

**Information Note
of the World Intellectual Property Organization (WIPO)
for the United Nations Secretary-General’s High-Level Panel on Access to Medicines
and the Expert Advisory Group**

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A. Background

1. The Secretariat of the World Intellectual Property Organization (WIPO) provides this Information Note to share with the UN Secretary-General's High-Level Panel on Access to Medicines and the Expert Advisory Group the array of data, knowledge and background information which is available in WIPO and can be freely accessed from its website. There is a wealth of factual, empirical and statistical information which can be used, assessed and evaluated by all interested stakeholders and, in this way, may help the High-Level Panel and the Expert Advisory Group in their assessment.

2. In addition, the WIPO Secretariat wishes to highlight certain pertinent activities which have been undertaken by the Secretariat upon request of its Member States and have produced results in support of international, regional and national policy processes and may be of interest to policy makers looking to improve policy coherence among them.

3. The WIPO mandate, its governing bodies and procedures are set out in the WIPO Convention,¹ which established WIPO in 1967. The objectives of the Organization include the promotion of the protection of intellectual property (IP) throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organizations and the administrative cooperation among the Unions that have been established by WIPO Treaties.

4. The core activities of WIPO include:

- administering multilateral treaties;²
- providing a global policy forum for addressing evolving IP issues in the various WIPO Committees and decision-making bodies;³
- providing global IP services for a fast, efficient and cost-effective route for protecting inventions, trademarks or designs across borders;⁴
- providing time- and cost-efficient alternative dispute resolution (ADR) options⁵ and domain name dispute resolution services;⁶
- cooperating with governments, intergovernmental and non-governmental organizations, and with multiple public and private sector stakeholders worldwide to, among other things, assist in developing and implementing national IP and innovation strategies, aligned with their development strategies;⁷
- cooperating with intellectual property (IP) offices, users and other stakeholders to develop shared tools, services, standards, databases and platforms to help IP institutions collaborate more effectively and deliver more efficient services to their users as well as enabling innovators and information-seekers worldwide to freely access the knowledge contained in the IP system;⁸

¹ http://www.wipo.int/treaties/en/text.jsp?file_id=283854

² <http://www.wipo.int/treaties/en/>

³ <http://www.wipo.int/policy/en/>

⁴ <http://www.wipo.int/services/en/>

⁵ <http://www.wipo.int/amc/en/>

⁶ <http://www.wipo.int/amc/en/domains/>

⁷ <http://www.wipo.int/cooperation/en/>

⁸ http://www.wipo.int/global_ip/en/

- delivering extensive demand-driven capacity building and training programs that are adapted to country needs and aim to help countries develop the skills and institutional capacity they need to administer, manage and use IP;⁹
- serving as a comprehensive source of data on the IP system, of empirical studies, reports and factual legal and technical information, such as free databases of patents, trademarks and industrial designs to facilitate access to knowledge building awareness, understanding and respect for IP.¹⁰

5. The UN, under Article 1 of the Agreement between the UN and WIPO of December 17, 1974,¹¹ recognizes WIPO as a specialized agency. The Agreement further states that WIPO is responsible for taking appropriate action “for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate economic, social and cultural development, subject to the competence and responsibilities of the United Nations and its organs”. WIPO is committed in particular to co-ordination and participation in the work of any UN bodies (Article 2), exchange of information and documents (Article 6), elimination of all undesirable duplication and most efficient use of statistical information (Article 7) and provision of technical assistance for development in the field of intellectual creation (Article 9).

B. Specific issues for the attention of the High-Level Panel

I. WIPO Program on IP and Global Challenges

6. Since 2010, WIPO has set up a program on IP and Global Challenges which addresses innovation and IP at the nexus of interconnected global issues, in particular global health.¹² WIPO cooperates actively with its partners, within and outside the UN system, to support the policy debate and to develop results-oriented partnerships that address these challenges.

7. The WIPO Secretariat prepares information materials, studies and substantive analyses in the form of reports and briefs that aim at a better understanding of the policy and strategic drivers of innovation. Global Challenges Seminars explore issues around the nexus of innovation and global challenges. For example, the new report entitled *Patents and the WHO Model List of Essential Medicines (18th Edition): Clarifying the Debate on IP and Access* will be published on April 12, 2016 at the WIPO headquarters.¹³

II. WIPO Re:Search

8. WIPO established in 2011 WIPO Re:Search¹⁴ in collaboration with BIO Ventures for Global Health (BVGH) and with the active participation of private and public sector research organizations and the pharmaceutical industry. The voluntary multi-stakeholder platform aims to catalyze new research and development for neglected tropical diseases (NTDs), tuberculosis,

⁹ http://www.wipo.int/cooperation/en/capacity_building/

¹⁰ <http://www.wipo.int/reference/en/>

¹¹ http://www.wipo.int/treaties/en/text.jsp?file_id=305623

¹² http://www.wipo.int/about-wipo/en/activities_by_unit/units/global_challenges.html

¹³ The Global Challenges Seminar "Patents and the WHO Model List of Essential Medicines (18th Edition): Clarifying the Debate on IP and Access" on April 12, 2016 at the WIPO headquarters in Geneva is open to the interested public. Registration is required under https://www3.wipo.int/registration/en/form.jsp?meeting_id=39383

¹⁴ <http://www.wipo.int/research/en/>

and malaria. WIPO Re:Search provides access to intellectual property, including pharmaceutical compounds, technologies, know-how and data available for research and development in those fields.

9. Members of WIPO Re:Search make their IP assets available via a WIPO administered database under royalty-free licenses for research, development and production anywhere in the world. Resulting product sales must be royalty-free in all least developed countries (LDCs). A Partnership Hub, managed by BVGH provides support to interested parties in licensing and research collaboration opportunities, networking possibilities and funding options for research and development. WHO provides technical advice as requested to WIPO.

10. By the end of 2015, WIPO Re:Search providers had made 193 contributions to the platform and 96 research collaborations were in place.

III. WHO-WIPO-WTO Trilateral Cooperation on Promoting Medical Innovation and Access

11. Since 2009, the Secretariats of the World Health Organization (WHO), WIPO and the World Trade Organization (WTO) have been strengthening their cooperation and practical coordination on issues around public health, intellectual property and trade.¹⁵ Coherence is vital in international action to address public health problems. The three organizations, therefore, share a responsibility to strengthen policy dialogue in a practical and effective manner among them and with their partners, to make their respective expertise available and to promote an efficient use of resources for cooperation.

12. The joint WHO, WIPO, WTO study entitled *Promoting Access to Medical Technologies and Innovation – Intersections between Public Health, Intellectual Property and Trade*¹⁶ is the first joint publication of the three Organizations. The study is intended to be used as a resource and background material for capacity building activities undertaken by the WHO, WIPO and the WTO either in cooperation or separately. The study is available in all official languages of the UN.¹⁷

13. The WHO, WIPO and WTO have convened five joint Symposia¹⁸ and two joint Technical Workshops.¹⁹

¹⁵ http://www.wipo.int/policy/en/global_health/trilateral_cooperation.html

¹⁶ http://www.wipo.int/policy/en/global_health/trilateral_cooperation.html

¹⁷ The trilateral study is available in Arabic (http://www.wipo.int/edocs/pubdocs/ar/global_challenges/628/wipo_pub_628.pdf), Chinese (http://www.wipo.int/edocs/pubdocs/zh/wipo_pub_628.pdf), English (http://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf), French (http://www.wipo.int/edocs/pubdocs/fr/wipo_pub_628.pdf), and Russian (http://www.wipo.int/edocs/pubdocs/ru/wipo_pub_628.pdf) and Spanish (http://www.wipo.int/edocs/pubdocs/es/wipo_pub_628.pdf).

¹⁸ (i) Symposium on Access to Medicines: Pricing and Procurement Practices on July 16, 2010 (http://www.wipo.int/meetings/en/details.jsp?meeting_id=20523); (ii) Symposium on Access to Medicines, Patent Information and Freedom to Operate on February 18, 2011 (http://www.wipo.int/meetings/en/2011/who_wipo_wto_ip_med_ge_11/); (iii) Symposium on Medical innovation – changing business models on July 5, 2013 (http://www.wipo.int/meetings/en/2013/who_wipo_ip_med_ge_13/); (iv) Symposium on Innovation and Access to Medical Technologies Challenges and Opportunities for Middle-Income Countries on November 5, 2014 (https://www.wto.org/english/tratop_e/trips_e/trilat_symp14_e.htm); and (v) Symposium on Public Health, Intellectual Property, and TRIPS at 20: Innovation and Access to Medicines; Learning from the Past, Illuminating the Future on October 28, 2015 (https://www.wto.org/english/tratop_e/trips_e/trilat_symp15_e.htm).

¹⁹ (i) Workshop on Patent Searches and Freedom to Operate on February 17, 2011 (http://www.wipo.int/meetings/en/details.jsp?meeting_id=22342); and (ii) the Workshop on Patentability Criteria on October 27, 2015 (https://www.wto.org/english/tratop_e/trips_e/trilat_workshop15_e.htm)

./ 14. For further information on the trilateral cooperation, please refer to Annex I. A short Brief that summarizes the main aspects of the trilateral cooperation is enclosed to Annex I and is also available on the internet.²⁰

IV. WIPO Development Agenda

15. The WIPO General Assembly in 2007²¹ adopted the WIPO Development Agenda²² with its 45 recommendations²³ and established the WIPO Committee on Development and Intellectual Property (CDIP)²⁴ which first met in 2008. The CDIP is composed of all WIPO Member States and is open to all observers with a permanent observer status at the WIPO. The CDIP monitors, assesses, discusses the projects agreed by the Committee and reports to the Annual WIPO Assemblies.²⁵ The mandate of the CDIP is to (i) develop a work-program for the implementation of the 45 adopted recommendations; (ii) monitor, assess, discuss and report on the implementation of all recommendations adopted, and for that purpose coordinate with relevant WIPO bodies; and (iii) discuss intellectual property and development related issues as agreed by the Committee, as well as those decided by the GA. The WIPO Development Agenda aims to ensure that development considerations form an integral part of the work of WIPO, as development is considered a cross-cutting issue which touches upon all sectors of the Organization.

16. The 45 recommendations are grouped into six clusters reflecting the main areas of focus of the Development Agenda. The recommendations require a wide range of actions for implementation, ranging from concrete development-oriented projects and activities to the application of certain principles and objectives that should continue to guide the work of the Organization. Its effective implementation, including the mainstreaming of its recommendations into the substantive programs of WIPO, is a key priority. Its introduction of a results-oriented, project-based methodology has led to a significant move forward in the implementation of the recommendations.²⁶

17. In this context, the High-Level Panel and the Expert Advisory Group may be particularly interested in a number of Resources and databases which result from the implementation of certain Development Agenda recommendations:

- The Intellectual Property Technical Assistance Database (IP-TAD) provides information on WIPO technical assistance activities where one or more of the beneficiaries was a developing or least developed country, or country in transition.²⁷
- The Development Matchmaking Database (IP-DMD) offers a user-friendly platform to match Member States' IP-related development needs with available resources.²⁸
- The Roster of Consultants (ROC) database contains information on consultants engaged by WIPO to undertake specific IP technical assistance activities.²⁹

²⁰ http://www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_10.pdf

²¹ http://www.wipo.int/ip-development/en/agenda/wo_ga/wo_ga_34_summary.html

²² <http://www.wipo.int/ip-development/en/agenda/>

²³ <http://www.wipo.int/ip-development/en/agenda/recommendations.html>

²⁴ <http://www.wipo.int/policy/en/cdip/>

²⁵ http://www.wipo.int/meetings/en/topic.jsp?group_id=1

²⁶ Information on the approved, planned and completed projects for the implementation of the Development Agenda Recommendations is available at <http://www.wipo.int/ip-development/en/agenda/projects.html>.

²⁷ <http://www.wipo.int/tad/en/>

²⁸ <http://www.wipo.int/dmd/en/>

²⁹ <http://www.wipo.int/roc/en/index.jsp>

- The Technology Transfer Portal provides information on meetings held and documents, studies and other material prepared in the context of three Development Agenda projects on technology transfer and open collaboration.³⁰
- The Development Agenda work on flexibilities reflects that IP systems have built in flexibilities to allow Member States to implement IP laws and policies that are most suited to their national and regional circumstances and capacities. The webpage on Flexibilities in the Intellectual Property System³¹ assembles resources on the use and implementation of flexibilities across the different domains of IP, and details of work taking place at WIPO and in other intergovernmental organizations.
- The Database on Flexibilities in the Intellectual Property System³² allows searches for information about implementation of patent related flexibilities in national IP laws in selected jurisdictions. It contains data drawn from WIPO documents on Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels.³³

18. In addition, the Secretariat conducted two studies examining the role of IP in the pharmaceutical sector in Chile and Uruguay respectively. The results of these studies are available online.³⁴ Data for these countries are available upon request.

V. WIPO Standing Committee on the Law of Patents (SCP)

19. The WIPO Standing Committee on the Law of Patents (SCP)³⁵ serves as a forum to discuss issues, facilitate coordination and provide guidance concerning the progressive international development of patent law. All Member States of WIPO and/or of the Paris Union are invited to the SCP as members. A number of accredited intergovernmental and non-governmental organizations also participate in the SCP as observers. “Patents and health” has been one of the substantive agenda items of the Committee during the last years.³⁶ Moreover, the Committee has undertaken a number of studies on the patent system as a whole as well as on various aspects of the patent system which are of particular interest for the High-Level Panel and the Expert Advisory Group, as well as for Member States that consider among other things the available flexibilities for implementation of the international IP frameworks into their respective national laws. These documents include *inter alia*: a Report on the International Patent System,³⁷ and studies on exceptions and limitations to patent rights,³⁸ transfer of technology,³⁹ quality of patents,⁴⁰ opposition systems and related mechanisms,⁴¹ certain

³⁰ http://www.wipo.int/ip-development/en/agenda/tech_transfer/index.html

³¹ <http://www.wipo.int/ip-development/en/agenda/flexibilities/>

³² <http://www.wipo.int/ip-development/en/agenda/flexibilities/search.jsp>

³³ namely documents CDIP/5/4 Rev., http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629, CDIP/7/3 Add,

http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=203319, CDIP/13/10 Rev,

http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=296576 and CDIP/15/6,

http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=298943. The references to laws were accurate at the date of publication of the above-mentioned documents. However, users are advised to cross-check laws in WIPO Lex (<http://www.wipo.int/wipolex/en/>) to ensure that the most up-to-date version of the law is referenced.

³⁴ Studies are available online in pdf version at: http://www.wipo.int/econ_stat/en/economics/studies/#socio

³⁵ <http://www.wipo.int/policy/en/scp/>

³⁶ http://www.wipo.int/patents/en/topics/public_health.html

³⁷ Document SCP/12/3 Rev.2, http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf; Annex II, which includes information on exceptions and limitations to patent rights in the national/regional patent systems, is regularly updated,

http://www.wipo.int/scp/en/annex_ii.html

³⁸ http://www.wipo.int/patents/en/topics/exceptions_limitations.html

³⁹ http://www.wipo.int/patents/en/topics/technology_transfer.html

⁴⁰ http://www.wipo.int/patents/en/topics/quality_patents.html

⁴¹ http://www.wipo.int/patents/en/topics/opposition_systems.html

patentability criteria⁴² and a Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents.⁴³ For further information, please refer to Annex II.

VI. Legislative and Policy Assistance

10. The WIPO provides legislative and policy assistance,⁴⁴ which is consistently based on the multilateral legal framework. More recently, a number of authorities in charge of legislative design and implementation have been seeking advice from WIPO regarding how to use available multilateral flexibilities so as to accommodate particular national interests that are specific to their countries. Therefore, the patent system as a mechanism to promote innovation in the pharmaceutical field, and access to medicines thereof, is one of the areas frequently covered by the advice provided. WIPO assistance is provided, inter alia, via (i) comments that are prepared at the request of the incumbent authorities; (ii) consultation meetings in capitals or in Geneva; or (iii) participation in seminars/workshops where these issues are part of the program.

VII. Source of legal and technical information

11 The WIPO makes available comprehensive data on the IP system as well as empirical studies, reports and factual information on IP.⁴⁵ The WIPO global databases provide access to information on IP rights in the IP system, namely on patents,⁴⁶ trademarks⁴⁷ and design rights.⁴⁸ They are based on the commitment to creating an inter-connected and inclusive knowledge-sharing IP infrastructure. This technical infrastructure is designed to help IP institutions collaborate more effectively and deliver more efficient services to their users as well as enabling innovators and information-seekers worldwide to freely access the knowledge contained in the IP system. The WIPO Lex database provides a search facility for national laws and treaties on IP of WIPO, WTO and UN Members and further pertinent information.⁴⁹

VIII. Patent Landscape Reports

20. The High-Level Panel and the Expert Advisory Group may be particularly interested in a number of Patent Landscape Reports which the Secretariat has prepared in the field of public health: Patent Landscape Reports on the two antiretroviral medicines Atazanavir⁵⁰ and Ritonavir,⁵¹ a Patent Landscape Report on Vaccines for Selected Diseases,⁵² a Patent

⁴² e.g. Document SCP/22/3, http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=308676 and Document SCP/22/4, http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=307341

⁴³ Document SCP/21/9, http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=287105

⁴⁴ http://www.wipo.int/ip-development/en/legislative_assistance/

⁴⁵ <http://www.wipo.int/reference/en/>

⁴⁶ <http://www.wipo.int/patentscope/en/>

⁴⁷ <http://www.wipo.int/reference/en/branddb/> and <http://www.wipo.int/madrid/en/romarin/>

⁴⁸ <http://www.wipo.int/reference/en/designdb/>

⁴⁹ <http://www.wipo.int/wipolex/en/>

⁵⁰ http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/atazanavir.html

⁵¹ http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/ritonavir.html

⁵² http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/vaccines.html

Landscape Report on selected neglected tropical diseases,⁵³ and a Patent Landscape Report on Assistive Devices and Technologies for Visually and Hearing Impaired Persons.⁵⁴

21. Patent Landscape Reports provide a snap-shot of the patent situation of a specific technology, either within a given country or region, or globally. They can inform policy discussions, strategic research planning or technology transfer. For example, the results of a patent analysis in the area of animal genetic resources showed that the patenting activity in the field of animal genetic resources is increasingly focused on the medical and pharmaceutical markets rather than products for human consumption, namely on medical proteins, animals models for research on human diseases, and xenotransplantation for organ transplantations.⁵⁵

./ 22. For further information on the WIPO Patent Landscape Reports, please refer to Annex III.

IX. The Economics of IP

12 Policy makers have a specific interest in the economic implications of IP when they endeavor to balance various policy fields with the goal of achieving policy coherence. The WIPO Secretariat seeks to contribute to a better understanding of the economic effects of different IP policy choices and to offer a first entry point for information on the economics of IP.⁵⁶ In this context, the Secretariat prepares economic and statistical reports and undertakes studies which address among other things the impact of IP protection on health. For further information, please refer to Annex IV.

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C. Conclusion

13 WIPO remains committed to working within the UN system, and with other multilateral organizations, such as the WTO, on policy issues related to innovation and global health. WIPO, as the specialized UN organization for intellectual property, is pleased to share its expertise and specialized data on various forms of IP with the HLP and indeed with the all interested stakeholders.

23. The High-Level Panel and the Expert Advisory Group are invited to take note of this information and they may wish to make it available for broader consideration and use, as appropriate.

[Annexes follow]

⁵³ The report will be published in early 2016, while an infographic with some of the key findings is already available from the WIPO website at

http://www.wipo.int/export/sites/www/patentscope/en/programs/patent_landscapes/reports/documents/neglected_diseases_infographic.pdf.

⁵⁴ The report is available in a format with enhanced accessibility features for print disabled persons, the first WIPO publication of this kind. It is available at http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/assistive_devices.html.

⁵⁵ http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/animal_gr.html

⁵⁶ http://www.wipo.int/econ_stat/en/economics/

Further Information on the Activities of the IP and Global Challenges Program

Background

1. The WIPO program on IP and Global Challenges addresses innovation and IP as they relate to global challenges, such as global health and climate change. As the specialized UN agency for IP, WIPO endeavors to facilitate international policy dialogue on the intersection between innovation, IP and global public policy issues. Developing countries face particularly acute challenges in these domains and solutions from innovation-driven initiatives are feasible. WIPO therefore cooperates actively with diverse international partners, both within and outside the UN system, to support the policy debate and help elucidate policy options and to develop results-oriented partnerships that address these challenges.
2. Key activities of the WIPO program on IP and Global Challenges include
 - the two multi-stakeholder technology transfer platforms *WIPO Re:Search* (see below for details) and WIPO GREEN (an interactive marketplace that promotes innovation and diffusion of green technologies);
 - providing support to Member States, intergovernmental organizations (IGOs), civil society, and other stakeholders and assisting them in the identification of feasible approaches; and
 - developing objective and balanced information on the relationships among global challenges, innovation and technology transfer, including the ongoing interagency collaboration with WHO and WTO, addressing the confluence of health, innovation and trade policies (for details, see below and the enclosed Brief: Promoting Medical Innovation and Access, Together).¹

Activities and projects of the WIPO program on IP and Global Challenges related to Global Health

WIPO Re:Search

3. The voluntary multi-stakeholder platform *WIPO Re:Search* aims at facilitating the diffusion and transfer of both health technologies consistent with the goals of the DA, in particular recommendations 19, 25, 30, 40, and 42.
4. *WIPO Re:Search – Sharing Innovation in the Fight Against Neglected Tropical Diseases* (NTDs)² is a voluntary, multi-stakeholder project created by WIPO in collaboration with private and public entities, including intergovernmental institutions, academia, industry, non-governmental organization (NGOs) and Product Development Partnerships (PDPs). Members of *WIPO Re:Search* commit to share their IP and expertise with others in the research community working on new treatments and vaccines for NTDs malaria, and tuberculosis (TB).

¹ http://www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_10.pdf

² <http://www.wiporesearch.org>

5. The Consortium aims to catalyze new research and development in this field by providing a platform where IP and know-how are made available to qualified researchers globally. Members make their IP assets available under royalty-free licenses for research, development and production anywhere in the world, and resulting product sales must be royalty-free in all least developed countries (LDCs).
6. A Partnership Hub, managed by BIO Ventures for Global Health (BVGH), a US-based non-governmental organization (NGO), provides support to interested parties in licensing and research collaboration opportunities, networking possibilities and funding options for research and development. WHO provides technical advice as requested to WIPO.
7. By end of 2015, there were 101 Members of *WIPO Re:Search*. *WIPO Re:Search* providers had made 193 contributions to the platform and 96 research collaborations were in place. Six “hosting” arrangements supported by Australia’s Funds in Trust (FIT) had placed scientists from Cameroon, Egypt, Ghana, Nigeria and South Africa at research institutes in India, Switzerland and the United States of America.

Providing support to Member States, IGOs, civil society, and other stakeholders and assisting them in the identification of feasible approaches

8. The WIPO program on IP and Global Challenges provides input, as appropriate and requested, in fora where innovation and IP are discussed in the context of global challenges. This activity responds particularly to DA recommendations 30, 40, 42.
9. WIPO provided support to the WHO Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits (IGM).³ WIPO engaged with the initiative of the Special Program for Research and Training in Tropical Diseases (TDR) to set up an African Network for Drugs and Diagnostics Innovation (ANDI), the African Union Pharmaceutical Manufacturing Plan for Africa, UNITAID and the Medicines Patent Pool.
10. In cooperation with the Medicines Patent Pool and the WIPO Patent Information Service, the patent status of two antiretroviral medicines was examined and the Medicines Patent Pool (MPP) published relevant information on its website.⁴ WIPO supported the MPP to obtain and regularly update data in the MPP patent database.⁵
11. Upon the request of the Global Health Program of the Graduate Institute of International and Development Studies, WHO, WIPO and WTO contributed to the organization of the Fifth High Level Symposium on Global Health Diplomacy, "Ten Years After the Doha Declaration: the Future Agenda at the Interface between Public Health, Innovation and Trade - an Outlook on the Next Ten Years". That event took place on November 23, 2011 at the WTO under the auspices of Madame Ruth Dreifuss, former Chairperson of the WHO Commission on Intellectual Property Rights,

³ WIPO, upon request by WHA Resolution 60.28, contributed a working paper Patent issues related to influenza viruses and their genes in 2007 (http://www.wipo.int/export/sites/www/policy/en/global_health/pdf/influenza.pdf), Annex to Working Paper (http://www.who.int/influenza/resources/documents/avian_flu_landscape.pdf?ua=1). Following a request of the WHO Open-Ended Working Group (OEWG) for Member States on Pandemic Influenza Preparedness (PIP) in December 2010, a WIPO Patent Search Report on Pandemic Influenza Preparedness (PIP)-related Patents and Patent Applications (http://www.wipo.int/export/sites/www/policy/en/global_health/pdf/report_influenza_2011.pdf) was prepared and submitted to the meeting of the OEWG in April 2011.

⁴ <http://www.medicinespatentpool.org/patent-data/>

⁵ <http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/>

Innovation and Public Health (CIPIH), and with the participation of the three Directors General of WHO, WIPO and the WTO.⁶

Developing objective and balanced information on the relationships among global challenges, innovation and technology transfer

12. Information materials, such as policy studies and substantive analyses, in the form of reports and briefs, aim at a better understanding of the policy and strategic drivers of innovation, demonstrate proactively the use of IP tools and support Member States' understanding of technology transfer in addressing global challenges. The Program collaborates closely with other IGOs as appropriate. This activity responds particularly to DA recommendations 19, 25, 30, 40 and 42.
13. Three Global Challenges seminars were held between 2012 and 2015 with the objective of exploring issues around the nexus of innovation and global challenges.⁷ A Global Challenges Seminar on April 12, 2016 at the WIPO headquarters will launch the new Global Challenges Report entitled *Patents and the WHO Model List of Essential Medicines (18th Edition): Clarifying the Debate on IP and Access*.⁸
14. The joint WHO, WIPO, WTO study entitled *Promoting Access to Medical Technologies and Innovation – Intersections between Public Health, Intellectual Property and Trade* is the first joint publication of the three Organizations. The study is intended to be used as a resource and background material for capacity building activities undertaken by the WHO, WIPO and the WTO either in cooperation or separately. The study is available in all official languages of the UN.⁹
15. WHO, WIPO and WTO have convened the following five joint Symposia: (i) Symposium on Access to Medicines: Pricing and Procurement Practices on July 16, 2010;¹⁰ (ii) Symposium on Access to Medicines, Patent Information and Freedom to Operate on February 18, 2011;¹¹ (iii) Symposium on Medical innovation – changing business models on July 5, 2013;¹² (iv) Symposium on Innovation and Access to Medical Technologies Challenges and Opportunities for Middle-Income Countries on November 5, 2014;¹³ and (v) Symposium on Public Health, Intellectual Property, and TRIPS at 20: Innovation and Access to Medicines; Learning from the Past, Illuminating the Future on October 28, 2015.¹⁴ Furthermore, they have convened the following two joint Technical Workshops: (i) Workshop on Patent Searches and Freedom to

⁶ http://graduateinstitute.ch/fr/events/_events/corporate/2011/event_7519

⁷ (i) Licensing and prices: new approaches in the pharmaceutical sector on June 27, 2012 (http://www.wipo.int/meetings/en/details.jsp?meeting_id=26822); (ii) Innovation and Access to Medicines: A Case Study for HIV/AIDS and Hepatitis C on December 5, 2014 (http://www.wipo.int/meetings/en/details.jsp?meeting_id=35262); and (iii) A New Generation of Products to Combat NTDs on October 21, 2015 (http://www.wipo.int/research/en/news/2015/news_0017.html)

⁸ The Global Challenges Seminar "Patents and the WHO Model List of Essential Medicines (18th Edition): Clarifying the Debate on IP and Access" on April 12, 2016 at the WIPO headquarters in Geneva is open to the interested public. Registration is required under https://www3.wipo.int/registration/en/form.jsp?meeting_id=39383

⁹ The trilateral study is available in Arabic (http://www.wipo.int/edocs/pubdocs/ar/global_challenges/628/wipo_pub_628.pdf), Chinese (http://www.wipo.int/edocs/pubdocs/zh/wipo_pub_628.pdf), English (http://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf) French (http://www.wipo.int/edocs/pubdocs/fr/wipo_pub_628.pdf), and Russian (http://www.wipo.int/edocs/pubdocs/ru/wipo_pub_628.pdf) and Spanish (http://www.wipo.int/edocs/pubdocs/es/wipo_pub_628.pdf).

¹⁰ http://www.wipo.int/meetings/en/details.jsp?meeting_id=20523

¹¹ (http://www.wipo.int/meetings/en/2011/who_wipo_wto_ip_med_ge_11/)

¹² http://www.wipo.int/meetings/en/2013/who_wipo_ip_med_ge_13/

¹³ https://www.wto.org/english/tratop_e/trips_e/trilat_symp14_e.htm

¹⁴ https://www.wto.org/english/tratop_e/trips_e/trilat_symp15_e.htm

Operate on February 17, 2011¹⁵ and (ii) the Workshop on Patentability Criteria on October 27, 2015.¹⁶

16. The Secretariats of WIPO, WHO and WTO have cooperated closely in providing input on their respective training activities, such as the WIPO-WTO Colloquium for Teachers of Intellectual Property, the WTO Workshop on Trade and Public Health, organized by the WTO Secretariat, in collaboration with WHO and WIPO, and national and regional seminars organized by the three organizations related to global and public health and the implementation of the TRIPS Agreement.¹⁷

[Annex II follows]

¹⁵ http://www.wipo.int/meetings/en/details.jsp?meeting_id=22342

¹⁶ https://www.wto.org/english/tratop_e/trips_e/trilat_workshop15_e.htm

¹⁷ For more detailed information, see document WIPO Document SCP/18/5, Projects and Activities on Patents and Health in WIPO, WHO and the WTO, http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=203879

Global Challenges Brief on Trilateral Cooperation



Promoting Medical Innovation and Access, Together

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1 minute read: key messages

- Improving access to, and promoting innovation in, health technologies are interconnected issues that touch the mandates of WHO, WIPO and WTO, which are deepening their cooperation in these areas to assist policymakers.
- Main joint activities include assembling fact-based information and empirical data to inform the policy-making process, publishing studies and reports on key issues, organizing symposia, and providing capacity building and training activities.
- Future work will include the launch of distance-learning courses to improve understanding among policymakers, researchers and NGOs of the policy options that exist in the fields of public health, intellectual property and trade.

Why is Trilateral Cooperation Needed?

Improving access to, and promoting innovation in, health technologies are crucial to improving public health. These twin global challenges must involve

stakeholders from all sectors: private, public, intergovernmental organizations (IGOs) and nongovernmental organizations (NGOs).

This paper addresses the trilateral partnership between the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). Each has distinct, but complementary, mandates to work on issues relating to public health, innovation, intellectual property (IP), and trade. As such, these organizations share a responsibility to strengthen dialogue among themselves and their partners to fulfil their mandates more effectively, to ensure efficient and coherent use of resources for technical cooperation.

Of the three organizations, WHO's work is the most directly relevant to public health, as it is the directing and coordinating authority for global health. But the process of achieving public health is complex and takes place within a broader policy environment that raises a range of issues relating to, for example, innovation, access, IP, and trade. This underlines the need for cooperation to assist countries in implementing policies that cut across the complex and interconnected areas of public health, IP and trade.

When implementing policies relating to public health, IP and trade, governments work within the framework of agreed international standards. Under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) for example, governments give effect to agreed standards but have some latitude or "policy space" to interpret and implement those standards in line with national needs and priorities when crafting domestic legislation.

Identifying the right mix of policy options to best advance their national objectives, however, is a huge challenge. Coherent, comprehensive and accessible information can help inform their decision-making. The complementary and coordinated expertise of the WHO, WIPO and WTO can offer real benefits to national policymakers.

What Each Organization Brings to the Table

- WHO brings vast expertise in all areas of public health, including medicine and vaccine policies, medical devices, regulatory issues, pricing and procurement, research, development and innovation, in addition to other factors affecting access to medicines.
- WIPO is uniquely positioned to promote a truly global understanding of the value of the IP system and the importance of the right policy mix to encourage innovation by providing information on patents, including the patent status of key medicines and vaccines in developing countries, and lending its expertise on patent law and its interplay with public policy.
- WTO works on several aspects of trade policy that have direct relevance to public health, including

international IP rules, regulations and flexibilities, and commitments on tariffs and easing trade barriers. These aspects of trade policy can affect both the innovation of and access to medicines.

Trilateral cooperation between WHO, WIPO and WTO traces its origins to the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which promotes TRIPS as part of the wider action to address public health challenges, and clarifies a number of public health-related flexibilities. In conjunction with making public health issues a central focus of WTO's work on IP and international trade, the Doha Declaration has been taken up by others, such as by various World Health Assembly (WHA) resolutions on ensuring innovation of, and accessibility to essential medicines. It was notably a point of reference in negotiations on the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

Similarly, the WIPO Development Agenda adopted in 2007, reflects, in part, broad interest in flexibilities in international IP law, including the health-related flexibilities specifically identified in the Doha Declaration. Since 2009, collaboration among WHO, WIPO and WTO has intensified with a marked increase in the sharing of knowledge to promote better understanding of the policy options surrounding public health, IP and trade (see Box 1).

Box 1: Steps towards increased coherence on public health, intellectual property and trade policy

| | |
|-----------|--|
| 2000 | United Nations Committee on Economic, Social and Cultural Rights General Comment on the Right to the Highest Standard of Health |
| 2001 | WTO Doha Declaration on the TRIPS Agreement and Public Health |
| 2002 | WHO-WTO joint study: <i>WTO Agreements and Public Health</i> |
| 2003/2005 | WTO creates new TRIPS flexibility for access to medicines in countries lacking manufacturing capacity |
| 2006 | WHO commissions report on <i>Public Health, Innovation and Intellectual Property</i> |
| 2007 | WIPO Development Agenda formally adopted by WIPO Member States |
| 2008 | Adoption of WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property |
| 2009 | Director Generals of WHO, WIPO and WTO commit to reinforce Trilateral Cooperation |
| 2010 | Inaugural Trilateral Symposium on Access to Medicines, Pricing and Procurement Practices ¹ |
| 2011 | Trilateral Symposium on Access to Medicines, Patent Information and Freedom to Operate ² |
| 2013 | Trilateral Symposium on Medical Innovation – Changing Business Models ³ |
| 2013 | Trilateral Study: <i>Promoting Access to Medical technologies and Innovation: Intersections between public health, intellectual property and trade published</i> ⁴ |
| 2014 | Trilateral Symposium on Innovation and Access to Medical Technologies: Challenges and Opportunities for Middle-income Countries ⁵ |
| 2015 | Trilateral Symposium on Public Health, Intellectual Property and TRIPS at 20: Innovation and Access to Medicines; Learning from the Past, Illuminating the Future ⁶ |

Trilateral Activities

Policymakers dealing with the challenges of public health, IP and trade work in a complex environment that is affected by a host of national, regional and international policy, legal and administrative structures. In this potentially confusing environment, policymakers need access to factual data and empirical evidence upon which they can base their decisions. In response to this need, the WHO, WIPO and WTO have taken steps to provide policymakers with reliable and accessible information that can assist and guide the process throughout.

The flagship “**Trilateral Study**”,⁷ published in 2013, is available in Arabic, Chinese, English, French, Spanish, and Russian. The study was prepared to serve the needs of policymakers, lawmakers, government officials, NGOs and researchers who seek a comprehensive overview of the full range of issues. The result of the close collaboration of dozens of experts from across the partnership, the study presents an accessible and comprehensive analysis of the interrelated issues associated with promoting innovation in medical and health technologies.

- On **health**, it explores new trends in the global disease burden, the importance of regulation and local production for innovation and access to quality medical products, and the innovation challenges associated with addressing neglected diseases.
- On **intellectual property**, it discusses issues of access to, and innovation of, medical technologies. It also takes an in-depth look at a range of technical issues around IP.
- On **trade**, it examines relevant WTO agreements, the role, *inter alia*, of competition policy, government procurement, trade flows of medical technology, and analyses relevant provisions of selected Free Trade Agreements.

In the framework of the negotiations for the sharing of influenza viruses and benefits, WIPO has, on request of WHO, contributed **patent search reports** on H1N1 and H5N1.⁸ WIPO has also published a comprehensive report on freedom-to-operate and global access related to dengue vaccines.⁹ In 2014, WIPO’s Standing Committee on Patents requested that the WIPO Secretariat prepare a “Feasibility Study on the Disclosure of International Non-proprietary Names (INN) in Patent Applications and/or Patents”.¹⁰ This report was prepared in close collaboration with WHO and WTO. WIPO also contributed its IP expertise to WHO’s Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property¹¹ as well as broader policy goals.

A series of **Joint Symposia** have been co-organized in Geneva by the trilateral partners since 2010 (see also Box 1). These events are designed to improve the flow of practical information and to guide and support

technical cooperation. The symposia achieve this by bringing together experts from all over the world to discuss current developments and trends in access to, and innovation of, medicines and other medical technologies. In addition to broadening public understanding of the issues, the symposia help the partner organizations to identify areas for further cooperation.

When implementing international standards at the country level, policymakers working on public health, IP and trade look to international organizations for guidance and training. WHO, WIPO and WTO cooperate and coordinate their **capacity in building and training activities** in order to make best use of their respective areas of expertise. These activities include a comprehensive IP and health component, which the three organizations design and implement in close collaboration (see Box 2).

The Response of Member States

The Member States of WHO, WIPO and WTO have welcomed the increased cooperation between the agencies and in particular, the information and insights generated in support of more effective policymaking and implementation. TRIPS Council delegates from China,¹² the EU,¹³ India,¹⁴ and the US, for example, have drawn on the Trilateral Study and related studies on tariffs on medicines, the burden of disease¹⁵ and innovation.¹⁶ Information from the study has also fed into the deliberations of WIPO’s Standing Committee on Patents, in particular its study on the role of patent

Box 2: Examples of trilateral cooperation in capacity building and training

- **National Workshops on Issues at the Intersection between Intellectual Property and Public Health.**
- **WIPO Seminars on Flexibilities in IP Law in South Africa and Kazakhstan (2013).**
- **WTO Workshops on Trade and Public Health (annual).**¹⁷
- **WTO-WIPO Colloquium for Teachers of Intellectual Property (annual).**¹⁸
- **WIPO-WTO Advanced Course on Intellectual Property for Government Officials (annual).**¹⁹
- **WHO/WIPO/WTO Joint Workshop on Patent Searches and Freedom to Operate (2011).**
- **WHO/Government of India Colloquium on IPRs for High-Level Policymakers in New Delhi (2014).**

Key Implications & Considerations for Policy & Policymakers

The following implications and considerations for policy and policymakers are intended as starting points for reflection, to be adapted to specific needs and circumstances:

- Public health has been a priority for global action for many years. The right to the enjoyment of the highest attainable standard of physical and mental health is a universal human right, just as the burden of disease is shared by all humanity. In the age of globalization, progress made in public health in one country has an impact on the international community as a whole. Consequently, a compelling case can be made for effective international cooperation in public health, and such cooperation is an essential foundation for sustainable development.
- Public health and medical technologies are an important focus of the international system, including in the system-wide work of the United Nations – most notably in the Millennium Development Goals (MDGs) and now the Sustainable Development Goals. The founding objective of WHO is the attainment by all peoples of the highest possible level of health. In addition, WIPO and WTO – in line with the mandates given to them by governments and their respective areas of expertise – have increasingly stepped up their efforts to support global endeavors to improve health outcomes.
- The complementary expertise of the three organizations, applied in coordination, can offer real benefits to policymakers at the national level. Given the “policy space” under the TRIPS Agreement, national policymakers and government officials are faced with the challenging task of identifying the right mix of policy options to best advance their national objectives. Coherent, comprehensive and accessible information can help inform their decision-making.
- There is today a richer, more diverse and more inclusive body of empirical data and practical experience available to guide technical cooperation. The technical cooperation offered by the three organizations has been characterized by active dialogue, coordination and partnership, leading to more effective and tailored capacity-building activities, all based on a better-informed factual background. The three agencies will continue to work, together with other international partners, towards the shared objective of better health outcomes for all.

systems in promoting innovative medicines, and in fostering the technology transfer necessary to make generic and patented medicines available in developing and least developed countries.²⁰

Future Plans

WHO, WIPO and WTO will continue to host annual trilateral symposia on topical issues. They will also continue to collaborate, within their respective mandates and budgets, to ensure the exchange of data, experiences and other information of benefit to policymakers.

A major activity underway is the development of distance-learning courses based on the Trilateral Study, facilitated by the WIPO Academy, to be launched in 2016. An introductory program provides an overview of the factors that shape access to, and influence innovation of medical technologies. The course describes the many overlapping factors that span the policy fields of public health, IP and international trade. A more advanced course will examine the subjects covered in the Trilateral Study in greater depth in far greater detail.

1 www.ow.ly/SMEhg
2 www.ow.ly/SMMvf
3 www.ow.ly/SMR0e
4 www.ow.ly/STWab

5 www.ow.ly/SMRbk

6 The 2015 symposium took advantage of the 20th anniversary of the establishment of the WTO and the TRIPs Agreement, and reviewed the information base on access and innovation in medical technologies. It also identified possibilities and limitations for better integrating data in support of policymakers' future work (see www.ow.ly/SMT5X).

7 www.ow.ly/SMRDV

8 www.ow.ly/SMSG5

9 www.ow.ly/TdfY8

10 www.ow.ly/TdgbB

11 www.ow.ly/TfuZy

12 IP/C/M/74/Add.1, para 79 and IP/C/M/77/Add.1, para 162

13 IP/C/M/74/Add.1, para 100

14 IP/C/M/74/Add.1, para 101, IP/C/M/77/Add.1, paras 153-155, and IP/C/M/79/Add.1, paras 201, 209-210

15 www.ow.ly/SMTT0

16 www.ow.ly/SMTT0

17 www.ow.ly/SMTgf

18 www.ow.ly/SMTIT

19 www.ow.ly/SMTs4

20 www.ow.ly/SMU2i

Citation: Krattiger A, T Bombelles, HG Bartels, Z Mirza, P Beyer, A Taubman, J Watal and R Kampf. 2015. Promoting Medical Innovation and Access, Together. Trilateral Cooperation between WHO, WIPO and WTO. *Global Challenges Brief on Trilateral Cooperation*, WIPO: Geneva. www.wipo.int/globalchallenges

WIPO Global Challenges Briefs provide overviews of issues relevant to debates about solutions to global challenges, such as climate change, public health and food security.

The views expressed in this work are those of the author and do not necessarily represent the positions or opinions of the Secretariats of WIPO, WTO, WHO or respective Member States.

**Activities and documents
of the Standing Committee on the Law of Patents (SCP)
in relation to the topic of patents and access to medicines**

Studies and documents

- Report on the International Patent System (SCP/12/3 Rev.2): http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf; Annex II of the document SCP/12/3 Rev.2 includes information on exceptions and limitations to patent rights in the national/regional patent systems and is regularly updated: http://www.wipo.int/scp/en/annex_ii.html
- Exclusions from patentable subject matter and exceptions and limitations to patent rights (SCP/13/3): http://www.wipo.int/edocs/mdocs/scp/en/scp_13/scp_13_3.pdf
- Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights (SCP/15/3): see, in particular, Annex IV "Patent Exclusions that Promote Public Health" by Shamnad Basheer, Shashwat Purohit and Prashant Reddy and Annex V "Patent Exceptions and Limitations in the Health Context" by Coenraad Visser: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=141352
- Responses by WIPO Member States to the questionnaire on exceptions and limitations to patent rights, including compulsory licenses, research exception, acts for obtaining regulatory approval, exhaustion of patent rights and preparation of medicines, can be found at: <http://www.wipo.int/scp/en/exceptions/>
- WIPO activities on patents and health (SCP/17/4): http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=186517
- Summary of the Sharing Session on Countries' Use of Health-Related Patent Flexibilities (SCP/20/REF/C/SUMMARY): http://www.wipo.int/edocs/mdocs/scp/en/scp_20/scp_20_ref_summary.pdf
- Exceptions and Limitations to Patent Rights: Experimental Use and/or Scientific Research (SCP/20/4): http://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_4.pdf
- Exceptions and Limitations to Patent Rights: Extemporaneous Preparation of Medicines (SCP/20/5): http://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_5.pdf
- Exceptions and Limitations to Patent Rights: Acts for obtaining Regulatory Approval from Authorities (SCP/21/3): http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_3.pdf
- Exceptions and Limitations to Patent Rights: Compulsory Licenses and/or Government Use (Part I) (SCP/21/4 Rev.): http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_4_rev.pdf
- Exceptions and Limitations to Patent Rights: Compulsory Licenses and/or Government Use (Part II) (SCP/21/5 Rev.): http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_5_rev.pdf
- Study on the Role of Patent Systems in Promoting Innovative Medicines, and in Fostering the Technology Transfer necessary to Make Generic and Patented

Medicines available in Developing Countries and Least Developed Countries (SCP/21/8): http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_8.pdf

- Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents (SCP/21/9): http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_9.pdf
- Member States' Experiences and Case Studies on the Effectiveness of Exceptions and Limitations (SCP/23/3): http://www.wipo.int/edocs/mdocs/scp/en/scp_23/scp_23_3.pdf
- All working documents of the SCP as well as the reports of each of the SCP sessions are available at: http://www.wipo.int/meetings/en/topic.jsp?group_id=61

Conferences and seminars

- Conference on Intellectual Property and Public Policy Issues (Geneva, July 13 and 14, 2009): http://www.wipo.int/meetings/en/2009/ip_gc_ge/. In particular, see the Report by Maximiliano Santa Cruz, Chair of the SCP, on the Conference on Intellectual Property and Public Policy Issues (SCP/14/8): http://www.wipo.int/edocs/mdocs/scp/en/scp_14/scp_14_8.pdf
- Seminar on Exceptions and Limitations to Patent Rights (SCP/20/INF/2): http://www.wipo.int/edocs/mdocs/scp/en/scp_20/scp_20_inf_2.pdf. Presentations can be found in the following link under "Other Related Documents": http://www.wipo.int/meetings/en/details.jsp?meeting_id=30925
- Seminar on Exceptions and Limitations to Patent Rights (SCP/21/INF/2): http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_1_inf_2.pdf. Presentations can be found in the following link under "Other Related Documents": http://www.wipo.int/meetings/en/details.jsp?meeting_id=32102
- Seminar on the Relationship between Patent Systems and the Availability of Medicines in Developing Countries and Least Developed Countries (SCP/23/INF/2 Rev.): http://www.wipo.int/edocs/mdocs/scp/en/scp_23/scp_23_inf_2_rev.pdf. Presentations can be found in the following link under "Other Related Documents": http://www.wipo.int/meetings/en/details.jsp?meeting_id=35600

[Annex III follows]

WIPO Patent Landscape Reports in the Area of Public Health

Background

Patent Landscape Reports (PLRs) are patent-based reports on a specific area of technology, providing information among other things on technology trends, geographical protection of various inventions, key and emerging players in these areas and collaboration among public and private sectors. The results are presented in a way that they can be understood by non-experts in the field and they are illustrated with the help of statistics and other types of visualization of the reviewed data. Such reports are broadly used, for example, in the private sector and provide the necessary factual evidence for managerial positions and for decisions related to research and development (R&D) planning, investment, partnerships, technology and know-how transfer, commercialization and local manufacturing.

The WIPO project on Patent Landscape Reports started in the context of a WIPO Development Agenda Project in 2010,¹ aiming at facilitating access for developing and least developed countries to knowledge and technology which could be important for their economic growth and development. Patent landscaping is a regular WIPO activity as of 2014.² Public health was among the key areas identified during the project planning.

The preparation of a report is demand-driven and is undertaken upon request by a cooperation partner with a specific need. For the preparation of each Patent Landscape Report, WIPO collaborates with various stakeholders, including other United Nations (UN) Agencies, Member States and non-governmental organizations (NGOs).

Specific Patent Landscape Reports

The following PLRs were prepared in the area of public health.

Patent Landscape Reports on Ritonavir and Atazanavir

The reports on the patent landscape of these the two antiretroviral medicines Atazanavir and Ritonavir were prepared in 2011, in cooperation with the Medicines Patent Pool.³ The data provided in these reports assisted the Medicines Patent Pool to complement and verify the patent information which they had gathered on these medicines, and supported their licensing negotiations with pharmaceutical companies. The PLR on Atazanavir⁴ examined the evolution of the patent environment protecting Atazanavir as of the first filing of this compound in July 1995. The report elaborates particularly on the various analytic and methodologic approaches for patent research on pharmaceuticals. The PLR on Ritonavir⁵ identifies a number of innovation tracks that devolved since the first Ritonavir patent document in 1994. An update of the PLR on Ritonavir was also prepared.

¹ http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131425

² http://www.wipo.int/patentscope/en/programs/patent_landscapes/

³ <http://www.medicinespatentpool.org>

⁴ http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/atazanavir.html

⁵ http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/ritonavir.html

Patent Landscape Report on Vaccines for Selected Diseases

The WIPO Patent Landscape Report on Vaccines for Selected Diseases followed a request from the WHO. This PLR undertakes to detect patterns of patenting activity and innovation in the area of vaccine research and manufacturing.

The report includes a part covering vaccines against infectious human and animal diseases in general, and a second part focusing on the patenting activity related to vaccines for three selected human infectious diseases of high economic and health importance: streptococcus pneumonia conjugate vaccines, typhoid conjugate vaccines, and influenza vaccines. The Report includes patent families that claim inventions directly related to vaccines, *i.e.* any patents that protect any aspect like the active ingredient (antigen, antibody) as such, derivatives thereof, combinations, methods of production, uses, etc. The data provided to the WHO were intended to support discussions related to local manufacturing of vaccines in certain countries. The report was published in 2012 and is available with an Infographic and the patent dataset with hyperlinks to the complete patent documents from the WIPO website.⁶

Patent Landscape Report on Selected Neglected Diseases

As a result of discussions with the Drugs for Neglected Diseases *initiative* (DNDi), the WIPO Secretariat prepared a Patent Landscape Report on the following selected neglected tropical diseases: Human African Trypanosomiasis, Chagas Disease, Leishmaniasis, Onchocerciasis and Lymphatic Filariasis. The report will be published in early 2016, while an infographic with some of the key findings is already available from the WIPO website.⁷ The report will include an analysis of the key and emerging players in the field and aims at assisting research collaborations, partnerships and technology transfer which will lead to more products in the area of neglected diseases being available on the market.

Patent Landscape Report on Assistive Devices and Technologies for Visually and Hearing Impaired Persons

Following discussions with the WHO Medical Devices and Assistive Devices Division, the WIPO Secretariat prepared a Patent Landscape Report on Assistive Devices and Technologies for Visually and Hearing Impaired Persons. This Patent Landscape Report explores technical solutions aimed at improving the lives of people with visual or hearing impairment and covers technologies related to vision and hearing aids, prostheses and implants, voice recognition and control, electronic stimulation, as well as specialized software/special accessibility features of technology products. The report was published in 2015 and is available in a format with enhanced accessibility features for print disabled persons, the first WIPO publication of this kind.⁸

⁶ http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/vaccines.html

⁷ http://www.wipo.int/export/sites/www/patentscope/en/programs/patent_landscapes/reports/documents/neglected_diseases_infographic.pdf

⁸ http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/assistive_devices.html

Patent Landscape Report on Animal Genetic Resources

This report is the result of collaboration with the FAO and its Animal Health Division. This was the first large-scale patent analysis in the area of animal genetic resources and served showing the IP perspective in that field, as well as identifying which breeds are used in research and for which purposes. The patent documents analyzed in the report were grouped into the following six technology clusters: artificial insemination, marker assisted breeding, transgenic animals, animal cloning, xenotransplantation and animal models. The results of the report⁹ showed that patenting activity in the field of animal genetic resources is increasingly focused on the medical and pharmaceutical markets rather than products for human consumption, namely on medical proteins, animals models for research on human diseases, and xenotransplantation for organ transplantations.

[Annex IV follows]

⁹ http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/animal_gr.html

Summary of economic and statistical work at WIPO related to “Access to Medicines”

Background

1. The WIPO Secretariat seeks to contribute to the better understanding of how intellectual property (IP) works through the dissemination of IP-related statistics, as well as through publications of economic and statistical reports on the effects of IP policies. This Annex provides a summary of the various economic and statistical outputs of the WIPO Secretariat that relate to the field of public health.

Statistics

2. The WIPO Secretariat collects IP-related statistics from WIPO Member States on a yearly basis and publishes a report based on its analysis of global IP trends in the World Intellectual Property Indicators (WIPI).¹ The statistics collected, which includes IP filings through the WIPO administered Patent Cooperation Treaty (PCT), the Madrid System for the Registration of marks and the Hague Systems for the registration of design rights, are available online through the Secretariat’s website.² Statistics on the different IP instruments may be retrieved according to the countries of origin, filing year, as well whether applicants are residents or non-residents, among other categories.

3. There is no specific theme or section on “access to Medicines” per se, but the data collected may be grouped into health-related fields of technology through the various classification systems that exist to facilitate searches by organizing information concerning inventions, trademarks and industrial designs into indexed, manageable structures for easy retrieval.

4. It is important to note that these classification systems³ are not intended to delineate between different industrial sectors. In many instances, it would be advisable to use various combinations of the different class fields to retrieve the needed information. For example, the IPC code A61K (excluding A61K-008) for patented products/processes refers to the pharmaceutical field.⁴ But if patented inventions in the biotechnology field are to be included under the health theme, then IPC codes C07G, C12M, C12N, C12P, C12Q, C12R, C12S, should also be considered. For trademarks, the corresponding NCL codes for the pharmaceutical, health and cosmetic sectors may be covered under classes 3, 5, 10, 44,⁵ while for industrial designs, the same industrial sectors may be identified under LOC classes 24 and 28.⁶

¹ <http://www.wipo.int/ipstats/en/wipi/>

² <http://ipstats.wipo.int/ipstatv2/index.htm>

³ The International Patent Classification (IPC) for technology for the purpose of patent protection (<http://www.wipo.int/classifications/ipc/en/>), the Nice Classification (NCL) for the classification goods and services for the purposes of the registration of marks (<http://www.wipo.int/classifications/nice/en/>), the Vienna Classification (VCL) of figurative elements of marks (<http://www.wipo.int/classifications/vienna/en/>), and the Locarno Classification (LOC) of goods for the purposes of the registration of industrial designs (<http://www.wipo.int/classifications/locarno/en/>).

⁴ See IPC Technology Concordance Table concept and methodology paper available online in pdf version at http://www.wipo.int/ipstats/en/statistics/technology_concordance.html

⁵ Classification grouping for different industrial sectors were composed by Edital. See Annex B of the WIPI 2015. Alternatively, concordance files developed by Travis Lybbert *et al* (2014) could also be used to link trademark data to specific trade data (see WIPO Economic Research Working Paper WP No. 14, at http://www.wipo.int/edocs/pubdocs/en/wipo_pub_econstat_wp_14.pdf)

⁶ Grouping developed by the OECD. See Annex C of WIPI 2015

Economics research work

5. Every two years, the WIPO Secretariat releases its major economic publication: the World Intellectual Property Report (WIPR) on specific IP and innovation-related themes. While the three published reports have not specifically focused on the health sector, there are elements of IP-related matters that relate to access to medicines and health. The latest publication, released in 2015, which focuses on *Breakthrough Innovation and Economic Growth*, has a section which looks into the innovation history of antibiotics and explores how IP played a role in its development.⁷ The 2013 publication on *Brands – Reputation and Image in the Global Marketplace* discusses the role of trademark filings in the pharmaceutical field.⁸ It further examines how brands have been used by firms, including those in the pharmaceutical sector, and their role in encouraging innovation.⁹ And lastly, the first WIPR 2011 on *The Changing Face of Innovation* discusses how patents affect access to innovation in a general manner.¹⁰

6. To encourage researchers to study the role of IP on economic activities, the Secretariat has undertaken to provide a short list of key academic literature that has influenced thinking in the field of the economics of innovation and IP.¹¹ Researchers who wish to identify economic studies on issues related to health may use the search engine to do so. The database is non-exhaustive and is updated on a yearly basis.

7. The WIPO Seminar Series on the Economics of IP¹² features economists from around the world, presenting their latest research to a policy-oriented audience. It seeks to stimulate an informed discourse on the effects of intellectual property (IP) policies on economic performance.

8. And lastly, as part of the WIPO Development Agenda mandate, the Secretariat undertakes studies on examining the link between IP and socio-economic developments in certain developing countries. Two studies have been conducted on examining the role of IP in the pharmaceutical sector in Chile and Uruguay respectively. The results of these studies are available online.¹³ Data for these countries are available upon request.

[End of Annex IV and of document]

⁷ See http://www.wipo.int/econ_stat/en/economics/wipr/

⁸ See Box 2.4 in WIPR 2013 at: http://www.wipo.int/edocs/pubdocs/en/intproperty/944/wipo_pub_944_2013.pdf

⁹ See Chapter 3 of WIPR 2013

¹⁰ See Chapter 2 of WIPR 2011 at: http://www.wipo.int/edocs/pubdocs/en/intproperty/944/wipo_pub_944_2011.pdf

¹¹ The Economic Literature Database is available at: http://www.wipo.int/econ_stat/en/economics/econdb/

¹² http://www.wipo.int/econ_stat/en/economics/seminars.html

¹³ Studies are available online in pdf version at: http://www.wipo.int/econ_stat/en/economics/studies/#socio