A NEED, IF ANY, FOR TRIPS-CBD LINKAGE

Session 1

**PUTTING THE CONTEXT TO THE CONFERENCE: INTRODUCTORY SESSION LAYING DOWN THE
ISSUES RELEVANT TO TRIPS-CBD LINKAGE AND DEVELOPMENT IN OTHER INTERNATIONAL
FORA**

Speaker: Prof. Chandni Raina, Centre for WTO Studies

PROFESSOR CHANDNI RAINA

The first session was aimed at highlighting the concerns that were relevant to the TRIPS-CBD linkage and in delineating the issues that would need to be focused on in the three-day conference. The speaker highlighted the growing significance of traditional knowledge (TK) and associated genetic resources (GR) as evident from the buoyant increase in trade in products based on such knowledge. She cited the findings of the trilateral report (2012) and WHO study (2013) to elucidate the fact that traditional medicines have served as an important source for new developments in modern medicine and that the strongest opponents of the TRIPS CBD Linkage have also been major consumers of TK based products.

The interaction between the traditional innovation/knowledge systems and the modern scientific system is especially evident in the patent system. Patents are granted for inventions that have novelty, are non-obvious to a trained eye or meet the inventive step and have industrial application. TK or knowledge held, preserved and developed by traditional communities/indigenous people forms the prior art in many patent applications where GR are being utilized and thereby may explain the novelty. In addition, it can also enable the patent examiner to evaluate the degree of non-obviousness of an invention whose origin lies in the TK and for which a patent is sought. It has

therefore been a long standing demand of the developing countries that patents should not be granted for existing TK and associated GR. Further, where TK and associated GR form the basis of scientific development, it is important that patent applications must disclose source or origin of the resource and also disclose whether the access was on mutually agreed terms. Disclosure is important not only to address information asymmetry at the Patent Office but to also enable a better assessment of the inventive step. This is imperative for ensuring adequate compensation to local communities whose livelihood thrives on the resource and also to enable conservation of the valuable genetic resource for posterity.

There is considerable evidence on how existing knowledge has been sought to be patented. In case of India, while some of the most prominent cases have been that of turmeric and neem patents granted in the US and EU respectively, the TK Digital Library team has since 2009 identified 1155 Patent applications at various Patent Offices like the United States Patent and Trademark Office (USPTO), European Patent Office (EPO), Canadian Intellectual Property Office (CIPO), German Patent and Trade Mark Office (DPMA), United Kingdom Patent & Trademark Office (UKPTO), IP Australia and Controller General of Patents Designs and Trademarks (CGPDTM). Success has been achieved in 206 cases where the patent applications have either been withdrawn/cancelled/declared dead/terminated, or have had the claims amended by applicants or rejected by the examiner(s) on the basis of TKDL submissions. Most other developing countries have also had to face the brunt of misappropriation/bio-piracy; prominent cases among these have been Kava (Pacific Islands-Fiji and Vanuatu), Ayahuasca (Amazon), Quinoa (Peru), Hoodia (South Africa) and Enola Bean (Mexico).

The problem lies in the fact that while the innovation systems continuously interact, this exchange or interrelationship does not get reflected in the patent applications because there is no specific requirement to disclose the source or the origin of the genetic resource and the associated TK, or to provide evidence of prior informed consent (PIC) and access benefit sharing (ABS). There is therefore an inherent information asymmetry between the information available to an applicant and the disclosure made to the patent office. This creates a situation where patents could be granted for existing knowledge or where the improvements over existing knowledge are obvious and lack inventive step. In such situations, we would have TK being patented, thereby providing a monopoly

right to an existing knowledge. This in turn will not only affect the livelihoods of the traditional practitioners, but also adversely affect access to these technologies by millions of people thereby impacting access to medicines...even through the alternative medicine system.

The problem of asymmetry of information is further accentuated by the peculiar nature of TK systems being predominantly non-codified and community held. In such situations, in the absence of a legal requirement of mandatory disclosure of source or origin of the biological resource and associated TK, it is very difficult to establish that a particular invention for which the patent is sought is in fact existing knowledge. Since there is no disclosure, it becomes impossible for communities/competent authorities to file oppositions or observations. It is also pertinent to note that access to genetic resource and associated TK which could be the basis of a claimed invention may have been obtained without the knowledge of the communities, or that the communities may not have been informed of the specific use that the resource and associated TK (passed on by them in strict confidence) would be put to. This is a clear case of stealing and could also involve trade secret violations.

Information asymmetry exists not only between the patent office and the patent applicant, but also between the applicant and the TK holder. It is important to prevent this from happening. This gives rise to the need for government intervention to ensure that there is better interaction between the formal intellectual property system and the TK system. Mandatory disclosure of source or origin of the resource and the submission of evidence of PIC and ABS address this issue. Addressing this asymmetry in information that exists at two levels will help resolve the inherent market failure and promote innovation in a big way.

The presentation then gave a brief background of the discussions in the Conference of Parties to the CBD, the World Intellectual Property Organization and the World Trade Organization. It was mentioned that while the Nagoya Protocol to the Convention on Biological Diversity sets an international regime to address ABS, it falls short of making the patent office a mandatory check point. To that extent, the Nagoya Protocol fails to address our concerns completely. With regard to the process going on in WIPO, it was said that WIPO is looking at a *sui generis* system to protect TK and associated GR. Discussions are fairly complex as they are not centered around mandatory

disclosure alone. Despite the passage of 16 years, the treaty documents still elude us. With respect to the discussions in the TRIPS Council, it was stated that the deliberations began in 1995 in the Committee on Trade and Environment, and then moved on to the TRIPS Council in 1999 as part of the built-in review of Article 27.3(b) of the TRIPS Agreement. Subsequently, we had the Doha Ministerial Declaration which mandates that the TRIPS Council examine the relationship between the TRIPS Agreement and the CBD, and the protection of TK and folklore. Since then, many proposals have been made by various countries. In 2008, developing countries could garner the support of the European Union to form a coalition of 106 countries (which included the African and Caribbean and Pacific Countries) for the proposal seeking an amendment of the TRIPS Agreement; the amendment was to enable the mandatory disclosure of origin and source of genetic resource and associated TK, the disclosure of the evidence of PIC and that of ABS in patent applications (TN/C/W/52). The last major proposal along similar lines, but incorporating the mechanism agreed to under the Nagoya Protocol to the Convention on Biological Diversity was submitted by India, Brazil, China, Columbia, Ecuador, Indonesia, Peru, Thailand and the African Group and the ACP countries (73 countries) in 2011. There has been no discussion on the 2011 proposal.

It was mentioned that the problem lies in the opposition from US, Japan, Australia, etc. to an amendment in the TRIPS Agreement. According to these countries, the issue is merely that of the erroneous grant of patents and not of a conflict between the CBD and the TRIPS, which can be addressed adequately through a database system. EU to an extent agrees with the need for an amendment, but believes that there is no actual conflict; EU supports the need for the disclosure of source or origin requirement.

The presentation outlined some of the issues that were expected to be discussed during the Conference. These included the following:

- Is there a need to document the evidence of biopiracy?
- Are there any commonalities in the access and benefit regimes which are being adopted by countries?
- Which organization should the focus be on?

- Have developing countries sought provisions (incorporating demands of the like that have been proposed before the WTO) in bilateral and regional trade agreements?
- Is there a possibility of a plurilateral treaty on the subject? Is it a possible way forward?

DISCUSSION FOLLOWING THE PRESENTATION

Specific issues were raised with respect to the possible outcomes that one could expect from the Conference. While some felt that a new submission to the WTO with concrete evidence of bio-piracy could be helpful, others felt that focus should be on advancing work on proposals that have already been submitted to the WTO. It was elaborated that the 2011 draft text had been submitted to the TNC, but that there had been no further discussion. There was also an acceptance of the fact that there needs to be a way in which the definitions of TK (which are based on traditional beliefs) and patent can be related. Another view expressed was the need to look at the two other issues in the W/52 proposal which are related to GI-extension and GI-registry along with the TRIPS CBD issue as these also have a linkage to TK. Others observed that it would be instructive to discuss why bio-piracy fell off the agenda of the WTO organization. It was stated that this would help us revisit our proposal. Context has changed since the proposal was made, and there is a need to look at whether the proposal is adequate to address the new challenges. It was also stated that the indigenous communities are concerned about the ethical aspects of bio-piracy. Irrespective of the consequences of erroneous patents being granted, the law itself should not create any space for the possibility of that to happen. It was also stated that we need to focus on how issues related to the seed industry are panning out in the treaty related to plant and GR. Views were also aired about the need to not only look at specific cases of bio-piracy but its scope as well. In this regard, the need for coordinated action at the national level was stressed.

Session 2

EVIDENCE OF BIO PIRACY AND HOW TO ADDRESS IT: IS THERE A RATIONALE FOR PROTECTION OF GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE UNDER THE TRIPS AGREEMENT?

Chair: Prof. Abhijit Das, Head and Professor, Centre for WTO Studies

Speakers:

- (1) Prof. (Dr.) Palpu Pushpangadan, Director General of the Amity Institute for Herbal and Biotech Products Development, Trivandrum
- (2) Mr. T.P. Ijinu, Senior Research Fellow, Amity Institute for Herbal and Biotech Products Development, Trivandrum
- (3) Ms. Sangeeta Shashikant, Legal Adviser at Third World Network
- (4) Mr. V.K. Gupta, Former Director, TK Digital Library

PROFESSOR PUSHANGADAN AND MR. T.P. IJINU

Prof. Pushpangadan described the indigenous TK as a community based functional knowledge system, developed, preserved and refined by generations of people through continuous interaction, observation and experimentation with their surrounding environment. Mr. Pushpangadan noted that 6560 species of Indian medicinal plants have been recorded from the codified systems of TK and folk traditions of health practices across 4635 ethnic communities of the country.

He briefly discussed the initiatives taken by India at various levels-which included the enactment of various legislations such as the Patent Act, 1970 (as amended), the Biodiversity Act, 2002, the Geographical Indication of Goods (Registration and Protection) Act, 1999, and the Protection of Plant Varieties and Farmers' Rights (PPV & FR) Act, 2001, CSIR-NISCAIR's "The Wealth of India" series), CSIR-led Open Source Drug Discovery (OSDD) Initiative and the TK Digital Library (TKDL) established by CSIR-NISCAIR in association with Ministry of Science and Technology and Department of AYUSH.

On the TRIPS-CBD Relationship, the speaker discussed the fundamental conflicts between CBD and WTO- pointing out that while CBD recognizes the sovereign rights of nations over their biological resources and associated knowledge systems, WTO does not recognize any informal knowledge/innovations of traditional communities for intellectual property rights. Further, WTO does not insulate TK from intellectual piracy, and does not provide a mechanism for compensation or benefit sharing with indigenous people. He however felt that the Doha Declaration (adopted on 14 November 2001) had got it right with respect to protection of TK and other related issues,

particularly, paragraphs 17-19, which showed a clear understanding of the current challenges of IP law, i.e. access to medicines, the extension of GIs protection, and the preservation of TK. Prof Pushpangadan was optimistic about the impact of the Nagoya Protocol. He said that the Nagoya Protocol will create greater legal certainty and transparency for both providers and users of GR.

Mr. Pushpangadan concluded with the message that sustainable development needs to be established on mutually beneficial pillars of mutual respect and legal clarity, with the active participation of indigenous and local communities.

MS. SANGEETA SHASHIKANT

Ms. Shashikant described bio-piracy to be the monopolization and the commercialization/commercial use of biological resources by third persons on the basis of information provided on its use by communities that have preserved and nurtured the genetic resource and the knowledge over generations without any fair and equitable sharing of benefits to such communities.

To illustrate her point, Ms. Shashikant discussed a few case studies of bio-piracy. The first case she discussed was about *Clarins utilization of medicinal uses of the Harunga tree* found in parts of Africa. She said that the company had learnt of *Harungana's* beneficial effect on skin by studying Africa's TK and is now a key ingredient in *Clarins* skin cream. She stated that the patent application for the same was filed by the company in France in 2015 and is also pending elsewhere. However as per her understanding, this resource was accessed without seeking PIC, and ABS with the concerned community.

Ms. Shashikant also discussed a study done on Professor Gary Strobel of Montana State University (dubbed the Indiana Jones of Fungal Bioprospecting) who is known for collecting plant samples and isolating the microbes found inside them. The Professor has collected endophytic fungi from various countries, and holds more than 10 US patents. These patents are subsequently licensed to a number of companies for a variety of uses. His efforts are focused on utilizing TK to identify plants that may have medicinal value. The access to these plants is again not based on any benefit sharing. "Yellow

Enola Bean” case was yet another case highlighted by her where patent was obtained in the US for the seed cultivated for generations in Mexico. She mentioned that the patent could be revoked only after a long battle challenging the grant.

Further, Ms. Shashikant highlighted the emerging issue of “pirates in the cloud” – bio-piracy which takes place through a combination of gene sequencing technologies synthesized from genetic material. She gave the example of DivSeek (Big data initiative engaged in mass genome sequencing efforts) which is trying to link databases to the genomic information, and is also working with various companies on this. The issue of sequence data is already being examined in the WHO which has already established a benefit-sharing mechanism in relation to pandemic influenza. However, the organization also realizes that if the mechanism does not include gene sequencing data, then the entire mechanism will be ineffective in the future. She stated that this issue was also being discussed in the International Treaty of Plant Genetic Resources, and as such Big Data initiatives impact farmers’ rights, and fair and equitable benefit-sharing. This is a benefit-sharing challenge, and gives rise to the need to update access and benefit-sharing systems. She added that the subject has also been put on the agenda of the Nagoya parties because it has to be noted that the access and benefit-sharing rules which are based on the tracking of the physical transfer of samples (material transfer agreements) may not give sufficient protection in the future.

While highlighting the key lessons which can be gleaned from bio-piracy case studies, Ms. Shashikant made an interesting observation that the line between non-commercial and commercial research is actually quite thin, and that very often non-commercial research becomes commercial in nature. In this context, she reiterated the need for a compliance mechanism for ABS rules, and demarcation of effective checkpoints to monitor bio-piracy, evidence of PIC, and fair and equitable benefit-sharing.

Speaking on the experience about the disclosure of Origin in Patent Applications under the Budapest Treaty, she mentioned that a study conducted on this by Third World Network, found that in 74% of the cases during January 2010 to June 2013, there was no disclosure. In the 17% of the cases where there was disclosure, it was found that the material and the applicant were from the same country. According to the data collected, the rate of disclosure was low in developed countries such as the United States, Switzerland and Germany. It was also noticed that in comparison to the rate of

disclosure during January 2010-June 2013, the rate of disclosure dropped during July 2013-November 2015. This indicated a very poor rate of disclosure on the part of applicants from developed countries. The rationale behind this could be the reluctance on part of applicants to disclose the use of GR from developing countries. She concluded by saying that the study supports the demand of the developing countries that disclosure of origin should be a mandatory requirement to identify cases of misappropriation.

MR. V.K. GUPTA

Mr. Gupta addressed two issues in his presentation, first the evidence of bio-piracy and how to address it, and second, the rationale for protection of GR, TK and folklore under the TRIPS Agreement.

Briefly discussing the progress in the Inter-Governmental Committee *on IPRs, GR, TK and Expressions of Folklore* (IGC) established in the World Intellectual Property Organization, he mentioned that despite 33 meetings of the Committee since its first meeting which was held in 2001, the developing countries have been unable to get a consensus on a binding sui-generis international legal framework on protection of TK, GR and expressions of folklore. Developed countries still recommend establishment of a TK & GR database as a prior art tool for the patent examiners. He pointed out that bio-piracy is a complex area, and at the international level, progress in this regard, has been slow. Recounting discussions in the WTO, he said that although India along with the coalition of other developing countries strongly supports the cause of TRIPS-CBD linkage, the opponents of the proposal (mainly US, Canada, Chile, Australia, New Zealand and Argentina) claim that there are no convincing arguments to justify TRIPS-CBD linkage. Mr. V. K. Gupta, in light of this negotiating position, noted that the crux of the Conference should be to identify a mechanism to develop evidence which justify the case for TRIPS-CBD linkage. He added that such a mechanism will lead to progress of negotiations on TRIPS-CBD.

He mentioned that one of the arguments proposed by the developed countries against TRIPS-CBD linkage is the existence of system of post-grant opposition of patents. According to them, the presence of this mechanism nullifies the need for TRIPS-CBD linkage. Mr. Gupta refuted this

argument by establishing the impracticality of post grant oppositions. He argued that it is a very time-consuming and costly process. He elucidated his claim by presenting examples of post-grant opposition for Neem, Enola Bean and Monsanto Soya Bean and Basmati patents where the entire cancellation process had taken more than 10 years with the exception of Basmati which had taken 4 years. The cost of the legal action to protect basmati had cost the Indian Government around US\$2 million. He stated that the cost of getting a granted patent invalidated at the international level is around US \$2-3 million. Thus, the process is highly expensive. Besides, this is an inappropriate method because the person who misappropriates already has the knowledge that does not rightly belong to him and has a right to appeal the decision.

Mr. Gupta stated that TKDL was set up with the objective of creating prior art tool for prevention of grant of erroneous patents. It seeks to provide information with respect to TK and GR in digital form in a language and format which is understandable by patent examiners across the world. So far, it has recorded information on 0.3 million medical formulations derived from *Ayurveda*, *Unani*, *Siddha* and *Yoga* practices. TKDL is provided to patent offices under an access agreement which allows its use for prior art search and examination, but prohibits any third-party disclosure. Council of Scientific and Industrial Research (CSIR)-TKDL unit has agreements with patent offices of Australia, Canada, European Union, Germany, Iceland, Japan, United Kingdom and United States. However, in most jurisdictions, patent examiners lack expertise in the area of TK, and are unable to make use of TKDL. To address this challenge, CSIR has made use of third party observation and pre-grant opposition mechanisms which are universally available, free of cost and without any time limit to provide information on applications as grounds for opposition. He informed that until 2013, TKDL had identified around 1500 applications. Out of these, 220 applications were rejected or amended and were acknowledged as being attempts at bio-piracy. TKDL also considerably reduced the duration of the time taken to obtain rejection of patent claims. For instance, patent claim for anti-vitiligo cream and claim for treatment of avian influenza were rejected in 3 weeks each, while patent for altering metabolism took 11 weeks, composition for heart disease took 9 weeks, composition for herbal cosmetics took 37 weeks, and method of stress management and treatment was rejected in 40 weeks. He pointed out that international media as well as local media have helped in publicising TKDL's efforts and success.

However, he added, that despite TKDL and its utilization for pre-grant opposition, patents could still be granted because patent examiners are not TK experts. Moreover, the database covers only codified Indian medicinal knowledge and is only a fragment of the total available TK. He also stated that the database or pre-grant as well as post-grant opposition procedures cannot implement PIC and access & benefit sharing, and therefore concluded that TRIPS-CBD Linkage is the only effective mechanism to address this. But for this to come into existence, he added that the developing countries need to submit comprehensive, credible and verifiable evidence of bio-piracy to the TRIPS Council to push the negotiation process forward.

DISCUSSION FOLLOWING THE PRESENTATION

There was discussion on the manner in which bio-piracy cases are identified. Ms. Sangeeta clarified that the CBD and the Nagoya protocol have laid down rules and principles such as requirement of PIC, benefit sharing on the basis of mutually agreed terms and fair & equitable sharing. All bio-piracy cases, including *Clarins (African Harungana Plant)* case, are examined and identified on the basis of these principles. On the issue of gene sequencing databases, she said that the issue needs to be examined further as it is difficult to identify country of origin. Consequently, it has been put on the agenda of the CBD and Nagoya Protocol Parties, and an expert group has been set up in this regard. Ms. Sangeeta also brought to the notice of the participants the inherent inequity in the treatment of the rights of the original right holder and that of the farmer under the International Union for the Protection of New Varieties of Plants (UPOV) system. UPOV requires permission of the original right-holder for commercialization of a new plant variety bred from a protected variety, whereas no such restriction is put on new variety bred from farmer variety. She remarked that Indian system does not follow UPOV and has many protections for farmers' rights. However, many developing countries are following UPOV which is inherently inequitable. On the issue of how biopiracy cases are identified and informed to the people at large, Mr. Gupta said that TKDL unit as a follow up measure has always tried to publicize cases of rejected/cancelled patents. He strongly felt that the documentation of the bio-piracy cases can be utilized during multilateral negotiations on TRIPS-CBD linkage to strengthen the arguments of the developing world.

Session 3

FRAMING AN ECONOMIC CONSTRUCT TO THE PROTECTION OF GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

Chair: Mr. Rajiv Aggarwal, Joint Secretary, Department of Industrial Policy and Promotion

Speakers:

(1) Dr. Biswajit Dhar, Professor at Jawaharlal Nehru University, New Delhi

(2) Mr. Ermias Tekeste Biadgleng, Legal Expert at the Intellectual Property Unit, UNCTAD

PROF. BISWAJIT DHAR

Prof. Dhar mentioned that at the time of implementing the TRIPS, a gross imbalance was created: rights of the owners of modern knowledge system got enhanced while the rights created through the modern informal knowledge system were continuously compromised. According to him, it was morally and ethically incorrect to pick up someone else's knowledge and to make commercial gains out of it. Whereas holders of TK have maintained it for the current generation's benefit, they themselves have got no benefits, and this thereby removed incentives for the TK holders to continue with the trade.

Dr. Dhar stated that knowledge and resources go side by side. If knowledge goes out of the window, then there won't be any incentive for the communities to preserve the resources. He questioned the absence of a system that did not allow TK holders to carry on this system which they have been doing so from time to time. He then spoke about the imperative for protecting TK. Firstly, even though the global market for TK products has been growing, India's share was miniscule for the reason that its value was being appropriated somewhere else. He argued that countries where TK originates deserve a larger share. Secondly, there was increasing evidence of misappropriation of TK. TK is not a museum piece, but actually "living knowledge". Thus, it has to be treated on par with the formal system of knowledge. Explaining the rationale for protecting TK, Dr. Dhar stated that it promotes sustainable use of resources, and contributes to habitat preservation. In many countries, TK was also a source of livelihood for indigenous communities (IC).

Dr. Dhar was of the firm belief that the conventional systems of IP were unsuitable for protecting TK. He argued for the need to incentivize TK protection, and to not just keep it alive, but to also help it grow. Speaking about the Traditional Knowledge Digital Library, he stated that though it had done its job, and worked upto a point, there were certain limitations. To begin with, it covers only traditional medicines and even this is not entirely captured. He emphasized the need to go beyond TKDL, and see what more could be done, in terms of protecting TK (since protection in TKDL was not comprehensive). In his view, it is important to connect TK with the traditional communities holding the knowledge.

Dr. Dhar spoke about the role of the Biodiversity Management Committees (BMCs), whose principal duty is to document the TK. He praised the role of BMCs. Describing the wide network of BMCs, he argued that we need to look at the amount of knowledge that there is, and to ensure that TK gets its due and finds its place under the sun.

Dr. Dhar discussed how economists only take into account the economic capital to justify need for IPR. In this regard, he questioned the absence of recognition of the social capital put in by the Indigenous People/local communities. He brought out the fact that most holders of TK are on the fringes of the market if not completely outside it. He stressed the need for putting the formal and informal knowledge systems on a single pathway of protecting knowledge in its entirety. He added that there is a need to think about proactive protection of knowledge rather than passive protection.

MR. ERMAS TEKESTE BIADGLEN BIADGLEN

In his introduction, Mr. Biadgleng gave a conceptual overview of the economic analysis of biodiversity and TK. While the general discussion on the economic framework has for a long time considered conservation as incompatible with economic development, recent economic thinking has shifted towards considering the environment/GR as an asset, not when exploited, but when also preserved, thus carrying an inter-generational dimension. The fundamental question is whether its exploitation in a manner that is more sustainable is good for the economy in general. The same rationale, he felt could apply to TK system and TK. Taking yoga as an example, he stated that

though it has huge commercial application, the preservation of the TK system that developed it is equally important to promote further traditional innovation, and neglecting it could negate benefits for the present and future generations.

The Convention on Biological Diversity (CBD) has placed conservation as its central objective, while making exploitation of biodiversity conditional on sustainable use. Even in case of customary use of GR, the CBD has imposed a condition that such use shall be in a sustainable manner. Discussing the sovereign right to exploit, Mr. Biadgleng explained that, the concept in CBD was about conservation, requiring a departure from international law principle that emphasis on ‘control’ over natural resources as the operative paragraphs of CBD only talk about the sovereign right to ‘exploit.’ According to him, even the sovereign right to exploit isn’t meant to challenge the pre-eminence of conservation as a means to ensure and sustain economic benefits of biodiversity.

Mr. Biadgleng spoke at length about commercial use of GR and TK which according to him was the second plank of the economic framework for GR and TK. Commercial exploitation could take place on the basis of ABS Agreement, or IP, or IP licensing, or other legal means as domestic laws sometimes authorize, or through just misappropriation or bio-piracy. In this context, he gave the example of New Zealand’s Maori Community’s certification marks, which differentiate between use by the community, use by the community in joint venture with or licenses for exclusive use by enterprises outside the community. According to him, over time it had developed strong economic incentives, and had evolved a framework for its sustainability as a form of commercial exploitation of traditional cultural expressions.

The speaker stated the central problem in the commercial exploitation of GR/TK is how to increase the use through legal means. In this context, he identified three factors that can shape the legal and sustainable commercial use: the bargaining power between the providers and recipients, the incentives to engage in ABS and other legal means and the risks for both the providers and recipients. Each of these factors should be assessed to examine how the current international cooperation contributes to sustainable commercial use of GR/TK, and what is missing. The bargaining power of providers depends on the control the providers have over their GR/TK either *de*

facto or because legal principles such as PIC to access GR/TK are being implemented effectively. The recipients bring with them the requisite technological capacity, capital, skill, and most importantly, the marketing channels. The incentive to engage, for providers, is the benefit sharing, and for the users are access to GR/TK and the possibility of claiming IP rights over their inventions based on or derived from GR/TK.

Speaking about the probable risk involved, he said that the providers wouldn't know the valuation of any specific GR or TK. Another risk for the providers pertain to their ability or otherwise in enforcing contracts and in asserting titles. For the users, there are more uncertainties. If competitors have cheaper or free access to the same GR/TK, then incentive for the users to engage in ABS is very limited. If there is no effective control of the GR, and if competitors can access the same material through trade or other means, then those who engage in ABS will be disadvantaged. Hence, the role of domestic law, international negotiations at the WIPO or the WTO is to address these issues. It is to deal with the incentives, the bargaining positions, and to reduce the risks for both the providers and users.

Mr. Biadgleng reviewed the various international instruments, including the Nagoya Protocol treaties and instruments dealing with material transfer agreements, and private international law to enforce contracts as well as domestic laws that implement the CBD. He was of the view that international law for enforcement of private contracts to address the incentives and risks associated with engaging in legal means of accessing GR and sharing benefits, has been strengthened by the Nagoya Protocol's (NP) Article 15 as it has proposed to enforce foreign law, and also addresses situations of non-compliance. He, however, pointed out that the NP's monitoring and reporting system is weaker than the WTO dispute settlement mechanism. NP was a good basis to further push the PIC and enforcement issues. The second important development that according to him, further contributes to the legal access and use of GR/TK is the development of mandatory disclosure requirements for patent applicants under domestic laws. He felt that although there is no agreement at the WTO, patent applicants seeking international protection are increasingly more likely to face the mandatory disclosure requirements in many parts of the world. He also outlined national

initiatives for monitoring the use of GR/TK and the development of digital libraries of TK as contributing to the strengthening of the commercial and sustainable use of GR/TK.

In his concluding remarks, Mr. Biadgleng stated that in defining the economic framework for GR/TK/TCEs, conservation is as important as commercial exploitation, if not more. There is an urgent need to monitor the effective implementation of Nagoya Protocol, especially the provisions concerning enforcement and access to justice, as it has the potential to reduce uncertainties. More membership of the Nagoya protocol is needed. Further strengthening of mandatory disclosure requirement in IP applications could increase the likelihood of patent applicants being conscious of the ABS rules. Such efforts, however, primarily addressed the concerns of the providers. For a better economic framework, the incentives and risks for users need to be considered. For this purpose, he suggested to better define the ambition for international negotiations, compared to the incentive for cooperation, and what can be achieved at national level. However, ultimately, the solution relies on advancement in technological and scientific capacity within the provider countries for sustainable exploitation of GR/TK.

REMARKS OF THE CHAIR AND DISCUSSION FOLLOWING THE PRESENTATION

In his initial remarks, Mr. Rajiv Aggarwal noted that there was no doubt that TK needs to be protected; the question is of 'how'. There needs to be a sustainable model of protecting TK that is not based just on a financial construct, but on an overall economic construct. There is a need for a system where TK is not just protected, but used for the larger welfare of society, and benefits are given to the right-holders. Mr. Aggarwal stated that the responsibility lies on us to make sure that the right people benefit from the knowledge they have held over the last several generations. Citing the example of how patents were granted for turmeric, he emphasized the need to ensure that TK is not misused, and that benefits go to the right people.

With regard to the TKDL, Mr. Aggarwal stated that there is no doubt that the TKDL as a body of knowledge needs to be augmented further. If we were to keep TKDL as a static system for prior art search system, then the benefits would be extremely limited. Using the TKDL for further research is one of the ways to make sure that benefits are enhanced for the concerned people. Mr. Aggarwal

also pointed out that Indian inventors are at a disadvantage as they are subject to legal obligations such as disclosure and the need for permission from NBA. Foreign inventors on the other hand do not have such a disadvantage in their countries. Thus, he added that the selective implementation of CBD is creating problems. He was of the view that developing countries should work together towards proper implementation of international regimes.

A question was posed regarding the market valuation of biodiversity and TK. It was cited that the figures quoted in some of the addresses in the Conference were not the actual value of the TK. Prof. Dhar had responded to this question by stating that these numbers were based on a whole lot of assumptions. He emphasized the need for case studies and narratives. On this point, Mr. Aggarwal stated that there may be a case for studying ABS agreements, and determining how much of the benefit actually goes to the Indigenous people and the local communities.

DAY 2

THEME II: TAKING STOCK OF THE DISCUSSIONS IN TRIPS COUNCIL, WIPO AND CBD (NAGOYA PROTOCOL) AND THE IMPACT OF THESE ON NATIONAL REGIMES

Session 4

STATE OF PLAY OF THE DISCUSSIONS IN THE TRIPS COUNCIL

Chair: Mr. Sudhanshu Pandey, Joint Secretary, Department of Commerce

Speaker: Ms. Jayashree Watal, Counsellor, Intellectual Property Division at the World Trade Organization

MS. JAYASHREE WATAL

Ms. Watal noted that the TK discussions in WTO were brought into the TRIPS Council in 1999 through the built-in review of Article 27.3 (b) of the TRIPS Agreement. Since 2002, discussions have been taking place in the TRIPS Council on the “Triple Agenda items” namely, the review of the provisions of Article 27.3(b), the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), and the protection of TK and folklore. The main discussions have centred around the theme of ‘Relationship between TRIPS and CBD’. Explaining the developments on the subject, she said that, after the adoption of the Doha Declaration, the General Council had directed the Trade Negotiations Committee in 2004, to redouble its efforts to find an appropriate solution, as a priority, to outstanding implementation-related issues. Subsequently, the Hong Kong Ministerial Declaration reiterated the General Council’s decision and requested the Director-General (DG) of the WTO to intensify his consultative process and to take appropriate action no later than 31 July 2006. Although the July 2006 deadline was not adhered to, the responsibility fell directly on the DG to take action. Following this, the Deputy Director-General and the Director-General took the consultations forward. According to the speaker, the most productive period in the DG’s consultative process was the year 2010 just before the Easter Package. The Easter Package in 2011 froze all the results in all areas of negotiations, including with respect to the outstanding implementation issues, of which only two remained (namely the TRIPS-CBD linkage and GI Extension). That report of

April 2011 is where we are currently. Immediately prior to this, a subset of interested developing countries (known as the “disclosure group”) submitted the TNC/C/W/59 proposal.

Ms. Watal highlighted the issues being discussed in the TRIPS Council. She stated that the discussion is two-fold. The first issue is whether there is a conflict between TRIPS Agreement and CBD, including in light of the grant of erroneous patents, and the second issue is that of non-compliance with CBD’s requirement with respect to ABS. The question then is whether something needs to be done at the WTO, particularly with respect to enhancing mutual supportiveness between TRIPS & CBD (even if there is no conflict) and if yes, what needs to be done? If not, which forum is the appropriate one to take action (the forum issue)? It was pointed out that some countries clearly prefer the WIPO-IGC whereas other countries say that inclusion in WIPO-IGC does not preclude the WTO.

Ms. Watal then noted that there is agreement among countries on the points that there should be mutual supportiveness between TRIPS and CBD, erroneous patents should not be granted, and that there should be compliance with national ABS regimes without the patent offices and patent applicants being unduly burdened. However there are three different positions that countries have with respect to the TRIPS-CBD linkage. According to proponents of the first position, there is no legal conflict between TRIPS and CBD. Both treaties have different and non-conflicting objectives- CBD is about access to GR (GR) and benefit sharing with the objective of the conservation of biodiversity, whereas, TRIPS protects IPRs. Proponents of the first position believe that nothing needs to be done on the TRIPS side to ensure that the two are implemented in a mutually supportive way at the national level.

Proponents of the second position believe that there is no inherent conflict (there could be potential for conflict) but that international action is desirable (Ms. Watal noted that this is the position which many WTO members hold). They believe that both can and should be implemented in a mutually supportive way and that a mandatory disclosure requirement on patent applicants is needed as an amendment to TRIPS.

On the other hand, proponents of the third position believe that there is inherent conflict, and that a TRIPS amendment is necessary to reconcile CBD and TRIPS and as part of the review of Article

27.3(b). They also believe that patents over GR are not compatible with sovereignty; endanger food security, environment, traditional practices, competition and development. They believe that Article 27.3(b) should be amended to ensure a mandatory prohibition of patents on life forms, including on microorganisms. They also support a disclosure requirement in TRIPS.

Ms. Watal then proceeded to discuss the national-based approach, that is, the US position on these issues; she remarked that the US position is supported most closely by Japan and Korea, and to some extent by Australia and Canada. The US believes that CBD has valid objectives but solutions to implement the CBD should lie outside the IP system, in particular to implement PIC, and ABS. The US argues that every valid objective in international law does not need to be achieved through the IP system. For instance, benefit sharing can be achieved through contracts (since CBD talks of ‘mutually agreed terms’ which indicates a contract). The US advocates that such contracts can include requirements with respect to PIC, access, benefit sharing and even mandatory disclosure requirements of every commercial application of the sourced GR and associated TK (TK). Regular reporting and monitoring requirements can also be included in such contracts. Further, permits and visas can be used for those entering the country to collect genetic material. Other suggestions include sharing of information between patent offices of different countries. In cases of non-compliance with the requirements, it has been suggested that effective remedies could include civil and criminal remedies, and administrative penalties.

Ms. Watal highlighted some of the claimed advantages of the national-based approach, some of which are immediate availability, necessary flexibility, agreed forum for enforcement of contracts, and flexibility to define terms in the contract. Ms. Watal also pointed out some of the issues related to the national-based approach that have been raised in the TRIPS Council. These include problems related to the enforcement of a contract covering multiple jurisdictions. Besides this, a national-based approach is limited in scope as it cannot address trans-boundary use of GR and TK. Further, she added that unequal bargaining power of parties (indigenous communities lack legal training) affects the implementation of contracts, and differing national legal systems raise transaction costs vis-a-vis a unified system. Moreover, remedies proposed cannot deter, those acting in bad faith. Also, revocation of IPRs (which is an effective remedy that could be made available under TRIPS) cannot be found in the contract system.

The speaker briefly discussed the famous turmeric case as an example of an erroneous patent to illustrate how both sides have used this case in the TRIPS Council. While India has argued that the litigation was very costly, making it very cumbersome and expensive for the Indian government to fight cases of misappropriation, the US reasoned that when it was brought to the US Patent Office's attention that a patent had been granted on TK, the USPTO cancelled the patent, which only demonstrated that the patent system worked.

Ms. Watal drew attention to the differences between the TN/C/W/52 and the TN/C/W/59 proposals on disclosure requirements. According to the W/52 proposal, the country or the source of GR should be disclosed, and/or Associated Traditional Knowledge (ATK) for which a definition will be agreed. Members agree to define the nature and extent of a reference to PIC and ABS, which, may also be raised and shall be considered in the negotiations. The W/59 proposal states that the country providing GR and/or ATK, that is, the country of origin and, the source in the country should be disclosed. Additionally, a copy of an Internationally Recognised Certificate of Compliance (IRCC) should be provided. If an IRCC is not applicable in the providing country, the applicant should provide relevant information as required by the national legislation of the providing country/country of origin. Moreover, the W/52 proposal does not talk about the trigger for disclosure, whereas according to W/59, the obligation to disclose would be triggered where the subject matter of a patent application involves utilization of GR and/or ATK.

She also noted that the two proposals differ significantly with respect to the legal effects of non-compliance. According to W/52 proposal, post grant sanctions may also be raised and shall be considered in the negotiations. W/59 states that members shall impose post grant sanctions; these may include administrative/ criminal sanctions, fines and adequate compensation for damages or other measures including revocation. The W/52 proposal contains no provisions on transparency. On the other hand, the W/59 proposal states that members shall publish the information disclosed jointly with the patent application or grant, whichever is made first.

Discussing some of the claimed advantages of the disclosure approach as expressed by their proponents, the speaker said that it is believed that the approach would contribute to the prevention of misappropriation of GR and associated TK as patent applicants would be legally bound to disclose source/origin and authorized access. Other advantages include prevention of the grant of

erroneous patents, increased transparency regarding ABS, greater legal certainty and predictability and enforcement of obligations under the CBD across different jurisdictions.

Summarizing the concerns raised by other parties on the disclosure approach, she said that it is felt that the disclosure approach will raise administrative costs and burdens, mandatory disclosure requirement will also adversely affect legal certainty and predictability within the patent system because rival companies could challenge perfectly valid patents for business reasons. It is believed by the opponents that the disclosure approach is neither necessary nor effective to attain CBD objectives or meet concerns raised. Difficulties may arise in ascertaining origin of the GR due to multiple sources of that resource and in defining terms such as misappropriation, TK, GR and country of origin. Moreover, remedies for non-compliance with disclosure requirements, including patent revocation is contrary to averred objectives such as benefit-sharing; this is because once the patent is revoked, there can be reduction in the benefits to be shared. To many, the trigger for disclosure in the W/59 proposal is also unclear.

Ms. Watal noted that since 2011, the procedural issues regularly raised before the TRIPS Council are whether the CBD Secretariat should be invited to brief the TRIPS Council on the Nagoya Protocol, whether the three Secretariat summary notes be updated, and whether the DG should resume his consultative process.

REMARKS OF CHAIR AND DISCUSSION FOLLOWING THE PRESENTATION (OPEN HOUSE)

The Chair noted that the engagements have not been that intense since the W/59 proposal and have focussed mainly on procedural issues. The session was then open to the house.

One of the participants observed that we are discussing TRIPS-CBD issue in the IGC but that is for a holistic agreement on GR. In the TRIPS Council, we are not trying to get a holistic agreement on GR rather we are trying to get one point clear, i.e. disclosure of the origin of GR. How we use the GR and share the benefits is the mandate of the IGCs. The participant highlighted that IP laws differ in various countries and therefore, we cannot implement IP laws cross-country unless we have minimum agreement on the IP issues among various countries. This is why we want to take TRIPS-CBD issue to the TRIPS Council, so that there is minimum agreement on how to use genetic material across borders. The participant also said that if the patent applicant discloses under the

mandatory disclosure requirement, then there would be no question of burdening the patent examiner, since the disclosure would do away with the need for the patent examiner to conduct an extensive search.

Session 5

STATE OF PLAY IN OTHER INTERNATIONAL ORGANIZATIONS; NAGOYA PROTOCOL – WHAT IS IN IT FOR DEVELOPING COUNTRIES?

Chair: Ms. Jayashree Watal, Counsellor, Intellectual Property Division at the World Trade Organization

Speakers:

- (1) Ms. Sangeeta Shashikant, Legal Adviser at Third World Network
- (2) Dr. R.S. Rana, Chairman of Bio-links, Bio-links, the National Working Group for promoting implementation of the UN Convention on Biological Diversity
- (3) Mr. Nirmalya Syam, Programme Officer, Innovation and Access to Knowledge, South Centre

MS. SANGEETA SHASHIKANT

Before beginning her presentation on the highlights of the Nagoya Protocol (NP), and how we should perceive it, Ms. Shashikant informed the audience that a lot of her analysis was based on TWN's follow-up of the NP negotiations. Some of the analysis was developed following the adoption of the NP.

Ms. Shashikant began by giving a brief overview of the CBD. She pointed out that even after the CBD was adopted, problems such as illicit access continued. So in 2002, there was a call for very specific benefit-sharing provision of the CBD to be implemented. In 2004, mandate was given for development of international rules in this regard. Subsequently, the NP got adopted in 2010 and entered into force in 2014.

The key components of the NP are ABC – access, benefit sharing, and compliance. According to Ms. Shashikant, developing countries stressed on securing benefit sharing compliance measures by

countries to ensure that users in their jurisdictions did not misappropriate or commercialize GR from provider countries. However, developed countries were more interested in access and wanted to ensure that the policy space for access was not restricted.

Ms. Shashikant proceeded to discuss some of the key features of the NP. She began with the NP's provisions on access. Article 6 of the NP requires the enactment of specific legislative, policy and administrative measures with regard to PIC in the provider countries. While the CBD did not require enactment of specific measures, the NP on the other hand, was very specific on the nature of measures required for PIC.

Ms. Shashikant then stated that the provisions on compliance as well as benefit-sharing tend to be more general and vague, but on access, the nature of measures is quite specific. These provisions call for legal certainty, clarity, transparency in domestic ABS legislation specifically requiring that the rules should provide for fair and non-arbitrary rules and procedures.

Ms. Shashikant then analysed some of the provisions regarding fair and equitable benefit sharing. According to the NP, parties have to take legislative, policy and administrative measures to share benefits in a fair and equitable way, with the party providing resources. The benefits to be shared are those arising from the utilization of GR and commercialization, as well as subsequent applications. She pointed out that this provision was insisted by the developing countries. The benefits may include monetary and non-monetary benefits.

Ms. Shashikant then discussed provisions regarding compliance. She pointed out that the relevant provisions on compliance were loaded qualifiers, and contained many provisions which were in the nature of best endeavour clauses. Further, these measures are not specified, and are placed at the discretion of the user country. Highlighting that these provisions do not give much teeth in relation to compliance, she pointed out that they were insisted upon by developed countries.

Ms. Shashikant proceeded to discuss proceedings relating to measures to monitor compliance. This was an area of contention between developed and developing countries. Developing countries

argued for establishment of effective monitoring, tracking and reporting requirements. They had also proposed designation of checkpoints where the user must disclose pertinent information. She pointed out that developing countries wanted a list of checkpoints to be specifically mentioned (such as IP offices, regulatory authorities, etc.). However, that list was not mentioned in the end. Developing countries had also proposed an indicative list, which was also not agreed upon. There was nothing much in terms of the kind of checkpoints in the NP. Ms. Shashikant stated that instead what the NP has are general provisions which are very limited on the specifics. On the Global Multilateral Benefit Sharing Mechanism, she mentioned that this was a demand by the Africa Group, but the NP falls short of establishing a mechanism, and only calls for future work on this in terms of the need for such a mechanism and modalities.

The speaker went on to discuss the scope of the NP, which she pointed out was one of the most contentious issues during the negotiation of the NP. She mentioned that it was very important for developing countries that derivatives be included. The developing countries demand the inclusion of derivatives because a number of the biopiracy cases are based on the use of biochemical compounds. The scope as it stands generally covers derivatives for ABS and compliance. But, there could be varying interpretations depending on the person concerned. She also went on to highlight that “pathogens” are also within the scope. She pointed out that there was an attempt by the EU to exclude pathogens from the scope, because at that time the WHO was also negotiating a framework for influenza viruses of pandemic potential. She clarified by stating that pathogens are included and are subject to ABS rules, but that Article 8(b) of the NP includes a compromise, whereby, in developing national ABS legislation, each party shall pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health. Parties may take into consideration the need for expeditious access and expeditious fair and equitable benefit sharing arising from the use of GR including access to affordable treatments. The emphasis is also on benefit sharing, in particular, access to affordable treatments.

Ms. Shashikant then discussed the issue of temporal scope, which is one of the most contentious issues and (perhaps) not even resolved. The issue is whether the NP applies to GR, derivatives and TK acquired before the entry into force of the NP? She pointed out that there exists difference of

opinion between the developed countries and the developing countries. The NP applies to GR acquired before the NP entered into force, but for new and continuing use under the NP. Otherwise, a lot of resources that have been acquired before the entry into force of the NP would be left out of its scope.

Pointing out the flaws in the Protocol, Ms. Shashikant said that the whole process of the NP was rushed through, and that many other concerns of the developing countries were not addressed (such as publicly available TK). She was of the view that the provisions are general and lacking in specificity, which would pose a problem not just for the providers but also for the users. She mentioned that a lot of uncertainty is also created for the companies that are based in developed countries because there is going to be different interpretations, for instance regarding the provisions on temporal scope.

Ms. Shashikant then pointed out that the NP is not the ceiling; it does not set the maximum standards. Countries may go beyond NP in their legislations, but without having an extra-territorial effect. The question always is whether developed countries would recognize such measures, would they then take measures against users in their jurisdiction? She pointed out that further clarity may be achieved through the decision-making bodies of the NP. This would depend on how firm countries are on their position. Further, developed countries need to take appropriate measures to comply with ABS rules. In this regard, she pointed out that unless certain common aspects such as check points are established, compliance would not really happen; it would merely remain elusive.

DR. R.S. RANA

Continuing on the topic of what could the implications of Nagoya Protocol be on the developing countries, Dr. Rana remarked that in his experience of being associated with the CBD process since 1992, he had observed a thinning of the line between developing and developed countries or, between the North and the South. Instead, he used the expressions “provider countries” and “user countries” because he felt that this was a more accurate representation. He explained this use of terms in the context of India which is self-sufficient in terms of resources, but is still 49% dependent on other countries for crop GR.

He called the NP as a “packaged deal” which started with the 4th Conference of Parties to the CBD (COP4) in Bratislava in 1998 with an agenda which included consideration for an international regime on the issue. He then mentioned a series of important events which defined the developments. He quipped that it was during the Sustainable Development Summit held at Johannesburg in 2002 that it was made mandatory for CBD to develop and explore by 2010 the process to be involved in formulating the international regime. An open-ended ad hoc working group was constituted in the CBD meeting in 2004 which saw polarization between the developed countries and the developing countries on the mandate of the NP. Inter-regional negotiation groups too were formed. Thus, intercessional work was conducted by the working group under two co-chairs to take the negotiations forward. In the COP 2010, a *heavily bracketed* report was submitted by the working group. The COP presidency then started an informal consultation group, talked to ministers and conducted discussions with individual delegations to prevent breakdown of negotiations. Dr. Rana informed that the COP President had announced it a “*take it or leave it*” time in negotiations.

Compromise was required to allow the protocol to come into being. The issue of derivatives went down till the very end when the Secretariat proposed to change the expression “material” to “bio resources” in the definition of “derivatives”, as mutually agreed upon by all the member countries. On acceptance of this proposal, the NP was adopted. Dr. Rana stated that despite these developments, there is a lack of uniformity between the definition of “derivatives” under Article 2 of the NP and its wording in the text (he called it a hazy wording) which could be open to interpretation.

Talking about the scope of the NP, Dr. Rana said that though the developing countries were pushing for a retroactive application of the NP, the Secretariat found no precedence of this kind in international instruments and thus, the proposal was dropped by the COP President. Additionally, the developing countries complained that their materials had been transferred to the developed countries prior to NP which made their position precarious. As a result, Japan announced compensation in the form of donation of USD 2 billion to the Bio Diversity Fund. Dr. Rana said that the benefit sharing

and utilization of GRs includes R&D, its subsequent application and commercialization. He stated that access under Article 6 of NP is clearer than benefit sharing under the protocol. One of the important aspects of NP is PIC of the provider countries that shall have legal, administrative or policy measures having certainty, transparency and clarity. The NP made the provider countries as well as the user countries bound under the text. As far as compliance of NP is concerned, Dr. Rana said that each party shall ensure that GRs and TK utilized within its jurisdiction are accessed according to PIC and mutually agreed terms (MAT) principles. This, according to Dr. Rana, was a major gain out of the negotiations leading up to NP and the provisions of NP.

Check points are an important proposition because the developing countries had a position that this was the point where user country could approach and meet requirements of PIC and MAT to claim and be verified by the provider countries. So, the developing countries insisted that the patent offices should be the uniform checking points. This proposal was not agreed upon. Likewise, there was no consensus on having the patent offices and the approval offices, both, as check points. The member negotiating countries could not reach an agreement on a proposed indicative list for check points. After failure to agree upon the issue, the check points were left undefined.

Going back to calling the NP a “packaged deal”, Dr. Rana said that the developing countries agreed to adopt global strategy only when the NP was adopted. The part on globalization of resources too was brought into the strategy and was agreed upon once the funds were provided. Application of the NP was an important issue according to Dr. Rana. The NP would apply where GRs are accessed and utilized in conducting R&D and subsequent application is done of the GRs (as stated by Dr. Rana earlier). Likewise, the demarcating line of when the NP would not apply was presented. The NP would not apply to GRs covered by other specialized ABS agreements (for example, the ITPGRFA, WHO’s Preparedness of Endemic Awareness, the Antarctic Treaty and treaties on forest GRs, fish GRs and microbes which have a possibility to be excluded from application of NP). While GRs acquired before the NP came into force were excluded, human genetic material was also excluded from the scope of application of the NP.

Dr. Rana then discussed the working of the NP, calling the provider country measures and user country measures as the crux of the working of the NP. He said that the EU proposed for the user countries to conduct a due diligence on GRs. Dr. Rana was convinced with this proposal because he believed that once EU user countries agreed with this disclosure requirement, though with its complex mechanism, the provider countries shall provide certainty, clarity and transparency under the legal instruments. Establishing National Focal Points (NFPs), Competent National Authority (CNA) are important in working of the NP. The CAN shall grant approval and access, and the Publishing Authority (PA) shall display all the legal frameworks of the country on its website for the user countries to know and access. This function was aimed at promoting and ensuring transparency in the entire due diligence process. Additionally, an ABS-Clearing House (ABS-CH) would be set up to verify that GRs are acquired in compliance with PIC and MAT principles and alert the check points of provider countries and the CNA of the same. With the help of a diagram, he explained the role of ABS-CH in monitoring “utilization of GRs” beyond national jurisdictions.

Dr. Rana informed the house about the implementation status of ABS in India. He stated that the NFP, CAN and PA have been identified in India, and that the provider country measures have been recognized to some extent. India has also notified the Guidelines on ABS Regulations, 2014. The access is granted through national permits which go to the ABS-CH. The clearing house then converts the national permits into a unique identity (also known as Internationally Recognized Compliance Certificate (IRCC) in India). However, a lot more is yet to be done in India on the implementation of ABS. India is yet to designate a check point. Additionally, user country measures are to be developed. Dr. Rana observed that this process would take long because unlike in the smaller countries, binding all the users in a big country, like India, is challenging.

India has also initiated inter-ministerial consultations, stakeholder consultations and creating awareness and capacity building. Government has approached the University Grants Commission (UGC) to spread awareness and undertake capacity building after the Bio Diversity Act came into force in India. As a result, the UGC required all the universities in India to have the Act on their websites. The importance of enforcing user country measures and an effective implementation of ABS (which depends on the degree of enforcement of user country measures) was highlighted by Dr.

Rana who also emphasized the importance of designating or delineating a trigger for the user obligations to kick in. While the EU proposed access to be the triggering mechanism, other countries argue that utilization of GRs should be the trigger. Countries like India say that both should be accepted as a triggering mechanism. So, there is still an ambiguity on what should be the triggering mechanism. Dr. Rana also stated that as far as check points are concerned, some countries, in his opinion, have agencies which are peripheral to the working of the NP. However, there is no ambiguity on the need of international and regional cooperation in this regard.

Dr. Rana hoped that more user countries would join the NP and adopt the national legal framework for enforcing users' obligations. He added that the parties should adopt a uniform triggering mechanism for invoking users' obligations.

MR. NIRMALYA SYAM

Mr. Nirmalya Syam made a presentation on the developments, state of play and the dynamics of the WIPO Intergovernmental Committee on GR, TK and Folklore (IGC) Negotiations. Introducing the IGC, he informed the house that the IGC was established in 2000 with a 2-year mandate which gets renewed on expiry by the WIPO General Assembly. He mentioned that for the first ten years, the mandate of the IGC was on exploratory work while it shifted in 2008-09, when it was renewed for undertaking textual discussions for international legal instruments on GRs, TK and Folklore (FL). The common thread which was recognized by Mr. Syam in all the negotiations since 2008-09 is a fundamental disagreement on the interpretation of mandate of IGC. Though the mandate of IGC includes undertaking textual negotiations for international legal instrument(s), it does not specify whether the negotiation of treaty is included in the mandate because the question on having a hard law approach or a soft law approach is yet to be decided. While the developing countries want a diplomatic conference for adoption of a convention in relation to TK, TCE and GRs, the developed countries hold the view that convention/ hard law approach is not required. The alternative proposed by the developed countries is a preference towards a soft law approach in the form of recommendations and guidelines. Mr. Syam informed the house that this uncertainty in the mandate of the IGC is to be negotiated in the next meeting of the General Assembly.

Another issue which arose, according to Mr. Syam, is the lack of genuine interest among the developed countries in reforming their IP norms and in accommodating issues of TK, GRs, TCE in the international IP system, and also in resolving ABS issues through private law contract outside the IP system. On the other hand, there are varied degrees of experiences and offensive interests among the developing countries. Some developing countries have more experience in national law implementation compared to others. Use of IP tools for positive protection of GRs, TK and TCE is also not uniform among the developing countries. Some developing countries have a preference towards *sui generis* models of protection under customary law while others want protection under the IP type tools.

Mr. Syam pointed out the difference between the titles of the texts being negotiated for protection of GR, TK and TCE. He observed that protection of GRs has been proposed under a “Consolidated Text on GRs” as compared to “Draft Articles on Protection of TK” and “Draft Articles on Protection of TCE”.

Mr. Syam presented a detailed understanding of the Consolidated Text on GRs wherein he pointed out the proposed *Disclosure Requirement* which continues to be under the square brackets. He called it the “most critical” provision in the Consolidated Text as it is found at the core of the developing countries’ demands. An alternative formulation proposed by the US and supported by other developed countries is called Defensive Measures/No Disclosure Requirement as they continue to advocate for a soft law approach having joint recommendations on GRs and associated TK, joint recommendation on use of databases for Defensive Protection of GRs and associated TK, study on measures related to the erroneous grant of patents and compliance with existing ABS mechanism, and a discussion on the disclosure requirement under specific national laws. The Swiss national law was suggested as the basis by the US.

On the issue of divergence in the position adopted by the developing and developed countries, Mr. Syam noted that while the former want prevention of misappropriation of GRs, including derivatives and associated TKs, the latter have backed prevention of grant of patents on inventions that do not meet the patentability criteria. Mr. Syam observed that the developed countries’ position is the same

as under Article 27 of TRIPS Agreement, and is not a substantial addition to that in the Consolidated Text.

The question of subject matter of the Consolidated Text remains to be addressed. Some issues which Mr. Syam left the house to ponder upon were on the question whether the derivatives and associated TK should be added as subject matter in addition to the GRs or whether the subject matter should be limited to patents (or other IPRs). Another question warranting attention of the negotiators is whether the subject matter should be limited to patents for inventions which are directly based on GRs. The issue of disclosure requirement, as discussed earlier needs to be addressed as the developing countries advocate for introducing new mandatory disclosure requirements with specific terms in the text, and the alternative view of the developed countries is to not bring any new disclosure requirement at all.

The square bracketed provision on Mandatory Disclosure Requirement proposed by the developing countries is in the hotbed of negotiations. Questions like when to disclose and should the claimed invention or the subject matter involve utilization or direct utilization of GRs and derivatives/associated TK are inherent to negotiations. The contents of disclosure are yet to be decided as either the country of origin or the source of GR could be required to be disclosed. Additionally, in an event when the country of origin is unknown, whether only source would be required to be disclosed needs to be finalized. The negotiators also need to come to a conclusion on compliance of ABS and PIC requirements, and a declaration if country or origin and source (both) are unknown. Other queries which Mr. Syam raised in his presentation were the issues related to IP offices. He raised the question whether the IP offices should have obligations to verify the content of disclosure, transmit the information to CBD/ITPGRFA clearing house mechanism, and make the disclosure information public (except in cases of privacy, business secrets and confidential information). Within these issues, suggestions have also been made to not have any patents on GRs or derivatives as found in nature or isolated therefrom.

The “No Disclosure Requirement” proposal of the US supported by other developed countries advocates for the existing standard patent law to be followed where disclosure is required to be made

only *if necessary* for the person skilled in the art to carry out the invention. This position encourages disclosure only when it is necessary to test the patentability criteria and be done only after grant of the patent. There should not be any disclosure requirement, if disclosure is not necessary for making or using the invention. The new formulation proposes adjustment of patent term to compensate procedural delays in examining the patent applications. The US also wants an opportunity to be given to the applicant to correct erroneous or incorrect disclosure.

Every country proposes to include exceptions and limitations to their proposals in relation to disclosure requirements. However, the developing countries hold a broad formulation of having specifications to be decided according to the domestic law and justifiable in public interest. On the other hand, the developed countries prefer specific exceptions like excluding marine GRs by virtue of being outside the exclusive economic zones (EEZ). While the developing countries want the Consolidated Text to impose specific sanctions on defaulters, the developed countries believe that an unintended failure to disclose should not affect the validity of the grant of patents.

Voluntary Codes of Conduct have been proposed; in this regard, the developing countries believe that the database and administrative measures should be complementary mechanisms and not alternatives to the disclosure requirements.

Mr. Syam then discussed the critical provisions of the Draft Articles on Protection of TK which includes the question on incorporating benefit sharing with PIC under the subject matter, and prevention of erroneous grant of IPRs. The disclosure requirements language in the Draft Articles is also unclear so as to whether it should require disclosure of source and/or origin of TK (developing countries' position) or have no mandatory disclosure (as proposed by the developed countries).

Mr. Syam concluded his presentation by pointing out the key challenges that lie ahead for the negotiators to overcome. He stated that the key challenge was for countries to come down to specificities of the mandate of the IGC, and then for the developing countries to come up with a common position in terms of advancing the core objective of ensuring disclosure requirements within the mandate of WIPO negotiations.

DISCUSSION FOLLOWING THE PRESENTATION

Participants wanted an assessment about the date by when it would be possible for negotiations on TK and GR to conclude in the IGC. Mr. Syam responded that there is no consensus on very crucial issues, and that countries are considerably far away from coming to a common position on the GR text. There is also this issue of how the negotiations are paced. The structure of the different sessions would also influence the pace of concluding the negotiations. Mr. Syam also pointed out that there is a necessity to ensure alignment between the different texts, hence how they progress will also have implications.

Another participant commented that since we don't have any option but to continue negotiations at the IGC, there are two important things to be kept in mind: one is the nature of instruments, and the second is the maturity of the text. He stated that there are two schools of thought: the first believes that countries should conclude agreement on all three subjects- TK, TCEs and GR at the same time and the second view is that the most mature text should be taken forward for negotiations and then the other two texts should be negotiated. He personally believed that agreements on TK and TCE might be easier to conclude. But if this happens, then we may never see an agreement on GR. This is one predicament. The other predicament would be that if we wish to have agreements on all three topics, we may never have an agreement at all.

Discussion veered towards the relative economic significance of the issues. It was felt that one should not have an agreement for the sake of having it. He pointed out that progress was being made with regard to TCE because there were no benefits. The same could be said of TK. It was pointed out that GR, confers a lot of economic benefits for developing countries. It was mentioned that instead of spending time negotiating *all* the three issues, it might be better to drop the first two and instead insist on a text on GR as it confers certain economic benefits for developing countries.

There was a question regarding what could be included in the list of effective checkpoints; whether it should just be the patent office or should that be extended to other departments. Considering that many countries don't have substantive patent examination in their jurisdiction, the role of the

regional patent office was also discussed. In response to this question, Dr. Rana stated that though the patent offices are usually the mainstay, there was divergence in the checkpoints. He stressed that whatever these additional checkpoints be, it was essential that they be relevant. While agreeing upon the importance of the regional patent office, he argued that designating regional patent offices would help in implementation.

Regarding the progress of negotiations, it was stated that the critical question is the common ground on the disclosure requirement. The participant pointed out that it is difficult to see common ground at the moment, as some countries such as the US are not even accepting the idea of disclosure requirement.

The limitation in the capacity of patent offices was also discussed. The participant pointed out that the checkpoint is not about engaging in substantive examination, but getting information about PIC, and ABS. The onus is on the patent applicant to show that they have complied with the requirement. She then highlighted the importance of regional patent offices, especially in Africa, such as the ARIPO and OAPI. She pointed out that though there are a lot of things which these patent offices can do such as disclosure, they were not happening due to various reasons. She added that they definitely had a role to play as checkpoints.

Regarding the ICG process, it was pointed out that at the end of the day, it is not how long the process will take that is important, but what one is deriving from the process, and the value that it has, which is important. It was added that whoever is negotiating the text, whether at the WTO or WIPO, that person had to be equipped with the information as to how the process operates, how it operates in a national context, what is happening in other related processes such as the NP, the CBD. It was emphasized the need to ensure that whatever we get at the end has to be of value or else, we would have fought a 15 year process with an outcome which has no impact.

Session 6

EXPERIENCE OF COUNTRIES ON DEVELOPING NATIONAL REGIMES FOR DISCLOSURE AND ACCESS BENEFIT SHARING

Chair: Dr. Amita Prasad, Additional Secretary, Ministry of Environment, Forests and Climate Change

Speakers:

(1) Mr. Andres Valladolid, President, Peru's National Anti-Biopiracy Commission

(2) Mr. Marco D' Alessandro, Policy Adviser, Sustainable Development and International Cooperation, Legal and International Affairs Division, Swiss Federal Institute of Intellectual Property

(3) Mr. YAO Xin, Deputy Director of Division III, Legal Affairs Department, State Intellectual Property Office (SIPO), Beijing

MR. ANDRES VALLADOLID

Mr. Valladolid observed that Peru is one of the world's 17 countries which possesses the majority of the world's biodiversity and belongs to the group of mega diverse countries. As a result, it is one of the world's major centres for plant and animal GR.

Legal Framework on ABS

Mr. Valladolid spoke about the legal framework on ABS at the national and international levels. He said that Peru is a party to the CBD which it ratified in 1993. The Andean Community of which Peru is a part, together with Bolivia, Colombia and Ecuador, developed a common legal framework in 1996. The common regime on access to GR establishes the conditions for access to GR. At the national level, the law 27811 was published in 2002. According to the law, 'collective knowledge' means 'accumulated generational knowledge evolved by indigenous people and communities understood as TK, concerning the properties, uses and characteristics of biological diversity'. He went on to briefly explain the provisions under their law for protection of GR and associated TK.

1. Main Instruments of the Law 27811

The objectives of this regime are: to ensure that the use of TK takes place with PIC of the indigenous people and to promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge.

To accomplish the objectives, the law mandates that the TK of indigenous people may be entered in 3 types of registers- Public National Register (based on public domain information), Confidential National Register (it is private) and Local Registers.

2. Public and Confidential National Granted Registers

To promote the registers, training of indigenous people's representatives is organized in the form of workshops at the national level. In 2006, the TK Registry was implemented. Since then, 4193 records were registered. Of the total registers, 68% are confidential while about 32% are public. There is a small fraction of records containing both public and private records. These records come from 45 indigenous communities from 12 different ethnic groups. The records are based on 897 different species, of which 69% used only one species, while 31% used a combination of different species.

3. Regulation of Access to GR

In relation to access to GR, the Andean Community of nations provides a common regime on access to GR (Decision 391). The regulation is law in each of the member country of the Andean Community. The Decision is regulated through Supreme Law (published in February 2009) and its purpose is to promote fair and equitable sharing of benefits of the access.

4. Competent National Authorities

The competent national authorities are state entities or public institutions appointed by the states, authorized to supply the genetic resource or its derivatives or intangible components and therefore, to supervise the access. Peru has established 3 different national competent authorities depending on the nature of resource accessed. The different competent authorities are as follows:

- i. National Forestry Service (SERFOR) for wild species of flora and fauna
- ii. National Institute of Agricultural Innovation (INIA) for cultivated species
- iii. Vice Ministry of Fisheries (PRODUCE) for hydro-biologic species

5. National Anti-Biopiracy Commission

Law No. 28216 of May 1 2004 established the National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples (The National Anti-Biopiracy Commission).

Mr. Valladolid said that the functions of the Commission are:

- a) To create and keep a record of Peruvian origin biological resources and one containing Peruvian indigenous people's collective knowledge. He brought to the participants' attention that to this date, there is a database of approximately 20000 records in which the endemic species of the country are identified.
- b) To identify, follow-up and technically evaluate patents granted abroad or patent applications abroad involving the mentioned resources and knowledge. Mr. Valladolid highlighted that at first, the National Commission prioritized 35 biological resources to identify possible cases of biopiracy in patent applications.
- c) To issue reports corresponding to studied cases including the suggested actions to be performed at the government competent instances.
- d) Interpose opposition or nullity actions against abroad granted or requested patents that involve mentioned resources or knowledge.
- e) Draw up proposals for the defense of Peru's interests in different forums- Peru has presented 4 position papers in the IGC and WTO.

Mr. Valladolid stated that to date, 24 cases of bio-piracy have been identified in the patent system, related to TK. Of these 24 cases, 18 have been resolved in favour of the Peruvian government.

MR. MARCO D' ALESSANDRO

Mr. Alessandro's presentation focused on the disclosure requirement in the Swiss Patent Act, and other regulations related to GR and biodiversity, in particular measures to implement the Nagoya Protocol. Mr. Alessandro focused on the following points:

1. Mandatory disclosure in patent applications

Switzerland is a party to the CBD and has introduced mandatory disclosure for source of the genetic resource and associated TK in 2008 in the Federal Act on Patents for Inventions. Mr. Alessandro noted that the requirement is not a measure to ensure ABS compliance as such (those measures are

explained in Point 3 below), but to enhance transparency in the patent system for inventions that are directly based on GR and/or on TK associated with GR (ATK). Mr. Alessandro said that this transparency measure would, however, also contribute to support ABS compliance.

Mr. Alessandro observed that their experience with this measure is limited because most of the patent applications are filed in the European Patent Office, and not in the Swiss Patent Office; this is also one of the reasons why Switzerland continues to support finding solutions at the international level both within WIPO and WTO.

2. Key elements of the disclosure requirement

Mr. Alessandro noted that the following are the three key elements of the disclosure requirement:

- a) Trigger: Inventions directly based on GR and/or ATK
- b) Information: Source of GR and/or ATK
- c) Pre- and post-grant sanctions, but no revocation! Mr. Alessandro pointed out that the Swiss patent system does not provide for revocation in the context of failure to disclose the source, for the reason that if a patent is revoked, there is no benefit-sharing; also, revocation would adversely affect legal certainty.

He then proceeded to explain the key elements in detail:

- a) Trigger: There is a need for a clear trigger that establishes a causal link between the invention and the GR and/or ATK, which was essential for developing the invention. There is no need for disclosure of laboratory tools, experimental organisms, or any other GR that may also be involved in developing the invention

- b) Concept of source:

There are different applicable sources, such as:

- i. Country of origin that supplied the GR
- ii. Multilateral System of the International Treaty on Plant GR for Food and Agriculture
- in this context, the concept of county of origin will not work.

- iii. Indigenous Peoples and local communities - in the case of ATK, it is felt that the indigenous peoples and local communities, which are the holders of the TK, should be disclosed as source.

3. Implementation of the CBD Nagoya Protocol

With the ratification of the Nagoya Protocol, the ABS compliance measures have been included through the amendment of the Federal Act on the Protection of Nature and Cultural Heritage. Two such measures were introduced, namely, a due diligence and a notification requirement before market authorization or commercialization. Mr. Alessandro was of the opinion that contrary to certain notions, the due diligence requirement is actually a very strong measure as it is applicable at all stages of research and development. He added that Swiss ABS user compliance measures are applicable, if:

- i. the country providing GR is also a Party to the Nagoya Protocol,
- ii. the country providing GR has ABS regulation in place, and
- iii. the GR was accessed after October 12, 2014.

He observed that in 2016, the Ordinance on Access to GR and the Fair and Equitable Sharing of Benefits Arising from their Utilisation came into force; the Ordinance contains more detailed regulations on the ABS measures.

Mr. Alessandro explained why from the Swiss perspective, the patent system is not suitable to implement ABS user compliance as such. He pointed out that ABS is a very complex issue and many issues within ABS have not been resolved. Patent Office may also lack expertise and resources to ensure ABS-compliance. The other point raised by Mr. Alessandro was that if ABS is implemented through the check-point of patent offices, it would cover only a very small part of the cases of utilization of GR; there are other cases that do not lead to patents, which may remain uncovered. As explained above, the due diligence requirement takes into account all cases.

4. Geographical Indications (GI)

According to Mr. Alessandro protection of GIs can also contribute to implement the CBD. He said that the Swiss system allows for two types of registration of GIs: appellations of origin and GIs. He said that both are collective IP rights, based on quality, reputation and specific characteristics of the goods. He noted that GI product specification can be linked to conservation of biodiversity, such as specific plant varieties or ecosystems. GIs also help in Protection/safeguarding of TK and/or traditional cultural expressions. Substantiating his argument, the speaker, gave two examples of GIs in Switzerland, namely, the Geneva Thorny Cardoon PDO and Gruyere (cheese) PDO; he noted that by protecting them as GIs, it has added value to the TK as well as to the products.

5. Conclusions and Way Forward

Mr. Alessandro concluded by saying that there is not a one-size-fits-all approach, but various measures are needed to implement TRIPS and CBD in a mutual supportive manner. Within the WTO-TRIPS context, further work should therefore be based on the coalition under TN/C/W/52, addressing GI Register, TRIPS Disclosure Requirement and GI Extension.

MR. YAO XIN

Mr. Xin underscored the importance of TK (TK) and GR (GR), and their use in innovation. He also stated that it is important for developing countries to protect and preserve TK and GR.

Protection of GR in China

China gives a lot of importance not just to the protection of GR, but also to the protection of its TK and traditional cultural expressions. The subject is under the Ministry of Culture, Ministry of Agriculture, Ministry of Environment, Ministry of Health and the State Intellectual Property Organization (SIPO) which are the relevant authorities for the protection of such resources. At the national level, the most important part of TK is traditional Chinese medicines. This is looked after by the National Chinese Traditional Medicine Bureau. Earlier, it was an independent department, now it is a part of the Ministry of Health. The “intangible cultural heritage” is an important concept in

China and it includes TK. Protecting this is the task of the Ministry of Culture. This is administrative protection, rather than IP protection. The objective behind this is to protect the heritage.

China also has a system of GI protection, which can give certain benefits to the TK holder. But, it is important to note that there is not just one system of GI protection. Even the trademark system and other systems can be used to protect GIs.

China's basic principle for the conservation of biodiversity is "Priority on conservation, sustainability in utilization, engagement by the public and sharing of benefits." Mr. Xin observed that the objective behind conservation was not to prevent the utilization of GR, but to ensure that such utilization happens with benefit-sharing. He then gave a brief overview of China's national legal system. Mr. Xin noted that the Act related to the protection of Chinese traditional medicines was adopted in 2016. However, it relates mostly to the administrative protection of traditional medicines.

The speaker felt that a reasonable mechanism needs to be evolved to protect GR. In his opinion, there should be some mechanism in the patent examination process which helps protect GR. He also discussed the possibility of the IP system being used to protect GR and TK. He was hopeful that databases can be useful in this regard. He voiced the concern that databases can also be expensive for countries. However, the IP system can be made mutually supportive for the protection of GR and TK.

He then discussed the Chinese patent system, and the adoption of two articles (Art. 5.2 and Art. 26.5) in 2008. He stated that while patent legislation may give the general principles, the specific regulations give a more detailed overview of the law. He also explained the use of the term "invention-creation" in Article 5.2. The articles are also concerned not just with the examination, but also the administrative management and protection of GR.

In the end, Mr. Xin concluded that we must ensure good utilization of GR, keeping in mind the principles of PIC and ABS. He said that there is a need to link the protection of GR, and the IP system.

DISCUSSION FOLLOWING THE PRESENTATION

A feedback was sought by one of the delegates on the experience of the Swiss IP office with respect to the disclosure requirement, and that whether the requirement burdens the patent office. It was informed that the disclosure requirement in the Swiss patent law applies to patent applications filed through the Federal Institute of Intellectual Property. However, the vast majority of applications go through the European Patent Office. The disclosure of source requirement in the Swiss patent law is a simple and practical measure to enhance transparency and it has been implemented in a way with no real difficulties.

During the course of the discussions, the need to link the patent system and the other systems of protection of GR was also espoused. In this vein, it was mentioned that the examiner can ask the inventor to give the information regarding the source and origin of the GR used in the invention, and the other departments can also collaborate on that front.

A reference was also made to the case study on Nestle's subsidiary accessing GR in South Africa (and applying for a patent on the same), and whether the Swiss law (which came into effect in 2014) would apply in case Nestle applies for a patent in Switzerland, and when access would be said to have occurred. In response, it was stated by the Swiss delegate that there was a need to keep the disclosure requirement in the patent law, and the ABS regulations under the Conservation Act, apart. The amendments to the Swiss patent law were brought in 2008, and are related to the disclosure of source. If an application would be filed through the Federal Institute of Intellectual Property it would be applicable for an invention directly based on a GR. The ABS law, on the other hand, was introduced with the ratification of the Nagoya Protocol and would only apply if access had occurred after the entering into force of the said law in 2014 and for Parties to the Nagoya Protocol that have access legislation in place.

Session 7

EXPERIENCE OF COUNTRIES ON DEVELOPING NATIONAL REGIMES FOR DISCLOSURE AND ACCESS BENEFIT SHARING

Chair: Dr. (Ms.) Amita Prasad, Additional Secretary, Ministry of Environment, Forests and Climate Change

Speakers:

- (1) Dr. Burcu Kilic, Legal Counsel, *Public Citizen Global Access to Medicine Program*
- (2) Mr. T. Rabikumar, Secretary, National Biodiversity Authority
- (3) Mr. Mustaqeem de Gama, Counsellor (Economic), Permanent Mission of South Africa to the WTO
- (4) Mr Adi Dzulfuat, Counsellor, Ministry of Foreign Affairs, Indonesia

DR. BURCU KILIC

Dr Kilic made her presentation on experience sharing with regard to developing national regimes for disclosure, ABS by drawing heavily from the findings of a WIPO report (that she co-authored along with Claudio Chiarolla, and which is soon going to be published). The report titled ‘Key Questions to Address in Developing Patent Disclosure Requirements related to GR and TK’ looks at the different approaches that have been adopted by countries, identifies key questions that policy-makers should be addressing while developing policies in this area, and presents policy alternatives that could contribute to the ongoing discourse. The report identifies 23 policy questions that the policy-makers should be asking themselves if they wish to implement a patent disclosure regime:

1. What are patent disclosure requirements (PDRs) related to GR and TK?
2. How do these new PDRs differ from conventional disclosure requirements under established patent law principles and procedures?
3. What is the relationship between new PDRs and ABS obligations?
4. What are the main critiques and opposing views?
5. Why have several countries introduced new PDRs related to GRs and TK?
6. What other interests and objectives may need to be balanced when shaping the contours of an appropriate disclosure obligation?
7. What is the difference between voluntary and compulsory PDRs?
8. Formal or substantive requirements: What could be the role of the Patent Office in checking their fulfillment?
9. Where to introduce new disclosure requirements?
10. Is it possible to introduce new disclosure requirements in legislation other than patent law?

11. What is the subject matter covered by these new PDRs?
12. What could be the possible content of disclosure?
13. What can be the geographical scope of disclosure?
14. Can there be subject matter or temporal exclusions from the scope of application of a new PDR?
15. What should be the relationship or “link” between the subject matter of disclosure and the claimed invention in order to trigger the application of a new PDR?
16. What kinds of remedies and sanctions are available to address issues of non-compliance with any new PDRs?
17. Who may have a right to take legal action for non-compliance with a new PDR?
18. Which evidence can be submitted in the context of new PDR-related compliance mechanisms and procedures?
19. What kinds of legal, institutional and policy capacities are needed to implement a new PDR?

Relationship with other Instruments

20. Under the Nagoya Protocol, is there a legal obligation to provide for new PDRs in order to monitor users’ compliance with domestic ABS requirements?
21. What are the implications of establishing the patent/IP office as a designated checkpoint under the Nagoya Protocol?
22. What is the possible relationship between a new PDR and ABS obligations under the FAO International Treaty on Plant Genetic Resource for Food and Agriculture (ITPGRFA)?
23. Are there alternatives and/or complementary measures or mechanisms that can be used to attain PDR-related objectives?

The Report also identifies four complementary measures:

1. Due diligence approach
2. Disclosure of the source as a contractual obligation
3. Databases and information systems
4. Subject matter eligibility

The Report also contains a comprehensive patent disclosure requirement table which maps the disclosure regime in more than 30 countries.¹

Dr Kilic outlined the objectives of the study and observed that on the basis of her study of extant PDR regimes, she was able to find answers to these objectives. *Firstly*, why have several countries introduced new patent disclosure requirements? PDRs are implemented in diverse ways, reflecting different policy motivations, political trade-offs, local priorities and needs, and legal and institutional systems. As a generalization, it can be stated that key motivations include but are not limited to the following:

- Preventing misappropriation
- Enhancing efficiency, legal certainty and transparency
- Complementarity/mutual supportiveness with international agreements

There are country examples for each of these policy objectives, and these have been illustrated in the report.

Dr Kilic also commented that there is plenty of evidence on actual instances of bio-piracy around the globe. She highlighted the case of “*Brazzein*”- a protein derived from *Oubli* berry, a West African fruit of the climbing plant of the same name. The protein is around 500 to 2000 times sweeter than sugar and contains zero calories.

People of Gabon discovered and nurtured the plant to help nursing infants “forget” their mother's milk. A researcher from Madison, USA found out about the uses of the berry from the Gabonese people, took some berries back to his laboratory and successfully isolated and reproduced the protein compound. He received three patents (5,326,580; 5,346,998; 5,527,555) in the US and one at the EPO (684995) for isolating and reproducing the protein in a laboratory without giving any recognition or sharing benefits with the people of Gabon. Interestingly, synthetic substitution of the berry obviated the need to collect and cultivate plant in Gabon, causing a significant fall in the price, and many Gabonese women who used to harvest the fruit lost their source of income.

¹ The table is available at http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf (last accessed April 10, 2017).

Dr Kilic discussed the issue of placement- whether it is possible to introduce new disclosure requirements in legislations other than patent and/or IP law. She answered in the affirmative by pointing out that many regimes have introduced PDRs through biodiversity laws (for example- Brazil, Costa Rica, France). The WIPO report also probes into what is the subject matter and content covered by a PDR obligation. With regard to the subject matter, Dr Kilic found that, from the review of national regimes, a PDR obligation raises three key policy issues:

- Whether disclosure obligations should apply only to patent rights (and patent applications) or also to other IP rights;
- Whether the subject matter of disclosure should encompass only GRs and biological resources or also include TK; and
- Whether the subject matter should encompass “derivatives”, raising the issue of the definition of the term “derivative” from Nagoya Protocol.

With regard to the content, Dr Kilic observed that, on the review of national laws, a disclosure obligation may require applicants to indicate one or more of the following categories of information:

- The country of origin of GRs, if any, and/or TK;
- The (direct) source of the GRs and/or TK;
- The legal status of GRs and/or TK (i.e., their legal provenance), in particular compliance with ABS requirements including PIC and evidence that mutually agreed terms have been established; or
- A mere due diligence declaration that the applicant has complied with all applicable legal requirements concerning access to and use of GRs and/or TK.

Dr Kilic also went into the question of what legal, institutional and policy capacities are needed to implement a PDR regime, and observed that this question is rarely asked or researched upon. The WIPO Report found that the implementation of a new PDR requires a plan to be drawn up in accordance with the nature of the obligation to disclose, and also instruments and resources to carry out that plan. The instruments and resources required to implement the PDRs can be grouped into four categories- (a) institutional framework, (b) examination capacity (c) information technologies (d) human and financial resources.

Concluding her presentation, Dr Kilic said that different countries have adopted divergent approaches while dealing with disclosure requirements related to GR and/or TK and that policymakers need to find the best combination for their countries given the specific country conditions. A key challenge will be to establish a coherent legal and policy framework, and to ensure balanced and energetic implementation in the context of national innovation systems.

MR. T. RABIKUMAR

Mr. Rabikumar elucidated the objectives and scope of India's Biological Diversity Act, 2002, and discussed the challenges to its implementation, particularly with regard to disclosure requirements. He noted that India is a party to the Convention on Biological Diversity (CBD) and Nagoya Protocol. It enacted Biological Diversity Act (BD Act) in 2002 with three specific objectives, namely **conservation** of biological diversity, **sustainable use** of its components, and **fair and equitable sharing** of benefits arising from the use of the biological resources. These objectives are derived from the CBD. He further added that for the implementation of these objectives, the Government of India established a three-tier institutional structure consisting of Biodiversity Management Committees (BMCs) at the grass-root level, State Biodiversity Boards (SBBs) at the state level, and National Biodiversity Authority (NBA) at the national level. NBA was established in 2003 at Chennai. It consists of a Chairperson and 15 members, 10 of them are representatives of different Union ministries, such as Ministry of Environment, Forest and Climate Change (MoEF), Ministry of AYUSH, Ministry of Agriculture & Farmer Welfare and Ministry of Science & Technology and other 5 members are experts from the field of conservation of biological diversity.

Scope of Biological Diversity Act, 2002

Mr. Rabikumar noted that the scope of the BD Act is wider than the Nagoya Protocol. Nagoya Protocol covers GR whereas the BD Act extends to all biological resources and associated knowledge except human genetic material. It regulates research, bio-survey and bio-utilization, commercial utilization, intellectual property rights, transfer of research results, and third party transfer of already accessed biological resources/ knowledge. BD Act also specifies the regulating authority (NBA or SBB) for each of the activities, depending upon the category of person.

Mr. Rabikumar also explained the relationship between IPRs and BD Act. He said that section 6 of the BD Act prohibits obtaining of IPR over certain inventions without prior approval of NBA. It is limited to the inventions which are based on research or information on, a biological resource obtained from India. It mandates prior approval for patents filed outside as well as in India.

The Biological Diversity Rules (BD Rules) of 2004 lay down the procedure for the approval. The approval is given in the form of an agreement based on mutually agreed terms. One of the essential conditions of the agreement is benefit-sharing upon commercialization of patent. Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 further provide for the percentage of benefit-sharing and such other terms and conditions for access. Final agreement (approval) is uploaded on ABS-Clearing House (ABS CH), a platform enabling information exchange on ABS. So far, India has uploaded around 46 approvals on it.

Alignment with Patent Office

Mr. Rabikumar also discussed the alignment with patent office. The 2005 amendment to the Indian Patents Act, 1970 mandates disclosure of source and origin of biological materials used in the biotechnological inventions. The Act also mandates declaration with regard to the obtainment of necessary approval from designated authority i.e. NBA. Furthermore, patent examination guidelines of 2012 instruct the patent examiners not to grant patents for inventions based on biological materials obtained from India without NBA's approval. This has been effectively followed during patent examinations. The Biological Diversity Act also takes into consideration priority requirements under the patent system and the prior approval of NBA may be obtained before the grant of patent. The harmony between the Patent Act as well as the Biological Diversity Act is further evident from the fact that wrongful disclosure of source and origin of biological material in a patent application constitutes one of the grounds for pre-grant and post-grant opposition, and for revocation of patents in India.

NBA Initiatives

The NBA has received 1200 ABS applications and 85% of them have been processed and communicated to the applicants. It has signed more than 400 agreements with the applicants, of which 265 are related to IPRs. It has also developed an online application system for simplification

of the process and its beta version is already in operation. In addition, it provides phone in facility to assist the applicants while filling up the approval form and online fees payment facility. These facilities are intended to improve the efficiency of the system in receiving the required information from the applicant, thereby enabling timely disposal of the applications received.

Plant Varieties Protection and BD Act

Section 6 of BD Act is applicable to obtaining breeder's right outside India. It mandates prior NBA approval. However, it is not applicable to registration within India. S. 18 (1)(h) of the Protection of Plant Varieties and Farmers' Rights Authority (PPVFRA) prescribes that the genetic/parental material used for breeding, evolving or developing the protected variety must be lawfully acquired. Section 34 of the PPVFRA provides for revocation of the registration on the ground of wrongful disclosure. Thus, the requirement under the Biological Diversity Act for legal acquisition of biological material, especially under section 3 is sought to be achieved through these provisions of PPVFRA. Considering the inbuilt ABS mechanism prevailing under the PPVFRA including the above-said provisions, the BD Act provisions are not made applicable to filing of applications for any rights under PPVFRA. To be precise, ABS rules of BD Act apply to obtaining similar rights outside India.

One of the most important functions of the NBA is to act on behalf of central government to take any measures to oppose grant of IPR outside India on any biological resource obtained from India or associated knowledge derived from India. Section 18(4) of the BD Act authorizes the NBA to do so. So far, the NBA has filed 8 third party observations before the European Patent Office, 1 opinion statement before the Chinese patent Office, 1 protest application before the Canadian Patent Office and 1 third party observation before WIPO. However, WIPO rejected the NBA submission on the ground that only submissions regarding inventive step and novelty are admissible. On the other hand, subsequent to the protest notice by NBA before the Canadian Patent Office, the applicant filed Form III application in NBA for obtaining the requisite approval. Mr. Rabikumar remarked that the purpose of the NBA is not to block the patent applications, but to ensure compliance of BD Act provisions, and to enable sharing of benefits with the community/ local people from whom biological resources were sourced.

Challenges

Mr. Rabikumar noted that within the country, the NBA has been able to discharge its functions efficiently due to its cooperative working relationship with the Indian Patent Office and Plant Variety Protection Authority. On the other hand, activities outside India pose major challenges for the NBA. Firstly, user country measures outside India focus mostly on access. The NBA is not equipped to efficiently deal with bio-technological patents due to lack of enabling provisions in patent laws of other countries. Secondly, illegal acquisition of biological material used in the invention is still not a ground for opposition and revocation. Thirdly, patent opposition and revocation in other jurisdiction is very costly and time consuming. Fourthly, third party observations haven't yielded many results. They have received very limited response. Fifthly, third party observations are mostly limited to novelty and inventive step, and are not related to the question of legal acquisition of biological resources. Lastly, awareness and sensitization of the stakeholders remain a significant task.

Mr. Rabikumar emphasized that coordination and partnering with the relevant authorities (PPVFRA, IPO, NBA) could curb misappropriation of biological resources in India. But with respect to the applications filed in other countries, coordination mechanisms are lacking and pose a challenge to NBA's functions. Therefore, a global framework for disclosure is required for effective prevention of misappropriation of biological resources and associated knowledge.

MR. MUSTAQEEM DE GAMA

Mr. de Gama stated that TK, specifically, is very politicized, and that there were many opinions on its actual scope. This is particularly the case in South Africa (SA). He explained that in SA, a large proportion of the people were denied their political, economic, and cultural rights for a long time. As a result, when SA became independent, the first thing that was done was to draft a constitution, which changed the whole perspective on how to approach rights, especially IPR, as well as the redressal of the violations of rights. Ultimately, this was done on the basis of redistributive justice. Mr. de Gama briefly explained that SA is a country with rich resources, comprising about 10 % of the world's plants, 7% of all land-based living creatures, and 15% of known marine species. He

explained that in terms of implementation, the efforts to ensure access started even before SA concluded international agreements.

One challenge Mr. de Gama highlighted was the concurrency of jurisdiction on certain matters. Implementation issues arose as jurisdiction which was vested with the national department responsible for GR and biodiversity was replicated at all three levels of political governance in the country.

In discussing the legal framework, Mr. de Gama stated that SA has a national Act that regulates environment management, specifically biodiversity. With regard to patents, he stated that SA is not an examining jurisdiction; this means that SA relies on filing alone, causing certain problems. Mr. de Gama then explained that SA has an indigenous knowledge system policy which was adopted in 2008. He pointed out that there are also regulations in respect of the implementation of the CBD, which was ratified by SA in 1995 and that the country ratified the Nagoya Protocol in 2013.

Mr. de Gama pointed out that there are a lot of other legal and policy frameworks including the regulations and timeframes that are applicable. Other supporting norms include protected species regulations, and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) Regulations. The Patent Act merely requires a statement stating whether or not the invention for which the protection is claimed is based on or derived from an indigenous biological resource, GR, or TK.

Mr. de Gama then highlighted the role of the Department of Environment Affairs (DEA), which is designated as an issuing authority. It can issue bio-prospecting permits, and also grant integrated export and bio-prospecting permits which collapse certain requirements into one efficient process. Mr. de Gama pointed out jurisdictional issues in this regard. Besides the replication of jurisdiction at the local and provincial levels, there are other departments as well. For instance, the Department of Trade Industry has the IP mandate and also looks into the national implementation of international obligations. There is also the Department of Science and Technology which looks at promoting and

developing indigenous knowledge systems. So, there are various agencies and departments that have certain chunks of the framework. All this requires coordination.

Mr. de Gama then discussed the scope of the measures in place. The National Environmental Management Act (NEMA) governs the use of indigenous biological resources and provides for various aspects. The first important principle is that the state is the trustee of biological diversity, and can assume the management and conservation of biodiversity. He pointed out that, however, ownership does not vest in the state. As per common law, the owner of the land also becomes the owner of the resource and its inherent value. Only if the resources are located on state land does the state actually become the owner.

Mr. de Gama discussed other aspects. The ABS legal framework is contained in Chapter 6 of the NEMA, which regulates bio-prospecting, exportation of indigenous Biodiversity Resource and GR, and fair and equitable benefit-sharing by stakeholders. It also provides for the naturally sustainable use of indigenous GR and BR. Mr. de Gama pointed out that SA has tried to emulate India in trying to implement the TKDL, in order to record and codify TK.

Mr. de Gama then elaborated the challenges in identification and protection of stakeholders, and of the access and verification of TK holders. In the absence of a database of traditional communities, the government has to designate particular communities as it pertains to their geographic location. However, the problem is that many other communities exist that are not recognized by governments. This gives rise to the issues related to access such as whom to negotiate with.

Mr. de Gama pointed out that SA has a problem with data management: there is no accurate data as to what happens at every stage of the value chain. The biggest impediment is actually a lack of resources. He however acknowledged that there are certain aspects SA wanted to change. For instance, as per draft IP policy, one objective was to centralize and coordinate IP related issues which would include TK. He stated that SA also wants to introduce a substantial search and examination system. This would however take time and resources, and therefore it would be nice to have disclosure requirements to close the gap. However, as there is no one to enforce it, this creates

many difficulties. In this process, he said that SA would also want to look at certain pre-grant and post-grant patent opposition mechanisms that would lead to the revocation and invalidation of patents that may have been granted erroneously.

MR. ADI DZULFUAT

Mr. Dzulfuat started his presentation by discussing the importance of GR-TK protection for Indonesia. Indonesia is a country with high biological diversity. With a large territory stretching from east to west, Indonesia has over 32,680 species including 29,000 vascular plants. There are more than 30 major groups, with more than 1000 sub-ethnic groups or indigenous communities (ICs). Mr. Dzulfuat pointed out that Indonesia is also susceptible to bio-piracy and misappropriation.

The speaker mentioned that Indonesia has taken many steps to protect its biodiversity. As a first step, Indonesia has as a strategy promoted national awareness on GR and its associated TK beyond those who are following the discussion. The outreach extends not only to the communities that are affected by the issue, but also the bureaucrats who have differences over issues or are not aware of the issues and the importance, and also local governments who are in direct touch with the local communities.

The second step has been to provide legal protection through national legislation.. Indonesia has ratified the CBD through Law No. 5 of 1994 and the Nagoya Protocol (NP) through Law No. 11 of 2013. There is also Law No. 13 of 2016 which is relatively new on patents that has a provision requiring applications for patents to disclose the source of the GR and TK if the patent has any such GR/TK. This law also says that the disclosure on GR and TK must be verified by an institution designated by the government. He pointed out however, that till date no such institution has been designated for the purpose but mentioned that in all likelihood, the work would be the responsibility of the Ministry of Environment and Forestry which is now the main focal point for implementing the CBD and Nagoya Protocol. The third point of this law is that the conduct of ABS must be guided by related national laws and related international agreements on GR and TK extending beyond the present generation CBD.

Mr. Dzulfuat then discussed a non-exhaustive list of national legislations related to protection of GR and TK. These are laws on protection and management of environment which define the government's authority on GR; forestry laws that guarantee the rights of IC on the utilization of forest resources including GR; human rights laws that guarantees the rights of IC who manage particular forest land based on customary laws, etc.

Mr. Dzulfuat stated that as a third step, Indonesia is also active in norm-setting multilateral negotiations such as the WTO and WIPO. He mentioned that Indonesia has been the coordinator of like-minded countries in the WIPO IGC, and is also an active member of the W52 coalitions in the WTO TRIPS negotiations. Indonesia is also advocating for the inclusion of GR-TK protection as part of the IP chapters in the negotiations on bilateral and regional trade agreements.

Mr. Dzulfuat then explained that the inclusion of protecting GR and TK is made with the objective of ABS. This is clearly provided for in the objectives of Indonesia's patent law. Indonesia is also reviewing its database on GR and TK, which is currently scattered with different ministries and institutions of the Indonesian government. The government is trying to integrate these databases so that there can be a common understanding and common scheme for protecting GR and TK. As part of his concluding remarks, he stated that Indonesia has a lot of homework to do. Drawing from presentations made on the experience of other countries, Mr. Dzulfuat noted that Indonesia would draw lessons from the laws of other countries to strengthen its own laws on the issue.

DISCUSSION FOLLOWING THE PRESENTATION

Presentations by the panelists were followed by an equally engaging discussion on the experiences of countries on developing national regimes for disclosure and ABS. One of the participants asked if the disclosure requirement under patent laws of various countries cover GR from other countries. Panelists from India, South Africa and Indonesia stated that their patent laws are limited to the disclosure of their national GR. Dr. Kilic observed that a few countries extend disclosure requirements to cover the GR of other countries on the basis of reciprocity arrangements, for example Costa Rica. She added that China has a universal application of disclosure requirements. One of the participants further added that Section 10(4) of the Indian Patents Act, 1970 requires

disclosure of the source and the origin of biological material where specifications of the patent applications are not sufficiently clear with respect to the invention's operation or use and the method of performance. This provision is not restricted to the Indian biological material; however, its purpose is not to serve the objectives of the Biological Diversity (BD) Act 2002.

Another participant enquired if inclusion of disclosure requirements in the IP chapter of regional and bilateral trade agreements is a better alternative to WTO negotiations for TRIPS-CBD linkage. Panelists in response commented that the negotiations at bilateral level are not an easy task as many countries oppose disclosure requirement in IP chapters. Moreover, bilateral and regional agreements are not sufficient to achieve the universal application of disclosure requirement for TK and GR, but they can be a step towards expanding the scope of protection of TK and GR and can ultimately result in a multilateral agreement. Dr. Kilic pointed out that the TPP includes provision on GR due to Peru's proposal. She remarked that negotiations for disclosure requirement for TK and GR can be simultaneously pursued in multiple fora.

DAY 3
THEME III: WAY FORWARD

Session 8

WTO-WIPO-CBD-WHERE SHOULD THE FOCUS BE?

Chair: Dr.Srikar Reddy, Counsellor, Permanent Mission of India to the WTO.

Speakers:

- (1) Mr. Luis Mayaute Vargas, Minister Counsellor, Permanent Mission of Peru to the WTO
- (2) Mr. Mustaqeem de Gama, Counsellor (Economic), Permanent Mission of South Africa to WTO
- (3) Mr. Caue Oliviera Fanha, First Secretary, Permanent Mission of Brazil to the WTO
- (4) Mr. Willyam A. Saroinsong, Third Secretary, Permanent Mission of Indonesia to the WTO
- (5) Ms. R V Anuradha, Partner, Clarus Law Associates

DR. SRIKAR REDDY

The session started with Dr Reddy introducing the theme for the session and recapping the proceedings of the previous two days. He recollected the accounts of previous speakers regarding the state of play of the negotiations on GR, TK and benefit sharing. Dr Reddy underscored the efficacy of organizing side events on these issues at Geneva before the TRIPS Council meetings for spreading knowledge about the same.

MR. LUIS MAYAUTE VARGAS

Speaking about the appropriate forum where the focus of future negotiations should lie, Mr Luis observed that it is important to keep all windows open, and to consider an inclusive and coherent approach. He reminded the audience that it took close to 18 years to harvest one multilateral agreement- the Trade Facilitation Agreement- after the WTO came into force in 1995 and another 4 years for the Agreement to actually come into force. Also, there has been no practical progress on several issues related to IP and it seems improbable at this juncture that any of the critical IP issues would be discussed at the upcoming Ministerial Conference in Buenos Aires.

Discussing the various alternatives that are available, Mr Luis remarked that W/59 is an important coalition that Peru is a part of. He also added that the TN/C/W/52 will be the best way to move forward. W/52 is composed of 109 members and the coalition is made up of developing and developed countries. The members of this coalition could organize side events, workshops and informal sessions to reinforce the internal work within the coalition. There has to be a political push at the level of ministers to reinvigorate the debate and to be taken seriously.

At the WIPO, the issue of formalizing a treaty on biodiversity related ABS is one amongst the many issues that are on the agenda. So we need to start by conceding that it will be a time-taking process. While treaty negotiations started in 2009, it has not yet been finalized. There are of course issues related to lack of enforceability or dispute settlement under the WIPO framework as compared to the WTO. But, it is important to recognize that the WIPO is the only forum where a possible treaty is being actively negotiated, and we cannot afford to neglect that. The focus should be on narrowing the gaps in the existing GR text. The effort should be not to replace the Nagoya Protocol but to complement it.

MR. MUSTAQEEM DE GAMA

Mr. Mustaqeem de Gama began his presentation by acknowledging that the Conference is being organized at an opportune moment considering that many of the delegates present are intimately working on the issues that are being discussed at the Conference.

He highlighted the changes in the context in which we operate at the multilateral level. One of the most prominent changes is visible in Paragraph 31 of the Nairobi Ministerial Declaration. It indicated the differences amongst WTO membership regarding the validity or the continued relevance of the Doha mandate. This is important because it is the Doha mandate that sets out the modalities and priorities of the negotiations. If some members have begun to question the very blue print on which the future work programme is based, this is an important change that developing countries need to take into account. Many countries are calling for negotiations to be launched on “new issues”. There is no clarity on what constitutes “new issues”- whether they refer to the Singapore issues or they are different from these issues. MC11 Declaration not only recognizes the differences between members on the process and substance of negotiations, but also reckons that the WTO has the right institutional balance to ensure that issues are taken forward.

Given this context, the MC11 Declaration also confirmed that work should continue on all of the issues including those in relation to the TRIPS Council. However, Mr. de Gama expressed concern about the fact that, as a delegate at the TRIPS Council, he has seen no progress on any of the issues that are on the agenda at the TRIPS Council. Statements that reiterate members' support for issues on the agenda are merely being reiterated and reintroduced. There has been no substantial progress on the path to be followed for fructifying the TN/C/W/52 text. As a co-sponsor of the W/52 proposal, South Africa's position has been that we cannot make progress unless there is a balanced perspective. He reminded the audience that a significant amount of time has been invested by the TRIPS Council on issues such as access to medicines and the entry into force of the protocol for access to medicines. Now that valuable work has been carried out on that front, the question is how to refocus our discussions.

Mr. de Gama pointed out that it is important to remember that GR/TK and access to benefit sharing is not the sole domain of the TRIPS Council, and that valuable work is being done at other adjunct forums. Fortunately, there is agreement at the TRIPS Council that members need to be mindful of developing an approach that is coherent with the discussions at these other forums to the extent that there is harmony between the CBD and TRIPS Agreement. However there is disagreement over how to achieve this coherence. Mr. de Gama observed that, given the lack of an appropriate enforcement mechanism in many of the other processes, the focus should necessarily lie within the TRIPS council. What has been particularly difficult has been the process of pushing the agenda forward at the TRIPS Council. He recalled that agreement on most of the issues at the TRIPS Council was reached around the time of the July Package, and that the remaining issues have been frozen in time. However, IP has remained at the core of many other agendas at the WTO- particularly the e-commerce discussions which have taken centre stage at the WTO lately. He felt that the issue of moratorium on non-violation complaints under the TRIPS Agreement is directly related to the proposal for a permanent moratorium on imposing customs duties on electronic transmissions. IP issues also figure in other issues like copyright enforcement. He observed that the discussions on e-commerce have resulted in diluting the more focused negotiations that should be launched at the TRIPS Council.

Discussing the way forward Mr. de Gama pondered the priorities of a post- Buenos Aires outcome. A good start will be to look at some sort of a ministerial declaration that will re-emphasize the issues within the TRIPS Council- specifically the issues that have been christened as the “triplets”. Simultaneously, it is also necessary to create political pressure to augment the momentum of negotiations, and to remove unnecessary blockages. He highlighted the role of the Director General in revitalizing negotiations. In terms of revisiting the proposals submitted before the TRIPS Council, Mr. de Gama seconded the Chair’s proposal to organize side events at the TRIPS Council, which he said, the Permanent Mission of South Africa will be happy to support and co-sponsor if necessary.

Highlighting the capacity constraints and institutional deficits in developing countries, Mr.de Gama observed that the network and support that is built up by the delegates of developing countries at the WTO is often not tapped into because of these constraints.

He concluded by stating that South Africa has just taken over as the chair of the TRIPS Council, and it will be examining the potential issues that could be put up for discussion at the upcoming Ministerial Conference. IP issues do not figure as prime candidates on the agenda for the Ministerial Conference, but there are crucial issues which need to be considered as priorities for the Ministerial agenda.

MR. CAUE OLIVIERA FANHA

Mr Fanha started by introducing the issue at hand: that there were numerous cases of misappropriation of GR and TK being reported from developing countries. The objective at the WTO has been to seek legal remedies to this issue that would complement the action taken under the CBD. Mr. Fanha emphasized that the point of view of Brazil has been that the CBD and TRIPS Agreement are mutually compatible. However, so as to ensure compatibility, amendment is required to the TRIPS Agreement.

Over the years, use of GR without benefit sharing has continued. Mr. Fanha pointed out two instances of plants found in the Amazon region- *Bauhinia* and *Psychotria ipeacacuanha*- for which patents have been filed despite civil society action and government intervention. The continuance of such cases points towards the need to build a coherent international framework on ABS. More importantly, GR need not respect national borders and might be shared with bordering nations. The

need for an international framework is further amplified by the fact that patent applications are not necessarily filed in the same jurisdiction as that of the genetic resource.

Mr. Fanha admitted that there is apparent policy tension between the CBD which provides for conservation of biological diversity through mechanisms such as ABS and PIC and the TRIPS Agreement which speaks about the appropriation of information produced through creative processes. Therefore the question arises- how do we reconcile the two sides?

Firstly, we need to recognize the greater social welfare that is generated through innovative products and services. Innovation in medicines has substantially contributed to enhancing life expectancy and health care. Secondly, innovation needs to be reconciled with adequate benefit sharing with local and indigenous communities.

Speaking of the state of play of the discussions at the WTO, Mr Fanha focused on the W/52 coalition, its limitations and the need to engage with the IP/10 coalition. At a broader level, the WTO is also faced with the “US conundrum” with the arrival of Mr. Donald Trump in the White House and the uncertainties that it gives rise to- such as the appointment of the US Trade Representative and the US delegation to WTO. Mr. Fanha noted that personally he did not believe that there will be overhauling policy changes from the US vis-à-vis the WTO, and that they will continue to pursue their domestic interests. But, there could be a difference in how much the US government is willing to engage at the multilateral level to arrive at outcomes.

Mr. Fanha emphasized the importance of framing issues in a manner that stresses the benefits for developed countries. There should be emphasis on the potential of producing innovative products for developed countries through access to GR in developing countries. Taking into account the diverse membership of the WTO, the aim should be to develop generic language on disclosure that will encompass the particular needs of maximum members.

At the WIPO, the most recent text is the one emanating from IGC 31 and the mandate is for “narrowing existing gaps including text-based negotiations, with the objective of reaching an agreement on an international legal instruments relating to intellectual property which will ensure the balanced and effective protection of GR, TK and TCEs”. This language, especially the last part, highlights the need for a balanced perspective.

Discussing the way ahead and starting first with the CBD, Mr. Fanha pointed out that COP 13 had yielded some concrete results particularly on guidelines for previously informed consent and discussions on ABS on digital genetic information. At the CBD, we have been witnessing greater convergence between representatives and the continuous development of norms, but the greatest drawback has been that it is a non-IP forum and lacks specialized knowledge on IP. Also, there is no enforcement mechanism under the CBD.

At the IGC, moving forward will be contingent on extending the current mandate which is set to expire in October. Some countries are discussing the need for a diplomatic conference or even turning the IGC into a permanent committee. The WIPO Assembly-General in October will be a good opportunity to create some consensus regarding the term of IGC. Mr Fanha pointed out that a concrete result at IGC will certainly have a positive influence on other fora, and will even influence the discussions at the WTO. Critical factors behind the push back at IGC have been what Mr. Fanha referred to as the “ping pong argument”- where developed countries keep raising the non-suitability at each fora, the IGC being a less than multilateral option and the issue of enforcement.

On the other side, the WTO is both a multilateral option and has effective enforcement mechanism under the Dispute Settlement Mechanism. However, there is a lack of engagement amongst members at the WTO.

Mr. Fanha noted the advances made in different fora including UPOV and ITPGRFA. Countries could also include ABS and PIC in FTA negotiations. Meanwhile, we could also make full use of the TRIPS policy space such as definition of novelty/inventive step; disclosure of the invention and whether it includes disclosure of origin; exclusions under Article 27.3; and provision of corresponding foreign applications (Article 29.2).

Mr. Fanha concluded by observing that there is a need to frame the issue in a more favorable reference point to highlight that the problem continues. We could also advance simultaneously in multiple fora, creating a coherent international framework, ensuring effective enforcement mechanisms and continuously developing the normative at the national and regional levels.

MR. WILLYAMA. SAROINSONG

The negotiations lost appetite in 2011. The progress in IGC is not really a progress in itself because the IGC is finding it hard to get consensus on the text. Mr. Saroinsong was of the opinion that the CBD and the Nagoya process have done their parts, so one of the ways forward is to use CBD & Nagoya as a basis for future negotiations. He said that when it comes to the question of where the focus should be, it is either WIPO or WTO. He believes that we should focus on both of these organisations and competence is relevant to the issues that we are talking about. It is only through these two organisations that disclosure and ABS can be realised. In terms of which organisation is more strategic, there is no clear answer because the two organisations carry different mandates and scopes. IP is more specific to trade in the WTO, and what we are asking for in the WTO is the amendment of one or two articles, whereas, in the WTO we are trying to create a whole new treaty.

WIPO and WTO are complementary to each other; what is being discussed in the WIPO should be supportive to the work in the WTO. However, this does not mean that we should prioritise discussions in the WTO more than we do in the WIPO. The WTO is unique because of the DSM which ensures WTO-compliance. Apart from this, the Ministerial Conference which is held every two years is also unique to the WTO and within the two-year window, there is the possibility to produce new political commitments which is what we are trying to achieve at this stage because discussions in the TRIPS Council has not moved much. A question then is which issues within the WTO do we want to willingly trade with the TRIPS? Some of the issues which are still being discussed are e-commerce, fisheries subsidies, agriculture etc. The underlying fact is that WTO by design is a continuous negotiation organisation unless members decided otherwise.

One of the ways for WIPO and WTO to be mutually supportive is to strengthen the co-ordination between the delegates to the IGC and the TRIPS Council. Once in a while, there should be joint co-ordination meetings between IGC and TRIPS Council delegates.

Mr. Saroinsong drew an interesting analogy with the discovery of chocolate to drive home the point that if it takes as many as 516 years 2 months and 17 days (the same amount of time used to develop chocolates) to amend the TRIPS Agreement to bring it in line with the CBD, so be it.

MS. R.V. ANURADHA

If we look back on the last 20 years, on the one hand we might feel that nothing really has materialised despite coalitions among like-minded countries and very concrete submissions while on the other hand, we do have the Nagoya Protocol which has set in place many of the implementation of crucial elements of the CBD. She remarked how we might be frustrated by the repetition of issues at both the WIPO and the WTO, however, this is also a sign of optimism that the issues have remained alive. There have also been numerous examples of erroneous patents granted on TK (like the turmeric patent) which highlight the challenges as well as the fact that the recognition of these issues and keeping them alive, has resulted in some concrete outcomes. This brings us to the question how do we define the common ground; the commonly acknowledged principle among countries is that erroneous patents should not be granted. The differences lie in terms of how we achieve this.

Ms. Anuradha then proceeded to discuss the practicalities of the problems and the challenges, for instance, what were the difficulties which India and other countries faced in the absence of disclosure norms and the absence of any concrete linkages between IP and the obligations that can arise out of the CBD. Ms. Anuradha remarked that these challenges are self-evident- in the absence of disclosure norms in the patent regime (the essence of the proposal underlying Article 29 (bis)), everything else becomes post-grant opposition.

She then highlighted that the post-grant opposition process works completely differently in the EU and the US. In the EU, a patent can be challenged within 9-12 months of the grant of the patent and there are also provisions for documentary evidence, oral hearing and appeal. On the other hand, the US system can be frustratingly obtuse- the challenger is never given an opportunity for an oral hearing and the entire process is a written documentary process. In both the EU and the US, the Indian government had to get documentary evidence for the fact that something like the wound-healing properties of turmeric is a known fact to practically all Indian households. The challenge which arose to India was because of the absence of disclosure of prior art. Ms. Anuradha stated that the challenges to the post-grant opposition (in the absence of disclosure of prior art) are the following:

- a) The process is extremely slow.
- b) Premium is given to documentary evidence.

c) No possibility of oral argumentation in the US.

These made the entire process far too uncertain, unpredictable and quite expensive for the developing countries to contend with. The problem with documentation of TK is that this would be only a minuscule of the range of TK available in all our countries, therefore, it cannot be the only way possible.

The question then is can we compromise on disclosure and look at only other systems which may be bilateral negotiations, contract-based or database related? The answer is no. Therefore, what is the consensus on the way forward? The common ground between EU, Norway, Switzerland and the coalition of developing countries is on the source of origin/country of origin of the TK and the genetic material. What is missing and present in India's proposal is that adequate credence should be given to disclosure and evidence relating to PIC and benefit-sharing.

Can we then look at a common ground with the EU & the others? Can we look at a common proposal to have a wider coalition of support if we innately believe that disclosure of the source of origin/country of origin of the TK and genetic material is a critical ideal to achieve. If that is possible, this approach is something which members can consider on the road to MC level.

Simultaneously, the WIPO process must continue. As has been acknowledged, the WIPO's agenda has been wider than that of the TRIPS Council in terms of the level of protection. At the WIPO, the parallel processes need to continue but we need to call the bluff on the constant emphasis on evidence. The evidence on misappropriation has been documented since the past two decades. The focus at WIPO has to be on a concrete outcome at some point; even though the discussions in the WIPO are helping to keep the issues alive, it is also a drain on the resources.

Ms. Anuradha concluded by saying that at least at the MC level, can there be consensus on the disclosure requirements with respect to source/country of origin of the GR and TK.

DISCUSSION FOLLOWING THE PRESENTATION

The Chair, Mr. Reddy, asked the following question:

The issue of TRIPS-CBD is on the Regular Agenda of the TRIPS Council since 2002, what can be done to re-invigorate the discussions in the TRIPS Council because they are standing agenda questions?

In response to this question, one of the panelists answered:

One of the ways to intensify the discussions is for members to take the floor. He further remarked that members who take the floor are very few in number. If we want to present a united front, more members need to take the floor on this issue. Delegates are too concerned about the political implications of what they are going to say, but at the end of the day this is a technical meeting and this is an opportunity to set out the position of your country. At the end of the day, we need more numbers in terms of countries and it cannot be a few countries taking the floor all the time.

The panelist also stated that there are many modalities behind how the TRIPS Council Agenda is composed. The panelist found it useful that last year, the Chair of the TRIPS Council would have an informal session before the main event (around two weeks before). This gave an opportunity to others to review what their intentions were for the upcoming meetings and also helped to set aside some of the management issues.

The panelist said that there should be more meetings for members to prepare and co-ordinate at the WTO level. Another point raised by the participant was that we can benefit with having more regular contact with our think-tanks.

Another panelist added that the discussion in the TRIPS Council will have its limits and there is need for a higher political engagement, such as initiation of consultations by the DG or meetings at the ambassadorial level.

Another panelist added that some of the members don't have attachment to this issue and don't know how to put it in concept, and therefore, it would be a good idea to have an agenda in the TRIPS Council to point out the cases of misappropriation and the challenges faced by other countries.

It was also felt that the proposal should have something for everyone and countries should see value in engaging in discussions on these issues.

Session 9

BUILDING AWARENESS AND UNDERSTANDING OF THE ISSUE: ROLE OF CIVIL SOCIETY ORGANIZATIONS AND MEDIA

Chair: Prof. Abhijit Das, Head and Professor, Centre for WTO Studies

Speakers:

- (1) Ms. Catherine Saez, Senior Writer at Intellectual Property Watch
- (2) Mr. Manuel Ruiz Muller, Director, Peruvian Environmental Law Society
- (3) Mr. K.M. Gopakumar, Legal Adviser at Third World Network

PROF. ABHIJIT DAS

After introducing the topic, Prof. Das highlighted the importance of building partnerships in garnering success in trade negotiations stating that in IPR-related trade negotiations, a partnership between the governments and trade negotiators, on one hand, and civil society, media and academicians, on the other hand, is important. The crucial role of civil society on the issue of access to medicines was pointed out by Prof. Das, who was optimistic about a similar contribution and partnership on the issues of bio-piracy and TRIPS-CBD linkage.

MS. CATHERINE SAEZ

Ms. Saez shared her in-depth knowledge and over 10 years of experience of working on the developments in the WTO's TRIPS Council and the WIPO. She emphasized the importance of sharing the perspective of civil society and media with trade negotiators, citing that often, the negotiators are unable to tap into a perspective beyond what is presented in the TRIPS Council. Ms. Saez made a presentation on the role and perspective of Intellectual Property Watch (IPW) as a non-profit independent news service reporting on international intellectual property policies and discussed the challenges which civil society and IPW, specifically have faced in the past to bring their perspective to the broader landscape of stakeholders.

After introducing IPW, Ms. Saez mentioned that during the time of the WTO's establishment and the introduction of new IP rules, many developing countries struggled to understand these rules;

which is when and why IPW was established. According to her, IP Watch's reach among the stakeholders *on all sides of the issues* makes it an important organisation. As a reporting news service, IP Watch does not take opinions but only reflects the different positions on IP-related questions, going to all sides, seeking to understand the rationale behind the positions. Due to the cross-cutting nature of IP across public policy issues such as food security and public health, IPW follows IP-related conversations in a number of fora, mainly focusing on WIPO, WTO, WHO, the CBD, the International Treaty for Plant GR for Food and Agriculture (ITPGRFA) and International Union for Protection of New Varieties of Plants (UPOV). She stated that IP Watch seeks to understand the real state of play in international organisations by interacting with as many delegates as possible. She added that the fact that the access to meetings is convenient as IP Watch is a UN accredited reporting service, helps them to carry out their role.

Ms. Saez then spoke about the wide readership of IP Watch spread across the globe, notably North America and Europe. Additionally, IP Watch builds cooperation among fellow civil society actors, the private sector, indigenous people and other staff of international organisations. Two aspects of IP Watch's working include making complicated matters on IP accessible to the readers in a simplified manner, and bringing transparency to a field that has traditionally been dominated by the developed countries. The complex issues of GR (GR) and TK (TK) and the issue of access and benefit-sharing (ABS) in international organisations like WTO, WIPO, etc are studied by IP Watch and reports are prepared to spread awareness on the issues to the readers who do not have a detailed understanding of the same.

Ms. Saez then emphasized the role played by IP Watch in reporting on the CBD/TRIPS/Article 27.3(b) issue since 2005. She mentioned that IP Watch reported on India presenting a paragraph to be included in the Hong Kong Ministerial Declaration linking CBD with the WTO, for a mandatory disclosure of origin in patent applications for GR and associated TK, for PIC and benefit-sharing. IP Watch also reported on the tension around inclusion of language on TRIPS/CBD relationship and on the first inkling of a linkage between the CBD/TRIPS and GIs issue. In addition to the Hong Kong Ministerial, the news service also covered developments related to the CBD since 2006. Ms. Saez pointed out that though the issue of TRIPS/CBD has remained stalled at the TRIPS Council, the

entry into force of the Nagoya Protocol was a ‘game changer’ which touches upon agencies including WTO, WIPO and WHO.

The importance of involving representations from the indigenous groups was emphasized upon by Ms. Saez who stated that such groups maintain that TK is not a species of IP as the indigenous people have complex systems for regulating the circulation of knowledge, which does not find place in the modern IP system (which regards TK as a product of the mind). Ms. Saez presented the change in mood and proactive strategy of developing countries (‘Like-Minded Countries’) on treaty language. On GR and disclosure of origin in patent applications, IP Watch found that only the US, Japan, Canada and South Korea resisted mandatory disclosure while countries like Switzerland, Australia, New Zealand and Norway supported it. However, Ms. Saez observed that the developing countries have softened their demands to be able to advance the discussions.

Talking about the challenges faced in reporting on TRIPS/CBD issues, the transparency of different organizations is of importance. While the plenary sessions of WIPO are available through webcast, she pointed out that the WTO holds most of the sessions are without media access. Ms. Saez noted that since the plenary sessions of WIPO are webcast, the discussions are guarded making it difficult for IP Watch to get access to transparent deliberations. Another challenge which IP Watch faced, according to Ms. Saez was the attempts of intimidation which they have to face in a politically-charged environment. Additionally, the climate of suspected surveillance of communications makes it sometimes difficult for media to get information from various sources. A safer way to communicate with sources, including encrypted emails was mooted by Ms. Saez.

Ms. Saez also raised the issue about influence of the WIPO Lisbon Agreement and of Genetic Sequence Data (GSD) on the TRIPS Agreement. According to her, the 2015 Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographic Indications adopted by WIPO met a lot of resistance from countries like Canada, Australia, South Korea and the US. These countries rely on a trademark system to protect geographical indications versus a *sui generis* system. There is still no clarity on how and if the Lisbon Agreement, once into force, could influence the TRIPS discussions on GIs and consequently, the CBD/TRIPS relationship conversation.

Ms. Saez threw light on the developments in relation to the GSD which is used by most modern laboratories to recreate organisms without the need to access the physical samples of such organisms. Though the GSD conversation has been underway in scientific circles for some time, it is gradually reaching policy and economic circles too. She cited the example of the WHO Pandemic influenza preparedness Framework (PIP Framework) which some countries prefer to be considered as a *special instrument on ABS* under the Nagoya Protocol, and which is under review seeking to address the issue of GSD. Ms. Saez stated that the WHO suggested that the GSD be included in the Framework. At the WIPO, during the IGC discussions on GR, EU has remarked on accessing physical GR materials with Namibia remarking on GSD. These are welcome signs for the things to come in the future. IP Watch has been keeping a keen eye on the developments on GSD and running stories on the same. She left the house with a question of what the increased attention on GSD would mean for the TRIPS Council discussion and that whether this would lead to a modification in the manner in which potential TRIPS amendment on disclosure will be phrased.

In her concluding remarks, Ms. Catherine Saez raised the question of making delegations have a conversation on the issues they do not want to engage in with the civil society and media. She stated that the need of the hour is to search for a plausible bargaining chip for the most resisting countries to enter into real negotiations at the IGC and the WTO. However, the important concerns, according to Ms. Saez, is the lack of IP-related knowledge among individual delegates (who are part of the negotiations) and in WIPO discussions from small developing countries, which renders them in a disadvantageous position. The possibility of addressing the questions on TK and GR in multilateral systems like WIPO and WTO were questioned by Ms. Saez. She also proposed to conduct consultations with private sector stakeholders since they actively lobby with their governments. Since the questions directed towards international organizations have largely remained unanswered, Ms. Saez doubted whether the current format of international conversations is still relevant.

MR. MANUEL RUIZ MULLER

In his introduction, Mr. Muller stated that there exists a very complex set of dimensions, issues and themes that are related to the linkages between the CBD and TRIPs, and that there is no simple

linkage. A number of dimensions open up when we try to find what these linkages are while discussing these issues at all international fora.

Mr. Muller highlighted the role played by NGOs such as RAFI, GRAIN, TWN, etc. in the early 1990s; these NGOs were denouncing patents and had coined the term “bio-piracy”. These ideas were being discussed in the Andean Community Process. In fact, initial ideas regarding the issues of disclosure were suggested by these Civil Society Organizations (CSO). This was a time when there was really no consensus on the role that disclosures could play. In fact, there was very strong opposition to finding the linkage between IP and access to GR regime for the protection of TK. Over time, this was streamlined into the agenda, and gradually became a part of the mainstream. Today, it is one of the core aspects which countries in the South have been fighting for over the last fifteen years. Another instance is the idea of user measures (which we take for granted now) that were almost non-existent in the 1990s. They have now been mainstreamed into international legal instruments such as the Nagoya Protocol.

A decade later, in the early 2000s, these notions were formally recognized and incorporated into the policy and legal frameworks and discussions throughout the world. CSOs had played an important role in placing these issues on the agenda. Mr. Muller also stated that CSOs had played an important role in bringing the attention of these issues to the general public.

Mr. Muller highlighted the critical role played by NGOs in undertaking research and generating papers, reports, documents, etc. over the past couple of years. He explained that in the early 1990s, it was difficult to find even a single document on GR and TK protection. However, now there is a wide range of options in terms of what literature has to offer, and NGOs play an important role in disseminating these resources.

Mr. Muller then discussed the role played by NGOs in being a voice of indigenous peoples and marginalized communities. NGOs take into account the issues affecting these stakeholders. NGOs also play an important role in building capacity to understand many of the aspects which we discuss now. NGOs also enable ICs in many cases, and also collaborate with them to build and strengthen

their capacities to ensure that ICs are informed and are able to effectively participate in many of the discussions at the various fora.

Mr. Muller also brought to attention the role of NGOs in supporting and assisting governments, even in the negotiations of some of these issues. He discussed how his NGO has a close relationship with a number of governmental institutions, and gave instances such as cooperation agreement with the patent offices of certain countries, and enactment of law for protecting TK. NGOs also support the policy processes as such, and help in streamlining many of the policy issues into the debate. In this regard, Mr. Muller also discussed the strategies played by NGOs, such as his, in collaborating with the government. Mr. Muller pointed out how, in recognition of their work in this field, NGOs have received several prizes from international institutions.

Some of the activities which CSOs undertake are also related to what the media and different types of outlets can do in regard to some of these issues (for example, understanding and disseminating what these issues mean). As a result, the community of people that are aware of these issues is substantially broader than what it was ten years ago, and this includes the IC. The media has thus played an important role in creating awareness.

Mr. Muller stated that investigating and collaborating with NGOs is critically important. He emphasized the importance of reaching out to the ICs and finding ways in which some of the messages which are extremely complex can be translated into a language which is understood by certain groups. These groups can then in an informed manner participate in policy and regulatory processes, and the general agendas where some of these aspects are being discussed.

Commenting on the well-informed nature of the participation in the Conference, he highlighted how the discussions were not merely confined to general policy but also extended to the nuances of the linkage between TRIPS and CBD. This shows how certain institutions including the media have, over the past ten-fifteen years, played a role and influenced positively discussions being undertaken in various international fora.

MR. K.M. GOPAKUMAR

Before beginning his presentation, Mr. Gopakumar made three broad observations which he distilled from the previous sessions. First, all negotiations are premised on 'give and take'. In the real world however, not everything is negotiable. As far as the WTO is concerned, developing countries have already given, and they are asking for reconciliation, and are now again asked to pay. If every negotiation is a give and take, you will never finish everything. This kind of notion requires a revisit.

Second, the issue of linkage between TRIPS and CBD is always associated with bio-piracy. But essentially, it is for bringing coherence in the international legal system, and CBD addresses the incoherence created by TRIPS. Though the CBD imposes certain obligations on member states, this obligation may not be fulfilled as patents may be granted without complying with the CBD. This incoherence is furthered by the non-membership of the United States in the CBD, an important player who does not have any existing international legal obligation. The purpose of law is to bring predictability and coherence. Third, the obligations related to PIC, benefit sharing, disclosure, etc are not going to prevent all kinds of bio-piracy. It will only prevent that part of bio-piracy where a patent is being obtained without following CBD obligations. However, bio-piracy in its broader sense is legally broader than that.

After these observations, Mr. Gopakumar then began to talk about the important role played by CSOs. He reiterated Mr. Muller's comment on how CSOs were instrumental in bringing these issues to light in a historical context. CSOs created awareness and were able to put pressure on states to act upon these issues. They were also able to place these issues at the agenda of international fora. Therefore, one of the important roles of CSO has been to keep decades of institutional memory as they are able to narrate the whole story as it has evolved, the state of play of affairs, and where we are.

CSOs have also played an important role in generating evidence of bio-piracy. Much of this evidence is produced by CSOs and the academia, rather than by the government itself. Another continuous role played by CSOs is to inform governments about misappropriation and instigating action. CSOs also bring more evidence on the lack of compliance with the CBD obligations, and also

inform the government and patent office about the granting of illegal patents. Many of these patents have been challenged by CSOs.

At the same time, there is a need to look at role of CSOs in the access to medicines (A2M) context. In the late 90s, the biggest issue discussed at that time was not access to medicines, but the TRIPS-CBD issue. It was the South African crisis and the HIV-AID crisis in Africa which brought to light the A2M issue. At that point of time, the African Group demanded a revision of TRIPS Article 27.3(b) rather than A2M. TRIPS CBD linkage was an important issue, but lost steam over a period of time as (probably) States and also CSOs decided to keep this issue on the backburner. Also, number of CSOs working on this issue continued to do so while the rest decided to move away from it. As far as A2M is concerned, the crisis was more severe and more visible with more resources being available.

In comparison, the issue of GR and TK was less visible and more long-term. However, this is not the case anymore. It is becoming more relevant, and you may have to discuss these issues at the WHO as well as its linkage with health issues. He cited the example of anti-microbial resistance, where the sharing of the pathogens becomes important. These may be raised by other international groups such as the G-8 and the G-20. Therefore, the question of ABS becomes relevant.

Regarding the participation of NGOs on the issue, Mr. Gopakumar stated that it is not just NGOs who are working on GR and TK issues that should be concerned, but also those NGOs who are working on IP issues should become involved, especially those working on A2M issues.

Mr. Gopakumar then flagged the issue of lack of coherence among CSOs on certain issues such as disclosure requirements and patent requirements. At the same time, they are aware of the fact that completely moving away from it may legitimize what is going on. So, there is a tacit understanding among CSOs on this issue and how to move forward.

Mr. Gopakumar pointed out that one fear among CSOs arising in the context of give and take is that during the course of negotiations, these proposals on TRIPS-CBD linkage may be diluted, especially

when it comes to sanctions. CSOs consider sanctions important, and obligations without sanctions tend to be problematic.

Mr. Gopakumar reminded the audience that there were around nine months left for the next Ministerial Conference. While CSOs are flagging the importance of the issue of TRIPS-CBD linkage, Member states are not showing any appetite towards the same. It thus becomes important for the CSOs to make States prioritize the issue, and to energize and galvanize them. Though a mandate exists, there is a need to push for actual negotiations on the mandate. In this context, Mr. Gopakumar also pointed out that there is a risk of the Doha Round Mandate being diluted. The Doha Round agenda was being substituted by discussions on global value chain and ecommerce, and this should be resisted by developing countries. He stressed that, while these new issues would continue to remain on the table, they should not be an excuse to ignore those issues which were recognized as important in 2001, and continue to be important.

DISCUSSION FOLLOWING THE PRESENTATION

On the issue of coherence and predictability in the international legal system, the participants agreed that the developing countries are victims of bio-piracy. It was emphasized that predictable disclosure requirement with clear sanctions, will enable better compliance. A question was also posed on how open delegates at plenary sessions were in their private discussions with CSOs.

A question was raised regarding mainstreaming of issues. The participant wanted to know how these issues could be broadcast to the ordinary citizen, who is not aware of the basic content, and to what extent we can take steps to actually deliver these messages. It was mentioned that this is an area where developing countries lack skills, unlike developed countries that use the media platform well for broadcasting their issues. Regarding this, Prof. Das agreed that there was a need to ensure a better-informed debate through the media.

On the question about openness of delegates in private discussions, the media representative responded by stating that delegates in private do not divulge more than they have done on the official platform. She stated that developed countries' delegates have become more open to

answering questions though they were still guarded in their explanations. Regarding mainstreaming of issues, she highlighted how in light of opposition from the EU to exceptions against copyrights, the community of people with visual disabilities mainstreamed the issue of access, and were able to secure a victory through the Marrakesh Treaty.

Representative of Civil Society responded to the issue of coherence and predictability by stating that if there is predictable ABS system, and if TRIPS is reconciled with CBD, it would increase research and access, and consequently benefit-sharing. He highlighted the importance of sanctions as most producers and markets are located in the North, and big corporations can ignore developing country markets and concerns.

Session 10

BUILDING ON THE DISCUSSIONS IN THE TRIPS COUNCIL-NEED TO FORGE ALLIANCES-COULD PLURILATERAL TREATIES BE THE WAY TO GO? WHAT WOULD BE THE STARTING POINT?

Chair: Prof. Chandni Raina, Centre for WTO Studies

Speakers:

- (1) Mr. Md. Nazrul Islam, Deputy Permanent Representative, Permanent Mission of Bangladesh to the WTO
- (2) Mr. M. G. Buba, Minister, Nigeria Trade Office, Permanent Mission of Nigeria to the WTO
- (3) Ms. R V Anuradha, Partner, Clarus Law Associates
- (4) Ms. Sangeeta Shashikant, Legal Adviser at Third World Network

PROF. CHANDNI RAINA

Prof. Chandni Raina opened the session by recalling the discussions from previous days on the progress made at the TRIPS Council in WTO and in CBD, and the factors that triggered the movement towards a treaty at the WIPO as well. She noted that although there were positive developments at the WTO through coalition-building in the form of W/52 and W/59, there has been no movement since 2011, when negotiations stalled. She welcomed the discussions proceeding at the WIPO under the aegis of the IGC. She said that the question now is how to move forward from here.

Prof. Raina encouraged the discussants to consider the appropriate way forward. She emphasized that the session will be focusing on whether a plurilateral treaty would be a viable option and what could be an appropriate starting point.

MR. MD. NAZRUL ISLAM

Mr. Islam noted that all IP mischief- whether it is infringement of copyrights, patents or bio-piracy- should be treated alike and should have appropriate legal remedies. There is no room for cherry picking amongst them. He also stated upfront that there is consensus that if amendment is being considered, then that should be of the TRIPS Agreement and not the CBD. This is because CBD considers GR, TK and TCEs as public property whereas TRIPS Agreement considers that all IP rights are private rights.

Mr. Islam observed that since we are considering an amendment to the TRIPS Agreement, WTO is the appropriate forum to engage in negotiations on disclosure. The current global patent application and granting system needs amendment. Also, domestic regulations on disclosure requirements are limited by their territorial jurisdiction making the need for a global consensus that much imperative.

Mr. Islam laid out what could be done at the TRIPS Council and once again emphasized the need to push for an amendment to TRIPS Agreement. He reminded the delegates that there have been instances of amendments based on Ministerial instructions- Paragraph 6 being the most recent example. He also brought attention to the present practice of considering TRIPS agenda items 3, 4 and 5 together. These items are dealing with amendment of TRIPS Agreement. The trend has been to take these three issues together and to continue reiterating the position without actually reaching any position on any of them. Members could perhaps consider treating these agenda items separately.

He also noted how for the past few years, developed countries have introduced an extension to the agenda by bringing a new item “IP and innovation” through which they are bringing issues that are actually further strengthening the current unfair and unbalanced IP regime. Mr. Islam suggested that similarly, developing countries should also introduce a new item to the TRIPS Agenda- “IP and misappropriation”. Under this agenda item, we could discuss all the instances of bio-piracy that are being reported globally. He also encouraged side events at the WTO for creating awareness amongst the delegates and general public.

Observing that we have two proposals before us- W/52 and W/59- that could better harmonize the TRIPS and CBD, Mr. Islam pointed out that W/52 enjoys more support than W/59. If there is consensus, we can introduce some elements from W/59 to W/52 and re-introduce the amended version of W/52 to the TRIPS Council. He also mooted introducing W/59 to revive discussions. Admitting that it might sound revolutionary, Mr. Islam suggested introducing a moratorium on Article 27 of the TRIPS Agreement and demanding that unless we have an agreement on disclosure requirements, the moratorium will continue.

Exploring the plurilateral option, Mr Islam agreed that it is indeed a novel idea. The WTO framework has had plurilateral agreements since the Tokyo Rounds, and they currently exist under Annex IV. However, if we agree on a plurilateral agreement we need to choose between an inclusive and exclusive agreement. For a disclosure agreement, an inclusive agreement will be more suitable. An exclusive agreement is applicable only to those members who accede to it. Inclusive agreements, on the other hand, are MFN-based (most-favoured nation clause). While we consider such an option, it is important to first set our ambitions realistically and such an agreement would necessarily contain provisions on special and differential treatment.

Noting that discussions for a disclosure agreement are simultaneously proceeding at various fora, he said there was a need to engage constructively in all forums to develop a constructive and harmonized outcome. WIPO will be an important forum because Parties are discussing an entire agreement on GR at WIPO, whereas there are only discussions for an amendment to the TRIPS Agreement at the WTO. To begin with, at the WIPO, there should be clarity that there will be three different binding agreements. He also pointed out that it is equally important to ensure that the mandate of IGC is extended and that it becomes a Standing Committee. Another proposal being mooted at the WIPO is to establish a database. Mr. Islam opined that databases cannot serve as a principal source for verification because they can never be complete. In cases of bio-piracy where the GR is not in the database, it will be extremely difficult to revoke the patent. At best, database can be a secondary source for verification. Amendment of PCT/PLT is another issue at WIPO. Mr. Islam stated that if we can introduce the disclosure requirement under TRIPS in WTO, the PCT/PLT amendment will naturally follow.

Amongst other measures on the way forward, he underscored the invaluable role played by civil society organizations in contributing to the knowledge base of country delegates and also in building momentum amongst the public outside the WTO. Mr. Islam noted that the level of Director General's involvement on this issue has been very limited, and that there is a need to energize the DG's office on the issue. Lastly, he highlighted the indispensable intervention that needs to be made at the ministerial level to take the issue beyond the finish line and achieve multilateral consensus.

MR. M.G. BUBA

Mr. Buba started his presentation by noting that discussions on disclosure of the source of biological material and associated TK have been going on at the WTO even before the Doha Ministerial Conference. Today, after 20 years of discussions, even after having a specific paragraph in the Doha Mandate and several proposals (W/59 being the most recent), the prospect of conclusion of the negotiations seems far. Consensus has eluded the negotiations where position remains entrenched. He noted that since it is becoming clear that we are unable to move forward in the traditional way of doing things at the WTO, we should start to look at other approaches.

The title of the present session raises the alternate approach of a plurilateral treaty. Plurilateral is neither new nor strange at the WTO as like-minded countries have come together to formulate, influence, or negotiate in the WTO or outside the WTO. He cited the plurilateral approach followed during the Tokyo Rounds. He also highlighted the Anti-Counterfeiting Trade Agreement (ACTA) which was negotiated outside the WTO framework.

Discussing the features of the plurilateral agreement, Mr. Buba reflected how a plurilateral agreement could pave the way for addressing specific issues and areas, and could also prepare members for multilateral rule-making in the future. It also guarantees flexibility in the choice of participants and promises to obviate the decision-making ordeal of the WTO. It offers to respond to changing needs, and signals a reaction to the failures of multilateralism.

Highlighting the limitations of the plurilateral approach, Mr. Buba shed light on the legal constraints. Attaching the Plurilateral agreement to Annex 1C (TRIPS Agreements) would require consensus. Enforceability through DSU will also require the amendment of the DSU. Admitting that there is divergence in the approaches of members, the choice of participating members for the plurilateral

agreement would be critical. Other constraints include the search for critical mass for an agreement, the level of ambition of participants, etc.

Elaborating on what could be a starting point, Mr. Buba put forth various alternative options such as implementing the Nagoya Protocol by the proponents, asking the WTO DG to resume his consultations on the matter, exploring the possibility of revisiting our proposal, and exploring the PCT route with a possibility of inclusion into the TRIPS Agreement.

MS. R.V. ANURADHA

Ms. Anuradha reflected upon the substance of plurilateral agreement if it were adopted. She said that if it followed Patent Cooperation Treaty (PCT) route on the basis of Swiss proposal on disclosure of source, it would remain limited to the disclosure norms. She raised doubts on the potential scope of such disclosure norms – either it could be limited to the disclosure of source and country of origin or it could be wider in scope requiring evidence of PIC and ABS.

She further added that if critical-mass approach within or outside the WTO is considered, its content can be at a more ambitious level than the PCT approach. She at the same time pointed out that the extent of ambition level for such an agreement too remains unclear. She acknowledged that at WIPO, like-minded group text on all three areas- TK (TK), GR (GR) and Cultural Expressions (CE) exist, but she expressed her reservations about it being a sufficient basis for a possible plurilateral treaty.

She remarked that the negotiation of a plurilateral agreement is an interesting idea, but at this stage it is not wise to divert energy towards achieving consensus among like-minded countries. She reasoned that the concerns lie with respect to the patent applicants who mostly come from countries which would not be part of the plurilateral agreement. Therefore, a plurilateral agreement among like-minded group of countries would not serve any purpose.

She observed that the proposals with respect to disclosure norms in FTAs have been fairly limited. The US FTAs with Peru and Columbia have hortatory soft obligations which talk about the importance of TK, but emphasis is on contractual protection (US policy). Therefore, it does not achieve the synergy which disclosure norms would. EU follows a similar approach. It reiterates the

synergy between CBD and IPR regime. EU-Cariforum and EU-Columbia talk about cooperation at multilateral level, but it is within the realm of soft obligations.

Ms. Anuradha highlighted interesting developments on the protocol on traditional medicines(TM) among SAARC countries. The subject matter of the protocol was not patent-linkage or disclosure, but recognition of TM as an area which requires protection along with access to TM, movement of TM practitioners, and recognition of TM regimes of other SAARC nations. A loosely worded version of this appears in China-Australia FTA. It talks about recognition of traditional Chinese medicines and the movement of traditional Chinese medicinal practitioners to Australia and their recognition as service providers.

She concluded with the statement that TM issues can be considered by countries whose concerns are not limited to TRIPS-CBD linkage, but more to the broad area of recognition of TM.

MS. SANGEETA SHASHIKANT

Ms. Shashikant highlighted various aspects which require consideration while deciding the way forward for TRIPS-CBD linkage. These aspects are as follows:

1. Cases of Bio-piracy- She emphasized the importance of continuing the exposure of bio-piracy cases. She said that the exposure of bio-piracy cases is not limited to evidence collection, but is significant in ensuring continued visibility of the issue and in galvanizing political commitment. She pointed out that many CSOs including Third World Network (TWN) have been continuously working in this area, and that TWN recently found a patent application in India for Indonesian rice gene. She observed that dissemination of knowledge about these bio-piracy cases may be lacking and requires more work.
2. Initiatives like TKDL- She acknowledged the importance of TK database as a complementary tool for preventing bio-piracy. However, she expressed concern that access to the database information may lead to facilitation of misappropriation. Moreover, not every country has pre-grant opposition system, and countries may lack capacity to carry out such process. Therefore, TKDL is difficult to replicate for other countries.
3. South-South Exchange of Experience: Ms. Shashikant noted that many countries have disclosure requirements in their national legislations. Exchange of experience regarding

enforcement and compliance of disclosure requirements and bio-piracy prevention can lead more countries to adopt disclosure norms at a national level. She gave the example of Netherlands' plant variety protection law which has included disclosure requirement.

4. Free Trade Agreements (FTAs): Ms. Shashikant remarked that with respect to FTAs, there is no free lunch. She stated that in case of North-South FTAs, countries should be careful that they are not giving up a lot of their interests in return for mere best endeavour provisions. She did not consider such FTAs the best strategy to follow.
5. Visibility of Bio-piracy Issue: She reiterated the importance of raising visibility of bio-piracy and patent linkage issue at the WTO. She added that increased focus on patent-linkage at WTO would also have a positive impact on WIPO, CBD process and national level legislations.
6. WIPO: She shared her apprehension regarding the Permanent Committee at WIPO becoming mere talking shop. She opined that the current system of setting an agenda every two years keeps the issue alive, and setting up a permanent committee may be counter-productive. She also said that WIPO should not be limited to patents. It should also cover plant variety protection (PVP). International Union for the Protection of New varieties of Plants (UPOV) deals with PVP, but it is has taken a clear position to not include disclosure requirements. Moreover, UPOV system is underdeveloped and not suitable for agricultural conditions of the developing countries.
7. Inter-forum Interaction: Ms. Shashikant also emphasized the importance of the interaction between WTO, WIPO and CBD-Nagoya Protocol on the issue of bio-piracy and disclosure requirement. She said that this will lead to a better understanding of the linkage between various forums.
8. Nagoya Protocol: She opined that the Nagoya Protocol has further scope for progress, and that its issues can be resolved through COP MOP decisions.
9. Plurilateral Negotiations: She noted that it is a good idea to bring together like-minded countries, particularly for compliance and enforcement of disclosure requirements. It can arise out of South-South experience exchange. However, she felt that even though a

plurilateral agreement can bring legal certainty for companies and induce developed countries to follow suit, at this stage it is premature.

DISCUSSION FOLLOWING THE PRESENTATION

One of the participants raised an issue regarding the compatibility of disclosure requirements with the TRIPS provisions. Article 29 of TRIPS has a 'shall' obligation and 'may' provision. She recalled the arguments given by Japan about inclusion of more requirements under Article 29 arbitrarily setting the standard very high for the patent applicants, and in turn violating Article 62 of TRIPS which mandates reasonable procedures. It was stated that although no dispute has been raised on the issue, but it requires reflection, particularly in light of a plurilateral agreement. Panelists observed that disclosure requirements are a result of the interface between different international obligations, it is necessary to fulfil CBD obligations, and they can therefore be justified under TRIPS. Moreover, disclosure requirements are not per se unreasonable especially in light of the grant of monopoly rights on inequitable grounds.

Others wanted to know the reasons for the loss of momentum on the TRIPS-CBD linkage issue. It was suggested that already prepared submissions and formed coalitions on the issue should be revived at the coming Ministerial at Buenos Aires. The need for submission of a non-paper at WTO on the issue was also reiterated.

Questions were raised on whether there is reduction in the bargaining power of the developing countries or if the collective will to resist certain issues has gone down. It was stated that a multilateral agreement may bring down the ambition level. A plurilateral agreement outside WTO, on the other hand, will be more suited to the ambition level of developing countries and can drive negotiation for a multilateral agreement.

It was observed that post 2005, momentum on the TRIPS CBD linkage issue died down even in the academic field. She highlighted the need of publishing literature on the issue to keep it alive and visible. She pointed out that e-commerce issues have gathered steam because of similar efforts, and that it can be a learning lesson for developing countries.

It was also stated that the loss of momentum was a result of the lack of leadership on the issue, and that countries should look into ways to translate W/52 modalities into an agreement text. The significance of exposing bio-piracy cases to increase awareness of TRIPS-CBD linkage issue within and outside WTO was also reiterated. He added that civil society and diplomats should take lead on the issue outside and within WTO, respectively. Ms. Shashikant too emphasized the need for a stronger political will to make progress on the issue.

A delegate felt that disclosure requirements need a pragmatic discussion. According to him, many delegations oppose these requirements because they consider its implementation impractical and therefore, discussions on practical functional aspects are necessary to bridge the gap. He further stated that theoretical discussions on TRIPS-CBD linkage have taken focus away from the implementation of already existing measures under CBD and Nagoya protocol. Ms. Shashikant replied that new issues and technological development must be taken into account to develop relevant disciplines. Dr. Kilic observed that arguments against TRIPS CBD linkage are same as the arguments against disclosure requirements with respect to pharmaceuticals and data exclusivity. Therefore, there is a need to show usefulness of the disclosure norms.

Prof. Chandni Raina in conclusion summarized the discussions into the following points:

1. Bio-piracy cases should be continuously exposed as a parallel process to keep the issue visible, and to build political momentum. Along with this, instances of benefit sharing and their impact should be recorded.
2. Subsequent to the W/52 proposal on disclosure (2008) and W/59 proposal (2011), Nagoya protocol has come into effect and its provisions are being implemented by various countries. In light of this, parties should re-look at W/52 proposal and re-initiate discussions on W/59.