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The IP Negotiations Monitor summarizes the latest developments in multilateral and regional fora where intellectual property negotiations are taking place, and informs on upcoming meetings and events.

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WORLD TRADE ORGANIZATION (WTO)

TRIPS Council

The meeting of the WTO TRIPS Council took place on 15-16 October in Geneva, Switzerland. The session was chaired by H.E. Ambassador Abdolazeez Al-Otaibi from the Kingdom of Saudi Arabia.

The discussions were focused on two key issues: (i) Non-violation and Situation Complaints[1]; (ii) LDC's extension on Pharmaceutical products[2].

The TRIPS Council proposed a draft ministerial decision for a further extension of the moratorium on the application of non-violation and situation complaints to disputes arising under the TRIPS Agreement, until the Eleventh Ministerial Conference in 2017. A number of members emphasized that discussions on a permanent solution to the question whether non-violation cases should apply to intellectual property or not should begin immediately after the Tenth Ministerial Conference in Nairobi in December 2015.

The TRIPS Council also agreed to extend until January 2033 the transition period during which provisions of the TRIPS agreement on patent and test data protection for pharmaceutical products shall not apply to the least developed countries (LDCs). It means that LDCs can choose not to protect pharmaceutical patents and clinical trial data till 2033. The TRIPS Council also recommended the General Council to extend an existing waiver for LDCs concerning exclusive marketing rights for pharmaceuticals, and to agree to a new waiver for LDCs regarding measures for receiving patent applications in this field.

WTO Ministerial Conference: Tenth Session

The Tenth WTO Ministerial Conference was held from 15 to 19 December 2015 in Nairobi, Kenya. The key decision related to intellectual property was on the TRIPS Non-Violation and Situation Complaints wherein the Ministerial Conference decided as follows:

"We take note of the work done by the Council for Trade-Related Aspects of Intellectual Property Rights pursuant to our Decision of 7 December 2013 on "TRIPS Non-Violation and Situation Complaints" (WT/L/906), and direct it to continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to our next Session, which we have decided to hold in 2017. It is agreed that, in the meantime, Members will not initiate such complaints under the TRIPS Agreement."

WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)

Assemblies of the Member States of WIPO: Fifty-Fifth Series of Meetings

The Assemblies of the Member States of WIPO and other bodies of the Member States of WIPO held its fifty fifth series of meetings from 5 -14 October 2015 in Geneva, Switzerland.[3] H.E. Ambassador Gabriel Duque from Colombia was elected as the Chair of the General Assembly and H.E. Ambassador Francois Xavier Ngarambe from Rwanda was elected as the Chair of the WIPO Coordination Committee.

Relations with other Organizations

The Coordination Committee approved a Memorandum of Understanding (MoU) between WIPO and the Center for Book Development in Latin America and the Caribbean (CERLALC) and a MoU between WIPO and the United Nations Economic and Social Commission for Asia and the Pacific (ESCAP) (document WO/CC/71/1, Annexes I and II).

Oversight Bodies

The WIPO General Assembly and Assemblies of the Member States of WIPO and of the Unions took note of the Report by the WIPO Independent Advisory Oversight Committee (IAOC) (document WO/GA/47/2), Report by the External Auditor (document A/55/9) as well as the Annual Report by the Director of the Internal Oversight Division (IOD) (WO/GA/47/4).

Program and Budget related decisions

The Assemblies of the Member States of WIPO and of the Unions took note of the following decisions taken by the Program and Budget Committee:

- "List of Decisions" taken by the Program and Budget Committee (document A/55/4) and of the updated "Status of the

[1] WTO, "Draft decision agreed on "non-violation" cases in intellectual property" https://www.wto.org/english/news_e/news15_e/trip_ss_23nov15_e.htm.

[2] WTO, "WTO members agree to extend drug patent exemption for poorest members" https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm.

[3] WIPO Assemblies, 'List of Decisions' Fifty-Fifth Series, (22 October 2015) http://www.wipo.int/edocs/mdocs/govbody/en/a_55/a_55_inf_11.pdf.

Payment of Contributions as at September 1, 2015". (document A/55/8)

- The Progress Report on the New Construction Project and New Conference Hall Project (document A/55/11), including the fact that discussions were ongoing with remaining three companies and three firms of specialists on their final accounts.
- Efforts by the Secretariat to minimize the potential additional funding requirement for the completion and closure of all accounts related to the New Conference Hall Project;

The Assemblies of the Member States of WIPO and of the Unions approved the following recommendations by the Program and Budget Committee:

- Recommendations by the PBC (document A/55/4).
- Approved the potential additional expenses related to the completion and closure of the New Conference Hall Project in excess of the 75.2 million Swiss Francs approved budget for that project to a maximum of 3.5 million Swiss Francs, be absorbed from the budget in the approved 2014/15 Program and Budget.

WIPO External Offices

The WIPO General Assembly decided to adopt the Guiding Principle on the establishment of new External Offices (EO). It further recognized WIPO's limited capacity to open new EOs and agreed to open not more than 3 EOs per biennium for the biennia 2016-17 and 2018-19, subject to the approval by WIPO GA. Priority is to be given to Africa.

Work of the WIPO Standing Committees and related bodies

Copyright and Related Rights

The WIPO General Assembly took note of the information contained in document WIPO/GA/47/5 related to Report on the Standing Committee on Copyright and Related Rights (SCCR). It further decided to direct the (SCCR) to continue its work regarding the issues reported in the document WIPO/GA/47/5.

Law of Patents

The WIPO General Assembly took note of the "Report on the Standing Committee on the Law of Patents" (document WO/GA/47/6).

Trademarks, Industrial Designs and Geographical Indications

The WIPO General Assembly took note of the "Report on the Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications" (document WO/GA/47/7). It also directed the SCT to examine different systems for protection of GIs within its current mandate covering all aspects.

The WIPO General Assembly agreed that the text of the basic proposal for the Design Law Treaty (DLT) should be finalized by the SCT at its thirty-fourth and thirty-fifth sessions and also agreed to convene a diplomatic conference for the adoption of a DLT at the end of the first half of 2017, only if the discussions on technical assistance and disclosure have been completed during the thirty-fourth and thirty-fifth sessions of the SCT.

Development and Intellectual Property

The WIPO General Assembly took note of the "Report on the Committee on Development and Intellectual Property and Review of the Implementation of the Development Agenda Recommendations" (document WO/GA/47/9). With respect to the document WO/GA/471/11 entitled "Decision on CDIP Related Matters", the decision on the CDIP related matters adopted at the Forty-Third Session of the WIPO General Assembly (document CDIP/12/5) and to report back and make recommendations on the two matters to the WIPO General Assembly 2016.

Genetic Resources, Traditional Knowledge and Folklore

The WIPO General Assembly agreed to revise the mandate of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) as follows:

- The Committee will continue to expedite its work with a focus on narrowing existing gaps with open and full engagement, including text based negotiations, with an objective of reaching an agreement on an international legal instrument (s), relating to intellectual property which will ensure the balanced and effective protection of genetic resources, traditional knowledge (TK) and traditional cultural expressions (TCEs) during the next biennium 2016/2017.
- The Committee's work in the 2016/2017 biennium will build on the existing work carried out by the Committee with a primary focus on reaching a common understanding on core issues, including definition of misappropriation, beneficiaries, subject matter, objectives, and what TK/TCEs

subject matter is entitled to a protection at an international level, including consideration of exceptions and limitations and the relationship with the public domain.

- The Committee will follow a clearly defined work program based on sound working methods for the 2016/2017 biennium. This work program will make provision for 6 sessions of the Committee in 2016/2017, including thematic cross cutting and stocktaking sessions.
- The Committee will use all WIPO working documents, including WIPO/GRTKF/IC/28/4, WIPO/GRTKF/IC/28/5 and WIPO/GRTKF/IC/28/6, as well as any other contributions of member states, using an evidence-based approach, including studies and examples of national experiences, including domestic legislation and examples of protectable subject matter and subject matter that is not intended to be protected; and outputs of any expert panel(s) established by the Committee and IGC-related seminars and workshops conducted under Program 4. However, examples, studies, seminars or workshops are not to delay progress or establish any preconditions for the negotiations.
- Taking note of the utility served by the 2015 WIPO seminars on IGC-related subjects and organize inter-sessional seminars and workshops to build regional and cross-regional knowledge and consensus on issues related to IP and GRs, TK and TCEs with a focus on unresolved issues.
- In 2016, the Committee is requested to provide a factual report to the General Assembly on its work up to that time and submit to the General Assembly 2017, the results of its work on an international legal instrument(s) relating to intellectual property which will ensure the balanced and effective protection of GRs, TK and TCEs. The General Assembly in 2017 will take note of the progress made and decide on whether to convene a diplomatic conference or continue negotiations.
- The Committee may also consider the conversion of the Committee into a Standing Committee and, if agreed, make a recommendation in this regard to the General Assembly in 2016 or 2017.
- The General Assembly requests the International Bureau to continue to assist the Committee by providing Member States with necessary expertise and funding, in the most efficient manner, of the participation of experts from developing countries and LDCs, taking into account the usual formula for the IGC.
- The six sessions of IGC would take place in February/March 2016, May/June 2016, September 2016, November/December 2016, and March/April 2017, June/July 2017 and September 2017.

WIPO Standards

The WIPO General Assembly took note of the "Matters concerning the Committee on WIPO Standards" (document WO/GA/47/13).

PCT System

The Assembly of the PCT Union took note of the Summary by the Chair of the eighth session of the PCT Working Group contained in the document PCT/WG/8/25 and approved the recommendation concerning the further work of the PCT Working Group set out in paragraph 5 of document PCT/A/47/1.

The Assembly took note of the proposed modifications of the Directives of the Assembly relating to the Establishment of Equivalent Amount of Certain Fees. The Assembly appointed the Visegrad Patent Institute as an International Search Authority and an International Preliminary Examination Authority with effect from the entry into force of the Agreement until December 31, 2017. The Assembly also approved the amendments to the Agreement between the State Intellectual Property Service of Ukraine and the International Bureau. (PCT/A/47/7).

The Assembly considered document PCT/A/47/8 with regard to a Proposal by the United States of America to the Patent Cooperation Treaty Assembly in relation to the matters concerning the Lisbon Union but did not reach consensus.

The Madrid System

The Assembly of the Madrid Union took note of the Final Report on the Information Technology Modernization Program of the Madrid International Registration System. It also took note of the "Progress Report on the Madrid System Good and Services Database" and requested the International Bureau to submit to the Assembly in 2016, a new progress report on the Madrid System Goods and Services Database, including the use of remaining project funds. The Assembly adopted the proposed amendments to the Common Regulations under the Madrid Agreement concerning the International Registration of Marks and Protocol relating to the agreement. The Assembly did not reach any consensus on a proposal by the United States of America matters concerning the matters related to Madrid and Lisbon Unions. (MM/A/49/4).

The Hague System

The Hague Union Assembly took note of the Final Report on the Information Technology Modernization Program of the Hague International Registration System. (HA/35/1)

The Lisbon System

The Assembly of the Lisbon Union took note of the Outcome of the Diplomatic Conference for the adoption of a new act of the Lisbon Agreement for the protection of Appellations of Origin and their International Registration (LI/A/32/1). It also approved the establishment of a Working Group for the Preparation of Common Regulations under the Lisbon Agreement and the Geneva Act of the Lisbon Agreement and designated Arabic, Chinese and Russian as languages in which official texts of the Lisbon Agreement and the Regulations had to be established.

Committee on Development and Intellectual Property (CDIP): Sixteenth Session

The Committee on Development and Intellectual Property (CDIP) held its sixteenth session in Geneva from 9 to 13 November 2015[4]. The session was chaired by H.E. Ambassador Alberto Pedro d'Alotto of Argentina.

In relation to Progress Reports (CDIP/16/2), the Committee decided to extend the "Pilot Project on Intellectual Property (IP) and Design Management for Business Development in Developing and Least Developed Countries (LDCs)" for a duration of six months. They decided to consider revised versions of two new projects at the next session of Committee in the Spring 2016.

In the context of the Evaluation Report on the project on IP and technology transfer (CDIP717), the CDIP requested the Secretariat to map WIPO's existing activities on transfer of technology for consideration at the next session. Member States are invited to submit proposals after the consideration of the mapping document for discussion at the eighteenth session of the Committee.

In relation to the update of the Database on Flexibilities, the Committee requested to propose at its next session, a mechanism that would allow a periodic updating of the database taking into consideration the comments made by the Member States.

On the subject of the role of WIPO in the post-2015 United Nations Development Agenda, the WIPO Secretariat is expected to prepare a follow up document in addition to the one presented at this session of the CDIP at its 17th or 18th session. (CDIP/16/8)

The CDIP also took note of the documents "Guide on Trademark Licensing" (CDP/16/INF/3) entitled "Guide on the Strategic Management of Open Innovation Networks" and "Guide on Intellectual Property and Commercialization. The Secretariat was tasked to consider organizing seminars to facilitate the understanding and use of the guides and their translation into other UN languages.

The Committee decided to continue its discussions on a proposal on Use of Information in the Public Domain for Economic Development at the next session (CDIP/16/4).

The CDIP decided to continue discussions on a proposed project on cooperation on IP rights education and professional training with judicial training institutes in developing and LDCs at the next session (CDIP/16/7).

At the next session of CDIP, discussions will also continue on the issue of the implementation of recommendations included in an external review of WIPO technical assistance in the area of cooperation for development.

The next CDIP will also continue discussions on the coordination mechanism of the WIPO Development Agenda through which WIPO committees report on their development-related activities. Two of the Committees including the WIPO Program and Budget, and the Committee on WIPO Standards are not currently abiding by the coordination mechanism.

In relation its future work, the CDIP agreed upon the following issues:

- The WIPO Director General shall report on the implementation of the Development Agenda.
- An evaluation report will be produced for the project on strengthening and development of the audiovisual sector in Burkina Faso and certain African countries.
- A document on the mapping of South-South activities including technology transfer should be developed.

[4] WIPO Committee on the Development of Intellectual Property, 'Summary by the Chair', (13 November 2015) http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_16/cdip_16_summary.pdf.

Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications (SCT): Thirty Fourth Session

The Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications (SCT)[5] held its thirty-fourth session in Geneva from 16 to 18 November 2015. The session was chaired by Mr. Adil El Maliki from Morocco.

The key items on the agenda of the SCT were: (i) Industrial Designs (ii) Trademarks and (iii) Geographical Indications.

In relation to the Agenda item on Industrial Designs, Nigeria, on behalf of the African Group, presented a new proposal for Article 3(1) (ix) in the draft Design Law Treaty (DLT) on the disclosure of the origin or source of traditional cultural expressions, traditional knowledge or biological or genetic resources utilized in the industrial design, as a non-mandatory part of the application process under the Design Law Treaty.

The Chair also presented text for a new Article 1*bis* on the General Principles on the lines of Substantive Patent Law Treaty and the Marrakech Treaty respectively. Some delegations supported the proposed sub-item (ix) in Article 3(1) (a) and some delegations indicated that they were not supportive of either Article 1*bis* or the proposed item (ix) of Article 3(1)(a).

The Chair concluded that both proposals would be included between square brackets in a revised version document SCT/33/2 for the consideration of the thirty-fifth session of the SCT.

In relation to the Agenda Item on Trademarks, the SCT adopted a Revised Reference Document on the Protection of Country Names Against Registration and Use as Trademarks (SCT 34/2 Prov.2). The Chair further requested the Secretariat to prepare a new document based on document SCT/34/2 on the protection of country names, identifying different practices and approaches as well as existing areas of convergence under different national systems respectively.

The SCT considered document SCT/34/3 regarding the Trademark related aspects of the Domain Name System and the Secretariat was requested to keep member States informed of the future developments in the Domain Name System.

The Agenda items on Geographical Indications will remain open for discussion at the next session of the SCT.

Standing Committee on the Law of Patents: Twenty Third Session

The Standing Committee on the Law of Patents[6] (SCP) held its twenty third session in Geneva from 30 November to 4 December 2015. The session was chaired by Mrs. Bucura Ionescu from Romania.

The key items on the agenda of SCP were: (i) Exceptions and Limitations to Patent Rights (ii) Quality of Patents, including Opposition Systems (iii) Patents and Health (iv) Confidentiality of Communications between Clients and their Patent Advisors (v) Transfer of Technology.
In relation to the agenda item on Exceptions and Limitations to Patent Rights (SCP/14/7, SCP/19/6, SCP/23/3), the delegations addressed development issues and shared their experiences by presenting the case studies on the effectiveness of exceptions and limitations.

In relation to the agenda item on Quality of Patents, including Opposition Systems (SCP/17/7,8 and 10, SCP/18/9, SCP/19/4, SCP/20/11 Rev. and SCP/23/4), the United States of America introduced a proposal for a study on work sharing. There was also a sharing session on experiences of experts from different regions on inventive step assessment in examination, opposition and revocation procedures.

Under the agenda item on Patents and Health (SCP/16/7 and 7 Corr., SCP/17/11 and SCP/21/9), the Committee continued discussion on the feasibility study on disclosure of International Nonproprietary Names (INN) in patent applications and/or patents. A seminar was held to discuss the relationship between patent systems and challenges related to availability of medicines in developing countries and least developed countries (LDCs) and the ways to promote innovation and technology transfer to facilitate access to generic and patented medicines in developing countries as well as LDCs.

Under the agenda item on Confidentiality of Communications between Clients and Patent Advisors, a sharing session concerning confidentiality protection applied to different types of patent professionals and to national ad foreign patent advisors was held. The Committee also continued discussion on the confidentiality of

[5] WIPO Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications: Thirty Fourth Session, 'Summary by the Chair' (18 November 2015) http://www.wipo.int/edocs/mdocs/sct/en/sct_34/sct_34_7.pdf.

[6] WIPO Standing Committee on the Law of Patents: Twenty Third Session, 'Summary by the Chair' (4 December 2015) http://www.wipo.int/edocs/mdocs/scp/en/scp_23/scp_23_5.pdf.

communications between clients and their patent advisors.

Under the agenda item on Transfer of Technology (SCP/22/4), the Committee discussed the issues relating to transfer of technology in relation to sufficiency of disclosure. The delegations suggested that activities be carried out by the Committee with respect to the transfer of technology.

Brazil submitted a proposal on behalf of the Group of Latin American and the Caribbean (GRULAC) for a revision of the WIPO Model Patent Law. The discussions would be continued on the proposal at the next session of the SCP and the interested delegations are invited to make relevant contributions.

The SCP could not reach an agreement on future work. The list of issues will remain open and will be discussed at the twenty fourth session of the SCP. Member States may submit proposals on the work of the Committee prior to its next session.

Advisory Committee on Enforcement (ACE): Tenth Session

The Advisory Committee on Enforcement[7] (ACE) held its tenth session in Geneva from 23 to 25 November 2015. The session was chaired by Ms. Amanda Lotheringen from South Africa.

The Chair encouraged the member States to engage in dialogues and share their national experiences including challenges and ways and means to enhance their national capacities for an effective enforcement mechanism.

The ACE agreed to a Future Work for the Committee (WIPO/ACE/10/3/REV). The elements are the following:

1. Exchange of information on national experiences on awareness building activities and strategic campaigns as a means for building respect for IP among general public, especially the youth, in accordance with Member States' educational or any other priorities.
2. Exchange of information on national experiences relating to institutional arrangements concerning IP enforcement policies and regimes, including mechanism to resolve IP disputes in a balanced and effective manner.
3. Exchange of information on national experiences in respect of WIPO's legislative assistance, with a focus of drafting national laws of enforcement that take into account the flexibilities, the level of development, the difference in legal tradition and the possible abuse of enforcement procedures bearing in mind the broader societal interest and in accordance with member state priorities.
4. Exchange of success stories on capacity building and support from WIPO for training activities at national and Regional Levels for Agencies and National Officials in line with relevant Development Agenda Recommendations and the ACE Mandate.

Standing Committee on Copyright and Related Rights (SCCR): Thirty First Session

The Standing Committee on Copyright and Related Rights[8] held its thirty first session from 7 to 11 December in Geneva.

The key issues on the agenda of the SCCR were: (i) Protection of broadcasting organizations (ii) Limitations and exceptions for libraries and archives (iii) Limitations and exceptions for educational and research institutions and for persons with other disabilities.

Under the agenda item on protection of broadcasting organizations, documents (WIPO/SCCR/27/2 Rev., WIPO/SCCR/27/6, WIPO/SCCR/30/5 and WIPO/SCCR/31/3) were taken into consideration. The document WIPO/SCCR/31/3 which was prepared by the Chair entitled consolidated text on definitions, object of protection and rights to be granted, was welcomed by the Committee. The Committee decided to continue the discussion on the current document and the revised document that will be prepared by the Chair for the next session of the SCCR. The Members of the Committee were asked to submit specific textual proposals for the consideration of the Chair at the next session.

Under the agenda item on Limitations and Exceptions for Libraries and Archives, documents (WIPO/SCCR/26/3, WIPO/SCCR/26/8, WIPO/SCCR/29/3, WIPO/SCCR/30/2 and WIPO/SCCR/30/3) were considered. The Committee welcomed the presentation on the copyright limitations and exceptions for museums contained in document WIPO/SCCR/30/2. The discussion progressed in light of a chart introduced by the Chair on exceptions and

[7] WIPO Advisory Committee on Enforcement: Tenth Session, 'Summary by the Chair' (25 November 2015) http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ace_10/wipo_ace_10_26_prov.pdf.

[8] Standing Committee on Copyright and Related Rights (SCCR): Thirty First Session ', Summary by Chair', (11 December 2015) http://www.wipo.int/edocs/mdocs/copyright/en/sccr_30/summary_by_chair.pdf.

limitations for libraries and archives. The item will be maintained on the agenda of the thirty second session of the SCCR.

Under the agenda item on Limitations and Exceptions for Educational and Research Institutions and for persons with other disabilities, documents (WIPO/SCCR/26/4 and WIPO/SCCR/27/8) were considered. The Secretariat informed the Committee about the progress made in response to the requests made at the thirtieth session of SCCR to update various studies on limitations and exceptions for educational teaching and research institutions published for the nineteenth session of the SCCR in 2009 and aimed to cover all the member States of WIPO as well as prepare a scoping study on limitations and exceptions for persons other than persons with print disabilities.

The update study has been commissioned and is expected to be presented at the thirty second session of the SCCR. Furthermore, the scoping study will be commissioned in early 2016 and is expected to be present at the thirty third session of the SCCR. The Committee also held discussions on the topic of limitations and exceptions for educational, teaching and research institutions and their relationship with the fundamental role of education in the society. Some delegations requested the preparation of a chart to facilitate an in depth discussion of the agenda while others asked for more time to consider the suggestion. Therefore, this agenda item shall be maintained on the next session of the SCCR.

In relation to the other matters, documents WIPO/SCCR/31/4 and WIPO/SCCR/31/5 were considered. Brazil put forth a proposal on copyright related to the digital environment (WIPO/SCCR/31/4). While there were initial positive comments to the proposal from various countries, the Committee agreed that the discussion will be continued at the next session of the committee.

Senegal and Congo submitted a proposal to include the resale right in the agenda on future work by the SCCR.

The Chair presented a proposal to hold an extraordinary session of the committee on protection of broadcasting organizations and to hold regional meetings on the subject of limitations and exceptions for libraries and archives. This proposal was supported by GRULAC, Asia and Africa but rejected by Group B. Asia proposed to include education and research institutions as well. The Chair's proposal will again be considered at the next session of the Committee.

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS (UPOV)

UPOV Council, Consultative Committee and the Administrative and Legal Committee

The UPOV Council, the Consultative Committee (CC), and the Administrative and Legal Committee (CAJ) held their sessions from 26 to 29 October 2015 in Geneva, Switzerland. The key issues which were discussed were:

1. Industry's proposal to establish a centralized and harmonized system for the administration and examination of plant breeder applications known as the "International System of Cooperation" (ISC).

2. UPOV's policy on documents.

3. Draft Program and Budget for the 2016-2017 Biennium.

4. Interrelations with the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), especially Article 9 on Farmers' Rights.

5. Examination of conformity of Iran's legislation on Plant Variety Protection with the 1991 Act of UPOV, and various "Explanatory Notes" intended to provide guidance with regard to implementation of the 1991 Act.

Consultative Committee and Council[9]

Proposal concerning an "International System of Cooperation" (ISC)

ISC is an initiative begun by the International Seed Federation (ISF), the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Plants (CIOPORA) and CropLife International (CLI). This initiative is aimed at establishing a harmonized mechanism for the filing and examination of applications for plant breeders' rights (PBRs), with standardized requirements and forms which would then be assessed for compliance with formal requirements and novelty by selected preliminary examining office(s) as well as centralized testing of DUS (distinctness, uniformity and stability).

After its first introduction, a number of UPOV members have questioned this proposal in particular the need for such a harmonized mechanism and its implications for national and

[9] See: UPOV documents, http://www.upov.int/meetings/en/details.jsp?meeting_id=26467

regional plant variety offices. To further the discussion on this agenda item, Secretariat prepared information (CC/90/10) about the need for ISC which was considered inadequate by the Member states to justify the embarkation on a harmonization initiative in UPOV by the Member States. The Member States also mentioned the existence of PLUTO and GENIE databases to expedite the work and promote cooperation with respect to DUS testing instead of launching the ISC system.

The Member States also raised issues in relation to average cost of production, different levels of development on regional system, the legal options for the creation of the system, and whether the establishment should be through a contract or other alternatives such as the Patent Cooperation Treaty or Madrid-like agreement. The members further questioned if the proposal would benefit all of the UPOV memberships and therefore proposed to discuss the matter further to deepen the understanding about the initiative.

Thus the Consultative Committee concluded with the following decision point, which was endorsed by the UPOV Council:

"The Consultative Committee agreed that more information, including statistical information, and a legal analysis was needed with regard to a possible ISC and agreed to request the Office of the Union to prepare a document containing a draft mandate and terms of reference for a possible working group (ISC-WG) to explore the issues concerning a possible international system of cooperation (ISC), as presented in the document of the eighty-ninth session of the Consultative Committee and additional issues raised by members of the Union, to be considered by the Consultative Committee at its ninety-first session, to be held in Geneva in March 2016. That document would also present the additional issues provided in writing by members of the Union".

UPOV documents and Publication of Information

also considered its policy on documents including communications by observers.

The Consultative Committee "endorsed the current practice that statements made by members or observers at sessions of UPOV bodies would not be reproduced in the reports on decisions, reports on conclusions, or reports on UPOV bodies, unless otherwise agreed by the UPOV body concerned, except where a member of the Union requested its statement to be included in the report, and statements made by States and organizations in relation to the examination of laws and on becoming UPOV members."(para 35 of C/49/16).

The Consultative Committee also "agreed that, in general, in cases where the Office of the Union received written comments in relation to a matter to be considered by a UPOV body, those comments would, if so requested, be circulated to the UPOV body concerned; however, for example in the case of documents that were to be considered by correspondence, the Consultative Committee agreed that the UPOV body concerned may, on an ad hoc basis, agree to publish written comments on the webpage of the UPOV body concerned." (paragraph 36 of document C/49/16).

Examination of the conformity of the "Act of Plant Varieties Registration, Control and Certification of Seeds and Plant Materials of 2003" of the Islamic Republic of Iran with the 1991 Act of the UPOV Convention (C(Extr.)/32/8)

The conformity of Iran's legislation on plant variety protection with the 1991 Act was discussed by the Consultative Committee based on UPOV Secretariat's analysis of Iran's legislation. The Committee recommended Iran to incorporate the additional provisions and amendments in the "Act of Plant Varieties Registration, Control And Certification of Seeds And Plant Materials of 2003", as provided in document C(Extr.)/32/8 and to resubmit the draft legislation for further examination in conformity with the 1991 Act. UPOV Secretariat recommended that provisions of Article 15 of the 1991 Act be incorporated.

This would have the effect of narrowing the scope of exceptions currently provided in Iran's by-law on PVP.

Adoption of Explanatory Notes and other Information Materials

A series of revisions of Explanatory Notes were adopted:

- Explanatory Notes on Cancellation of the Breeder's Right under the UPOV Convention
- (Revision)
- Explanatory Notes on the Nullity of the Breeder's Right under the UPOV Convention
- (Revision)
- Explanatory Notes on Provisional Protection under the UPOV Convention
- (Revision)

The Russian delegation proposed a further revision of the Explanatory Notes on Provisional

Protection. Also, the revisions of four Technical Guidance Protocols were adopted, as well as the revisions of three Information documents. (UPOV/INF-EXN/8)

Election of the new President and Vice-President of the Council

The UPOV Council elected Mr Luis Salaices Sanchez (Spain) as the new President and Mr Raimundo Lavignolle (Argentina) as the new Vice-President of the Council for a term of three years ending with the autumn session of 2018.

Administrative and Legal Committee (CAJ)[10]

Rescheduling of meetings of the Administrative and Legal Committee (CAJ)

The CAJ discussed reducing its sessions to a single two-day session instead of holding a one-day CAJ session in March/April and a two-day CAJ session in October/November as per its current practice. It suggested a rescheduling of its meetings and the autumn sessions will decide the need for a one-day spring session would take place in the following year. The CAJ agreed not to hold a CAJ session in March 2016 and to hold a two-day CAJ session in October 2016.

Explanatory Notes

The CAJ considered revised drafts of Explanatory Notes on Essentially Derived Varieties and on Propagating Material.

Explanatory Notes on Essentially Derived Varieties (document UPOV/EXN/EDV/2 Draft 6)

The CAJ endorsed the proposal for the Secretariat to organize a meeting to exchange information with the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Varieties (CIOPORA), the International Seed Federation (ISF) and the World Intellectual Property Organization (WIPO), in order to explore the possible role of UPOV in alternative dispute settlement mechanisms for matters concerning essentially derived varieties, including the provision of experts on EDV matters.

The CAJ session also discussed amendments to the Draft Explanatory Note.

The next CAJ session will discuss the revised draft of the Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention (Revision). The European Seed Association (ESA) and the International Seed Federation (ISF) will also provide to the next CAJ session, proposed text regarding essential derivation from the parent lines of hybrids, and the use of molecular data, for further discussion at the 73rd session of the CAJ.

Propagating and Harvested material

The CAJ heard presentations made by Argentina, the European Union and the Russian Federation on harvested material. (CAJ/72/4 Add). The CAJ agreed to propose to the Council to organize a one-day seminar on propagating and harvested material to be held in conjunction with the UPOV sessions in October 2016. A draft program will be prepared for consideration by the Consultative Committee and approval by the Council in March 2016. The seminar will take place on 24th October 2016.

Future UPOV Meetings

- The following UPOV sessions will take place from **14 to 16 March 2016** in Geneva, Switzerland.
- UPOV Technical Committee – **14 to 16 March 2016** (TC/52).
- UPOV Council – **17 March 2016**(C(EXTR.)/33).
- UPOV Working Group on Variety Denominations – **18 March 2016** (WG-DEN/1).

WORLD HEALTH ORGANIZATION (WHO)

Member State Mechanism on Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) medical products

The Member State Mechanism on substandard/spurious/falsely-labelled/counterfeit medical products[11] held its fourth meeting from 19 to 20 November 2015 in Geneva. The session was chaired by Dr. Rassoul Dinarvand from the Islamic Republic of Iran. The session was attended by 50 member States and one regional economic integration organization.

An informal working group on Activity A was convened by Brazil on 17 November 2015 and the meeting provided comments on the discussion document on "Framework /Guideline on developing a national plan for preventing, detecting and responding to SSFFC medical products." Member States were also asked to submit training materials concerning the

[10] See: UPOV documents, http://www.upov.int/meetings/en/details.jsp?meeting_id=37027

[11] Member State Mechanism on Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) medical products**:** Fourth Meeting (15 December 2015) http://apps.who.int/gb/ssffc/pdf_files/MSM4/A_MSM4_10-en.pdf

prevention, detection and response to substandard/spurious/falsely-labelled /falsified /counterfeit medical products to the Secretariat through the Mednet platform within the mandate of the above mentioned activity.

The United Kingdom presented the terms of reference for a Global Focal Point Network for substandard/spurious/falsely-labelled/counterfeit medical products, as contained in A/MSM/4/2. Amendments were made to the document and it was approved by the MSM. It was agreed that the Secretariat will continue to work under the mandate of Activity B and will continue to work with the Member States to formalize and expand the network into 2016.

An informal working group was also convened by Argentina on Activity C (track and trace models). The document A/MSM/4/3 was accepted by the fourth meeting of the MSM. It was also agreed that the table containing the list of national experiences would be periodically updated and made available on the MedNet Platform. The Member States were encouraged to share their experiences in using authentication and detection technologies and methodologies. There was an agreement on the extension of the mandate for Activity C until one year in order to complete the work.

The Secretariat also presented a review of WHO's work on the issue of access to quality, safe, efficacious and affordable medical products as given in A/MSM/4/5 (Activity D). The Secretariat was asked to submit a concept note and proposed budget for further work on element 8C at the Steering Committee due to take place in March 2016.

The United Kingdom presented a proposal for implementing activity E (communication and awareness raising materials) to create a working group comprised of technical communication experts from Member States and national and regional regulatory authorities to develop and leverage existing recommendations for effective risk communication and recommendations for awareness campaigns on substandard/spurious/falsely-labelled /falsified /counterfeit medical products and related actions, activities and behaviours as given in A/MSM/4/5. It was also agreed that the information on the group's remit, scope and objectives, as well as on the draft comprehensive project plan would be posted on the Mednet platform for the consideration of the steering committee in March 2016.

The Secretariat provided an update on a proposal for a study on the public health and socioeconomic impact of substandard/spurious/ falsely-labelled/falsified/counterfeit medical products as in A/MSM/4/6. The update shall include the comments from the discussion and certain time lines would be adhered to.

The Secretariat also put forth an estimation of costs of the prioritized activities for the year 2016.

The MSM agreed that the list of prioritized activities for 2016-2017 would include the activities contained on the list of prioritized activities for 2014-2015 that had not been completed as well the following new activities:

- The Secretariat would submit to the Steering Committee in March 2016, a concept note and proposed budget for a study to increase the understanding and knowledge on the links between accessibility and affordability and their impact on the emergence of SSFFC medical product and recommendations to minimize their impact.

- An MSM working group of experts from national and regional regulatory agencies to work on refining the working definitions has been established. The modalities of the working group including the update on existing working definitions would be submitted to the Steering Committee in March 2016.

- The MSM reviewed the outcome of the informal discussion on element 5(b) of the work plan on the identification of the activities and behaviours that fall out of the mandate of the mechanism which was convened by India on 17 November 2015. The consensus was not reached but the discussions were useful and would be continued at a future point in time. The issue of transit would also be considered by the Steering Committee for the agenda of the fifth meeting of MSM on SSFFC.

The MSM discussed the analysis provided by the Secretariat in A/MSM/4/8 on WHO's participation in the global steering committee for quality assurance for health products. The MSM decided that the Secretariat should could continue to observe on a provisional basis meetings of the global steering committee for quality assurance for health products and to provide a report to the 5th meeting of the MSM on the global steering committee, including documents and information on its nature, legal status, governance and participants, in response to questions and comments presented during the Steering Committee.

The Secretariat also provided an update on WHO's work on regulatory system strengthening for medical products.

The Secretariat outlined its proposed process for the review of the MSM in 2017 as given in A/MSM/4/9. There was an agreement that the WHO's review process should be led by WHO's office for evaluation and learning and that further details on the review including the questionnaire would be provided to the Steering Committee at its meeting in March 2016.

The MSM decided that the term of office of the current chair be extended to the end of the fifth session of the MSM in 2016. The MSM also decided to amend Appendix 1 of document A66/22 on the structure, governance and funding of MSM to reflect decision WHA66(10). It was also confirmed that subsequent terms of office of the chair and vice-chairpersons will expire at the end of every second regular session of the MSM.

The MSM decided that its fifth meeting would be held in October or November 2016. There would also be a discussion at a future meeting of the Steering Committee about the panel discussion of national regulatory authorities.

Framework of Engagement with non-State actors (FENSA)[12]

An Open-ended Intergovernmental Meeting on the draft WHO framework of engagement with non-State actors took place at the WHO headquarters in Geneva from 8 to 10 July 2015.

FENSA originated during the launch of WHO's programme at the 64th World Health Assembly in 2011. This policy framework is to lay out the norms for the regulation of the engagement of WHO with Non-state actors (NSA) i.e. non-governmental organizations (NGOs), the private sector, philanthropic foundations and academic institutions.

The Open-ended Intergovernmental Meeting on the draft framework of engagement with non-State actors could not conclude its work. The meeting was suspended and the Chair was mandated to conduct informal consultations with member States. The meeting was resumed from 7 to 9 December 2015 and the resumed meeting managed to agree on some parts of the framework, but some paragraphs still remain unresolved and will require further discussions. The meeting requested the 138th session of the Executive Board to extend its mandate, so that it may resume its work for a final session between the Executive Board and the Sixty-ninth World Health Assembly, in order to submit a consensus text of the draft Framework As well as a draft resolution to the Health Assembly in accordance with resolution WHA68.9.

The draft framework of non-State actors will be sent for deliberation at the World Health Assembly in May 2016.

Future WHO meetings

The 138th session of the WHO Executive Board will take place from **25 to 30 January 2016** in Geneva, Switzerland.

FOOD AND AGRICULTURE ORGANIZATION (FAO)

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA): The Sixth Session

The Sixth Session of the Governing Body (GB) of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was convened from 5 to 9 October 2015, at the headquarters of the Food and Agriculture Organization (FAO) of the UN, in Rome, Italy. The session was chaired by Matthew Worrell from Australia.

Many countries highlighted the urgent need for the improvement in the implementation of the Treaty. Two main areas of concern are 1) the ineffective functioning of the benefit sharing mechanism, in particular the lack of contributions from private firms and governments to the Benefit-sharing Fund (BSF), and 2) the need to strengthen the implementation of Farmers' Rights under Article 9 of the ITPGRFA.

The GB adopted thirteen resolutions. Some of the main discussions decisions taken are as follows:

Farmers' Rights

Submissions

A new submission was made and discussed by the GB on lessons from practice concerning the implementation of Farmers' Rights as provided for in Article 9 of the International Treaty and according to the request made by the GB through resolutions 6/2011 and 8/2013. The joint submission was made by Oxfam, ANDES, CTDT, SEARICE and CGN-WUR.[13] The submission

[12] FENSA, 'Report by the Secretariat' (27 November 2015) http://www.who.int/about/collaborations/non-state-actors/A_FENSA_OEIGM_2-en.pdf?ua=1.

[13] Joint submission by Oxfam (Netherlands), Asociación para la Naturaleza y el Desarrollo Sostenible (Asociación ANDES, Peru), Community Technology Development Trust (CTDT, Zimbabwe), Southeast Asia Regional Initiatives for Community.
Empowerment (SEARICE, Vietnam), Centre for Genetic Resources (Netherlands, Wageningen University and Research Centre, CGN-WUR). Available at

provides lessons and policy recommendations that relate both to Article 6 on Sustainable Use of Plant Genetic Resources and Article 9 on Farmers' Rights, and can further help guide the selection process of the Treaty's Benefit Sharing Fund.

The policy recommendations derived from the best practices of the project include:

- Sustainable use of PGRFA requires the strengthening of both the technical capacities and the rights of indigenous peoples and smallholder farmers.
- The right of farmers to participate in decision making on the improvement and use of PGRFA is an important requirement
- The sharing of best practices should also focus on scaling up such practices and on designing impact pathways to reach many more farmers, especially women, and in clarifying the various stakeholders' roles
- Need for access to additional and novel diversity. Community to community exchanges offer one reliable gateway to access
- Farmers need access to materials under the Multi-Lateral System, including germplasm of locally high potential for the purpose of further enhancement and use. In order to facilitate this, research institutions and CSOs have a role in realising farmers' access to these materials and in helping farmers develop an informed selection process.
- Gene banks and breeding institutions should treat farmers' requests for local varieties as a matter of priority.

The GB also discussed a report on all submissions made to date concerning the implementation of Article 9 on farmers' rights.[14]

Decisions by the GB

On the issue of ***farmers' rights***, the GB decided to:

- Consider developing national action plans for the implementation of Article 9 which includes protection of Traditional Knowledge of indigenous people, framing of national policies for Traditional Knowledge, protection of TK related to genetic resources and the rights of farmers and local communities.
- Recognizing the importance of rewarding the farmers for their contribution to the conservation, improvement and availability of plant genetic resources for food and agriculture. Giving farmers an effective right to participate in benefit sharing includes both monetary and non-monetary benefit sharing. The activities such as reward and support systems in the form of community seed banks, seed fairs or seed registries; various forms of capacity building and marketing activities.
- Facilitating participation of farmers in the decision making process by public consultations or through their relevant agricultural representative at the national level. The participation of farmers throughout the decision making and implementation process on the conservation and use of PGRFA.
- Allow the farmers the flexibility to save, use, exchange, and sell farm-saved seeds as seeds are regarded essential to the survival of farmers. Community seed banks are considered a viable way for farmers to access their seeds.
- Establishment of a Special Global Fund to finance some of the small-scale projects for the conservation and protection of the genetic resources held by peasants and farmers.
- Promoting the application and use of locally adapted and innovative technologies and practices, agricultural and food sciences, research and development as well as the transfer.
- Take initiatives to convene regional workshops and other consultations with farmers' organizations to promote the realization of the rights of the farmers.
- UPOV and WIPO must jointly cooperate to finalize the possible areas of interrelations and report at the next session
- The Secretariat further announced the launch of the Global Forum on Agricultural Research, a joint capacity building programme that will support smallholder farmers, farmers' organizations and government authorities in developing countries to improve the implementation of the rights of the farmers. It will support and facilitate dialogue and networking to share experiences and underwrite the role of farmers as both custodians of plant genetic resources for food and agriculture and innovators of food crops relevant for food security.

Multilateral System

Under the issue of Multilateral System (MLS), GB decided to extend the mandate of the Ad Hoc Open-ended Working Group to Enhance the

http://www.planttreaty.org/sites/default/files/Submission_Oxfam.pdf.

[14] The report compiling the submissions is document IT/GB-6/15/Inf.05, available at http://www.planttreaty.org/sites/default/files/gb6i5e.pdf.

functioning of the System for the 2016-2017 biennium and requested the Working Group to:

- Elaborate options for adapting the MLS coverage based on different scenarios and income projections;
- Present a revised draft of Standard Material Transfer Agreement (SMTA);
- Liaise closely with the Ad Hoc Advisory Committee on the Funding Strategy;
- Take into consideration, the issues regarding the genetic information associated with the material accessed from the MLS; and
- Increase the availability of PGRFA through MLS and consider issues regarding the genetic resources.

Funding Strategy

The GB agreed to undertake a review with a view to enhancing the funding strategy at the next session and reconvene the Ad Hoc Advisory Committee on the funding strategy in the 2016-2017 biennium.

- Develop measures to strengthen the implementation of Funding Strategy;
- Consider possibilities of resource mobilization to implement the relevant provisions of the Sustainable Development Agenda;
- Mobilization of resources through the high-level task force and strategic planning and calls upon national, regional, international private sector associations, NGOs as well as parties and other donors to make contributions to allow the launch of the funding project.

Cooperation with UPOV and WIPO

The GB invited WIPO and UPOV to jointly identify possible areas of interrelations among their respective national instruments.

- The Secretary invited the Contracting Parties, Stakeholders and others to share any relevant information on the identification of interrelations between the International Treaty, especially the Article 9 and the relevant instruments of UPOV and WIPO
- The Ad Hoc Committee on Sustainable Use reviewed a tentative list of the issues that were mentioned in these submissions and recommended to forward the entire list in slightly amended form to UPOV and WIPO. The different issues promote different forms of innovation in the use of plant genetic resources for food and agriculture by farmers and breeders, including formal and informal systems.
- The Secretary has requested UPOV and WIPO to discuss jointly on the areas of interrelations via the appointment of a small team of experts.

Compliance

The GB requested the parties to submit their reports according to Section V of the Compliance Procedures in a timely manner and also requested the secretariat to place the format of the Standard Reporting online by the end of the year and support the parties in fulfilling their reporting commitments and elect the members of the Compliance Committee for the 2016-2019 term.

Cooperation with the Convention on Biological Diversity

The GB requested the Secretariat to continue monitoring and participating in relevant CBD and updating their national protocol processes, review and update national their National Biodiversity Strategies and implement the Strategic Plan for Biodiversity 2011-2020 as well draw the attention of parties to work on developing a global multilateral benefit sharing mechanism under the Nagoya Protocol. The GB further requested the Secretariat to continue facilitating interactions between ITPGRFA and CBD Secretariats, African Union Commission and Biodiversity International.

Sustainable Use

The GB emphasized the role of key sustainable use of PGRFA and the link between farmers' rights under Article 9 and the sustainable use under Article 5 and Article 6 of the Treaty. It encourages the parties to implement the sustainable use of PGRFA, provide policy and guidance, promote transfer of technology, capacity building on farmers' rights and awareness raising on crop wild relatives. It also requests the parties to promote the access of all farmers, small holder farmers, indigenous peoples and local communities to PGRFA in Multilateral System.

Cooperation with the Global Crop Diversity Trust

The GB provided policy guidance to the Trust on resource mobilization, scientific and technical matters, the Global Information System and the Communication and Outreach. The GB urged the parties and donors to provide financial support as well as support the work of the Ad Hoc Advisory

Committee on the Funding Strategy in developing measures to enhance the functioning of the Funding Strategy, and to continue and expand cooperation with the Treaty on resource mobilization in joint fund raising activities. The GB also advises on the scientific and technical matters of the trust and supports the development of an efficient and sustainable conservation system under the Treaty.

Cooperation with CGRFA

The GB requested the Secretary to continue strengthening collaboration with the CGRFA secretary to promote coherence in the development and implementation of ITPGRFA and CGRFA respective work programmes in particular with regard to the work programme on Access and Benefit Sharing. [15]

Challenges for the Treaty:

1. The first challenge is to prove that it can generate meaningful and stable revenue flows for benefit sharing. The Global Information System could provide additional incentives for users to access PGRFA through the Multilateral System.
2. The second challenge that the Treaty needs to address is treating farmers as custodians of PGRFA by delivering benefits to them.

Future ITPGRFA Meetings

The Second Global Consultation on Farmers' Rights will take place in Indonesia in **July 2016.**

The sixteenth regular session of the Commission on Genetic Resources for Food and Agriculture of the FAO will take place from **30 January to 3 February 2017** in Rome, Italy.

The seventh session of the Governing Body to ITPRGRFA will take place in the second half of **2017**.

CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

Ninth meeting of the Ad Hoc Open-ended Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity

The ninth Ad Hoc Open-ended Inter-sessional Working Group on Article 8(j)[16] and Related Provisions of the Convention on Biological Diversity held its ninth meeting in Montreal, Canada, from 4 to 7 November 2015.

It adopted five recommendations concerning (a) voluntary guidelines for the development of mechanisms, legislation or other appropriate initiatives to ensure the prior informed consent of indigenous peoples and local communities for accessing their knowledge, innovations and practices, the fair and equitable sharing of benefits arising from the use and application of such knowledge, innovations and practices relevant for the conservation and sustainable use of biological diversity, and for reporting and preventing unlawful appropriation of traditional knowledge; (b) task 15 of the multi-year programme of work on the implementation of Article 8(j) and related provisions: best practice guidelines for the repatriation of indigenous and traditional knowledge; (c) a glossary of relevant key terms and concepts to be used within the context of Article 8(j) and related provisions; (d) recommendations from the United Nations Permanent Forum on Indigenous Issues to the Convention on Biological Diversity and (e) an in-depth dialogue on thematic areas and other cross-cutting issues.

The draft decisions contained within the recommendations will be submitted to the Conference of the Parties to the Convention on Biological Diversity for consideration at its thirteenth meeting.

Future CBD Meetings

The Expert Meeting on Article 10 of the Nagoya Protocol on Access and Benefit-sharing will take place from **1 to 3 February 2016** in Montreal, Canada.

UNITED NATIONS FRAMEWORK CONVENTION ON CLIMATE CHANGE (UNFCCC)

Conference of Parties (COP): Twenty First Session

The twenty-first session of the Conference of the Parties (COP)[17] and the eleventh session of the Conference of the Parties serving as the meeting of the Parties to the Kyoto Protocol (CMP) took place from 30 November to 11 December 2015, in Paris which led to the culmination of the Paris Climate Change Agreement. The summit was attended by 196 countries in total.

[15] Ibid 17

[16] Ad Hoc Open-ended Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity: Ninth Meeting, 'Report' (7 November 2015), https://www.cbd.int/doc/meetings/cop/cop-13/official/cop-13-03-en.pdf.

[17] COP: Twenty First Session, 'Adoption of the Paris Agreement' (12 December 2015) http://unfccc.int/resource/docs/2015/cop21/eng/l09.pdf.

The Paris Agreement marked the latest step in the evolution of the U. climate change regime, which originated in 1992 with the adoption of the Framework Convention. The UNFCCC established a long-term objective, general principles, common and differentiated commitments, and a basic governance structure, including an annual COP.

The Paris Agreement aims to achieve two long-term goals: Firstly, reducing the emissions as soon as possible while recognizing the fact that it will take longer for developing countries and secondly, a goal of net greenhouse neutrality through reduction in carbon emissions and promotion of clean technology. Countries are to assess their progress toward emissions reduction goals every five years.

Technology development and transfer is an important theme under Article 10[18] of the Paris Agreement wherein parties share a long-term vision on the importance of fully realizing technology development and transfer in order to limit global warming and reduce the emissions of greenhouse gases. The developed countries shall provide appropriate support, through financial means to support the research and development in order to facilitate access to technology, in particular for the early stages of the technology cycle to developing, least developed and small-island countries.

Article 9[19] of the Agreement states the developed countries shall provide financial resources to assist developing countries in order to achieve a balance between adaption and mitigation so that the vulnerable nations are able to fight the adverse effects of climate change.

Article 11[20] of the Agreement discusses the provision for capacity building wherein the capacity and ability of particular developing and least developed countries must be enhanced for effective climate change action by facilitating technology development, dissemination and deployment, access to climate finance, training and public awareness and transparent, timely and accurate communication of information to implement adaption and mitigation actions.

[18] Ibid 19.
[19] Ibid 20.
[20] Ibid 21.

INTERNET GOVERNANCE

Annual Internet Governance Forum (IGF) Meeting: Tenth Session

The tenth annual meeting of the IGF[21] was held from the 10th to the 13th of November 2015 in João Pessoa, Brazil. The session was chaired by the Brazilian Minister of Communications, André Figueiredo. The theme for IGF 2015 was: 'Evolution of Internet Governance: Empowering Sustainable Development'.

The session addressed both opportunities and challenges under the following key issues: Cybersecurity and Trust; Internet Economy; Inclusiveness and Diversity; Openness; Enhancing Multistakeholder Cooperation; Internet and Human Rights; Critical Internet Resources; and Emerging Issues.

The discussions of importance were:

- IGF 2015 was planned in consultation with the host country and in accordance with guidance from the IGF's Multistakeholder Advisory Group (MAG). Both the preparatory and the intercessional work of the IGF were guided by recommendations of the Commission on Science and Technology for Development (CSTD) Working Group on Improvements to the IGF4.
- In line with the CSTD Working Group recommendations, the IGF demonstrated its capacity to produce tangible outcomes within multistakeholder collaboration frameworks.
- The session again aimed to facilitate increased participation among stakeholders from developing countries and to enhance linkages between the growing number of National and Regional IGF initiatives, the global IGF and the rest of the Internet governance ecosystem.
- The participation of the UN Special Rapporteur on the promotion and protection of the right to freedom of opinion and expression and the UN Special Rapporteur on the right to privacy in the digital age facilitated the debate related to human rights.
- Privacy issues were debated at length and stress was laid upon the enforcement of encryption and anonymity while respecting other human rights. Other workshops emphasized that privacy, transparency and security need to complement, not compromise each other. Workshops related

[21] IGF: Tenth Session, ' Chair's Summary'(13 November 2015) http://www.intgovforum.org/cms/10th%20IGF%20Chairs%20Summary_Finalv2.pdf.

to human rights stressed the importance of the universality, indivisibility, interdependence and interrelation of all human rights and fundamental freedoms, both online and offline.

- There was a discussion about the cross-cutting area of Critical Internet Resources (CIRs). Since its inception, the IGF has proven its value in the cross-cutting area of Critical Internet Resources (CIRs) as the IGF community has encouraged discussions and debates about the handling of CIRs.
- Discussions also focused more on sharing information and enhancing mutual education; covering a diversity of interest under the CIR banner: top-level domains, internationalised domain names, the exhaustion of IPv4 and the realities of the IPv6 transition, and the role of Internet Exchange Points (IXPs).
- IGF 2015 also saw discussions about the Internet Assigned Numbers Authority (IANA) transition addressed at an informative and constructive level.
- The IGF once again served as a platform for UN agencies, intergovernmental organizations and major institutions tackling challenges related to Internet public policy. During the week the UN Commission on Science and Technology for Development (CSTD) held an open session on the ten-year review of the progress made in the implementation of the WSIS outcomes; the UN Educational, Scientific and Cultural Organization (UNESCO) organized a number of events and workshops, including the launch of an Internet Freedom Series Publication and presentation of a Comprehensive Study on the Internet. The International Telecommunication Union (ITU) presented a new 'e>merge' partnership and discussed the implementation of its Connect 2020 Agenda. Open Forums were convened by the UN Conference on Trade and Development (UNCTAD), the UN Office of the High Commissioner for Human Rights (OHCHR), the Council of Europe and the Organisation for Economic Cooperation and Development (OECD), among many others.
- Emerging groups and initiatives such as the Global Commission on Internet Governance, the NETMundial Initiative and the Global Forum on Cyber Expertise held sessions. The Italian Chamber of Deputies presented an "Internet Bill of Rights"; the "African Declaration on Internet Rights and Freedom initiative" was discussed; Stanford University carried out a deliberative poll exercise on the subject of access; and shared experience related to Internet Governance and its importance in future developments.
- Youth participation was particularly strong during the 10th IGF. The Youth Coalition on Internet Governance developed an 'IGF for Newbies' resource to help assimilate young people with the IGF and Internet governance issues.
- Gender, diversity and intersectionality were important topics as well, with debate on human rights
- Internet intermediaries' roles in protecting, enabling and upholding human rights were also discussed and how access will impact sustainable development and human rights.
- Other important issues addressed at IGF 2015 included the Internet of Things, jurisdictional and trade issues, child online protection, the rights of persons with disabilities online, and big data.

Future IGF Meetings

The World Summit on Information Society (WSIS) will take place from **2 to 6 May 2016** in Geneva, Switzerland.

WSIS+10 United Nations General Assembly High Level Meeting (WSIS+10)

The meeting on the UN's ten-year review of World Summit on Information Society took place from 15to 16 December 2015 in New York, United States of America where the WSIS+10 Resolution[22] was adopted.

The resolution majorly covers digital development and strongly links itself with the 2030 Agenda for Sustainable Development. Cyber Security's effect on the modern society is the second message of WSIS+10 and the application of Human Rights offline equally is the third message.

The session reaffirmed three core elements of the 'Tunis Compromise': Firstly, it extended the IGF mandate for 10 years and addressed the IGF under the UN umbrella in a multistakeholder manner. Secondly, it retained the roles and responsibilities of the stakeholders as outlined in the Tunis Agenda. It also maintained the element of ambiguity around an enhanced cooperation arrangement which allows for different interpretations.

The key issues discussed were:

- The information and communications technologies (ICTs) are key achieving the

[22] WSIS+10: Seventeenth Session, 'Outcome Document', (13 November 2015) http://workspace.unpan.org/sites/Internet/Documents/UNPAN95735.pdf.

sustainable development goals (SDGs) and bridging the link between development and digital divide.

- Greater internet access to people and whether the technical aspects are sufficient and the necessary elements for digital inclusion such as digital skills and policy framework. Access to mobile technology, transparent policy processes and attention to content and capabilities (UNCTAD), assistance from developed countries, strengthen the Digital Solidarity Fund, Public-Private cooperation, Business engagements, Government support for investors, multilingualism and availability of local content will facilitate access.
- The discussion on Capacity Development proceeded in two main directions: traditional development assistance and the creation of a culture of cybersecurity wherein education plays a crucial role.
- The discussions also revolved around cyber security which is a major threat and highlighted the concern that cooperation among governments is not enough for secure and safe internet.
- Support for inclusiveness and participation of all stakeholders in Internet governance was called for strongly. The IGF has insufficient capacity to respond to internet related challenges so an internationally regulated system is needed. NETMundial was considered an important example of the multistakeholder approach.
- Human Rights do apply offline as well. There were discussions in relation to protection of freedom of expression and privacy rights. Discussions emerged on whether human rights and security are complementary or mutually exclusive.
- Other issues which were raised in the statements at the WSIS+10 included: net neutrality, open data, cloud computing, responsibility of intermediaries, common heritage of mankind, global public good, e-government, smart cities etc.

FREE TRADE AGREEMENTS

Trans-Pacific Partnership Agreement (TPP)

The Transpacific Partnership agreement[23] was negotiated for more than five years and was finalized on October 5, 2015 in Atlanta. The countries negotiating the agreement together are US, Japan, Canada, Australia, New Zealand, Mexico, Peru, Singapore, Vietnam, Malaysia and Brunei. The final text has thirty chapters plus annexes.

TPP's Intellectual Property Chapter covers patents, trademarks, copyrights, industrial designs, geographical indications, trade secrets and enforcement of intellectual property rights.
The main issues related to this trade agreement are:

- Coverage of IP in the TPP Investment Chapter[24]- The investment chapter provisions on prohibited performance requirements includes a number of exemptions for intellectual property rights, compulsory licences to patents under Article 31 of the TRIPS or for copyright, or to remedies to anti-competitive practices that protects U.S. State practice in those areas. There is a limited exception for national treatment which may be there to protect the provisions in the Bayh-Dole act on the local working on patents.
- Non-confirming measures – The non-confirming measures are included under Article 9.11 of the TPP's investment chapter including two separate annexes. These include non-discriminatory treatment of digital products, cross-border trade in services, location of computer facilities and source code. Concerns have been raised by the Civil Society groups wherein as the exclusion of government procurement and data practices narrows down the application of the e-commerce chapter. Also, it has been stated that U.S. Copyright Office has proposed limitations on remedies for infringement of orphaned copyrighted works which are inconsistent with the TPP obligations for damages, injunctions, attorney fees. The investment chapter does not provide an exception for remedies to enforce rights. The issue of infringement of patents on biological drugs is also in conflict with the TPP standards.
- Access to medicines also appears to be in conflict with the TPP provisions on damages.
- TPP provisions on Public Health and Intellectual Property-
  - Patents for new uses and new methods of using existing products (Article QQ.E.1.2,p.17);
  - Patent Term Extensions to compensate for delays in granting patents and delays in marketing approval (Article QQ.E.14, p. 22);

[23] Text of the Transpacific Partnership (5 November 2015) https://www.mfat.govt.nz/en/about-us/who-we-are/treaty-making-process/trans-pacific-partnership-tpp/text-of-the-trans-pacific-partnership

[24] Despite assurances to contrary, intellectual property covered asset for TPP ISDS mechanism (5 November 2015) http://keionline.org/node/2358

- Data protection for small molecule drugs – at least 5 years for new pharmaceutical products plus 3 years for new indications, formulations or methods of administration (Article QQ.E.16, p. 23-24);
- Patent linkage provisions likely to result in delays in marketing approval for generic drugs (Article QQ.E.17); and
- Market exclusivity for biologics, provided through one of two options: at least 8 years of data protection, or at least 5 years of data protection and other measures to "deliver a comparable outcome in the market" (Article QQ.E.20, p. 25-26).

The transition period for the Marketing Exclusivity for Biologics is 5 years each in Malaysia and Mexico whereas 10 years each in Peru and Vietnam. This will lead to delayed entry of Biosimilars or the follow-on-biologics thereby inhibiting access to affordable and important medicines in developing countries. Such a concern has been raised by civil society organizations such as Doctors Without Borders and Public Citizen. This will lead to extension on monopolies on expensive Biologics. Patent Linkage provisions will result in delayed marketing approvals for generic drugs.

Transatlantic Trade and Investment Partnership (TTIP)

On 5 November 2015, the British Chamber of Commerce in Denmark (BCCD), in collaboration with other partners, held the TTIP Nordic Debate on Regulatory Issues[25] in Copenhagen, Denmark. Speakers included the Danish Prime Minister Lars Løkke Rasmussen, the EU Chief Negotiator for TTIP Ignacio Garcia Bercero, the US Ambassador to Denmark Rufus Gifford, as well as representatives from the Nordic governments and industry experts.

The event provided a forum for a Nordic region perspective on regulatory cooperation in TTIP and its impacts on the region's trade with the US. It allowed the European Commission, governments and leaders of business and industry to secure public endorsement of the deal, by engaging civil society in an open debate on the pros and cons.

[25] TTIP Nordic Debate: http://www.bccd.dk/en/News/Latest%20News/2015/11/media-coverage-nordic-ttip.aspx.

UN GENERAL ASSEMBLY

Statement by Special Rapporteur in the Field of Cultural Rights at the 70th session of the UN General Assembly

The Special Rapporteur in the field of Cultural Rights, Ms. Farida Shaheed presented two thematic reports at the 70th Session of the UN General Assembly the 20 November 2015: 1) on the interface of copyright policy and the right to culture and science (A/HRC/28/57) and 2) on patent policy (A/70/279). These reports address the unresolved issues between intellectual property and human rights through the illustration of right to science and culture.

Following are the unresolved issues between patent rights and the right to science and culture highlighted in the two reports:

1. Patents do not extend as far as to interfere with the dignity and welfare of individuals. So, wherever there is a conflict between patents and human rights, human rights must prevail. Patent rights and policies impact the access to essential technologies. It is important to address the gaps between access to technologies and fulfilling the right of persons to participate in the political, social, economic and cultural life.
2. The effects of intellectual property rights are strongly context-dependent. Therefore, claimed benefits of granting patent rights and implementing international treaties such as the TRIPS Agreement must be assessed keeping in view differentiated contexts and with varied outcomes across different countries depending on their technological capacity and industry profile. The Special Rapporteur further stated that in accordance with Article 7 of the TRIPS Agreement, "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". The word "should" indicates that such effects do not automatically result from intellectual property protection, and that countries should frame their legislation with the aim of reaching these effects.
3. Exclusions, exceptions and flexibilities are fully part of international intellectual property law, such as the TRIPS Agreement. These can be used to implement multilateral treaties as well is the

key to striking a proper balance between private and public interests and to ensure respect for human rights.

In the area of copyright, the Special Rapporteur submitted the report on copyright in accordance with Human Rights Council resolution 19/6. In the report, the Special Rapporteur examined copyright law and policy from the perspective of the right to science and culture, emphasizing both the need for protection of authorship and expanding opportunities for participation in cultural life. She proposed several tools to advance the human rights interests of authors. She further proposed to expand copyright exceptions and limitations to empower new creativity, enhance rewards to authors, increase educational opportunities, preserve space for non-commercial culture and promote inclusion and access to cultural works.

The Special Rapporteur recommended that the international intellectual property instruments including trade agreements, be negotiated in a transparent way, permitting public engagement and commentary, and that national patent laws and policies should be adopted and reviewed in forums that promote broad engagement, with input from innovators and the public at large. She also stated that resolution 27/3 in particular extends the mandate of the Special Rapporteur on truth, justice, reparations and guarantees of non-recurrence referring to memorialization initiatives and processes, and of resolution 27/31 on civil society space, emphasizing the important role of artistic expression and creativity in the development of society.

UN launches High-Level Panel on Access to Medicines[26]

The United Nations Secretary-General's High-Level Panel on Access to Medicines held its first meeting in New York on 11 December 2015. UN Development Programme in collaboration with UNAIDS serves as the Secretariat for the High Level Panel.

The panel committed itself to finding solutions that will increase access to medicines, while continuing to promote investment in new treatments to save the lives of millions. Its aim is to ensure that everyone can access quality, affordable treatment while incentivizing innovations and new health technologies. The High-Level Panel will review and assess proposals and recommend solutions to policy incoherencies between the rights of inventors, international human rights law, trade rules and public health in the context of access to health technologies.

It was noted by the panellists that millions of people are suffering because of disease and poor health as they cannot access lifesaving medicines. "Disease and poor health are still big barriers to social and economic development in many countries, and our world has yet to witness truly inclusive and equitable development," said UNDP Administrator Helen Clark.

"Governments and the private sector have a responsibility to ensure that medicines are accessible to everybody," said UNAIDS Executive Director Michel Sidibé. "The AIDS response is proof that access to affordable and effective medicines can halt and reverse an epidemic, contributing to an increase in life-expectancy and healthier communities."

Generic competition in the pharmaceutical industry, fostered by the use of flexibilities in the application of intellectual property has helped make life-saving HIV medicines much more affordable and allowed the massive scale-up of HIV treatment programmes. For example, in 2000, the price of antiretroviral medicines was around US$ 10 000 per person per year. The price of first-line treatment has now been reduced to as low as US$ 100 per person per year in some countries, ensuring access to life-saving medicines for around 15.8 million people in 2015.

The treatment costs for some very important diseases like Cancer in the US and other high-income countries are rising. The press release stated that 1.2 million died of AIDS in 2014 and over 400 million people died of Hepatitis B and C and 1.4 million have died from those illnesses while 38 million have died from non-communicable diseases such as cardiovascular diseases, diabetes and cancer. Despite certain price reductions, the price of second- and third-line HIV medicines are out of reach of many people. Since HIV treatment is for life, there is a continuous need for innovation on treatment regimens and sustained price reduction in HIV-related products, including diagnostics and treatment of opportunistic diseases, co-infections (like hepatitis B and C, and TB), and co-morbidities, and more funding for research and development into a vaccine and cure for HIV.

The high-level panel is composed of 16 members with expert knowledge of the broad range of trade, public health, human rights and legal issues associated with innovation of health technologies and access to treatment. The panel co-chaired by Festus Mogae, former President of Botswana, and Ruth Dreifuss, former President of Switzerland will look at the threats including diseases for which financial returns are not guaranteed. They will

[26] See: UNAIDS, http://www.unaids.org/en/resources/presscentre/featurestories/2015/december/20151211_accessmedicines.

cover infectious diseases such as HIV and hepatitis C as well as non-communicable diseases and the affordability of health technologies. The panel shall present its report to the UN Secretary-General in June 2016.

REGIONAL DEVELOPMENTS

Third India Africa Forum Summit: Delhi Declaration[27]

The Third India-Africa Forum summit was held from 26 to 29 October 2015 in New Delhi, India. It was attended by the Heads of State and Government and Heads of Delegation representing the continent of Africa, the African Union (AU) and its Institutions, and the Prime Minister of India. The summit adopted the Delhi Declaration 2015 which identified several areas where India and Africa agreed to cooperate with each other, including on health and access to medicines.

Under the section on Health, it was decided that there will be joint cooperation between India and Africa in health and pharmaceutical development as well as telemedicine. A combined effort will be made to combat diseases and pandemics and increase the efficiency of health institutes through comprehensive training programmes and coordinate the harnessing of modern scientific technologies for medicine and treatment at an international level.

India and Africa also agreed to cooperate in the training of doctors and healthcare personnel including through tele-medicine, medical missions, development and utilization of modern technology, enhanced access to generic medicines, promotion of the use of traditional medicines and regulatory procedures as well as combating the challenges proposed by pandemics.
Furthermore, India and Africa will collaborate to ensure access to affordable medicines and foster innovation to address public health needs of developing countries by making full use of the flexibilities available under the WTO TRIPS Agreement.

[27] Third India Africa Forum Summit, Delhi Declaration Page 8 http://mea.gov.in/Uploads/PublicationDocs/25980_declaration.pdf.